WASTE, FRAUD AND ABUSE: A CONTINUING THREAT TO MEDICARE AND MEDICAID

HEARING

BEFORE THE

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WASTE, FRAUD AND ABUSE: A CONTINUING THREAT TO MEDICARE AND MEDICAID

WEDNESDAY, MARCH 2, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2322 of the Rayburn House Office Building, Hon. Cliff Stearns (chairman of the subcommittee) presiding.

Members present: Representatives Stearns, Terry, Myrick, Murphy, Burgess, Bilbray, Gingrey, Scalise, Gardner, Griffith, Barton, DeGette, Schakowsky, Gonzalez, Dingell and Waxman (ex officio).

Staff present: Stacy Cline, Counsel, Oversight/Investigations; Todd Harrison, Chief Counsel, Oversight/Investigations; Sean Hayes, Counsel, Oversight/Investigations; Debbee Keller, Press Secretary; Peter Kielty, Senior Legislative Analyst; Carly McWilliams, Legislative Clerk; Andrew Powaleny, Press Assistant; Krista Rosenthall, Counsel to Chairman Emeritus; Ruth Saunders, Detailee, ICE; Alan Slobodin, Chief Investigative Counsel, Oversight; Sam Spector, Counsel, Oversight/Investigations; John Stone, Associate Counsel, Oversight/Investigations; Kristin Amerling, Democratic Chief Counsel and Oversight Staff Director; Phil Barnett, Democratic Staff Director; Brian Cohen, Democratic Investigations Staff Director and Senior Policy Advisor; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; Ali Neubauer, Democratic Investigator; and Anne Tindall, Democratic Counsel.

Mr. STEARNS. Good morning, everybody, and let me welcome everybody to the Subcommittee on Oversight and Investigations of Energy and Commerce.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. We convene this hearing of the Subcommittee on Oversight and Investigations today to examine the efforts of the Department of Health and Human Services and the Centers for Medicare and Medicaid Services to address fraud, waste and abuse in the Medicare and Medicaid programs.

This issue is of great importance to us. During this Congress and the last, I introduced the Medicare Fraud Prevention Act, which would increase the criminal penalties for those convicted of defrauding the Medicare program. As a Member of Congress from Florida, I have personally seen how this issue can greatly impact

my State and its citizens. During my town hall meetings last week, many of my constituents shared their concerns with stories about waste, fraud and abuse in Medicare.

Recently, the Government Accountability Office listed the Medicare and Medicaid programs as "high risk." High-risk programs are identified as having greater vulnerability to fraud, waste and abuse and mismanagement. As much as $60 billion is lost to Medicare fraud every year. This is an estimate because the exact number is unknown. When my staff asked the folks from CMS how much fraud was being carried out, they had no idea.

So it is hardly news that the Medicare and Medicaid programs are at high risk. GAO has listed Medicare as high risk since 1990 and Medicaid as high risk since 2003. Over the years, this committee has had countless hearings on this subject and yet nothing seems to change. The volume of Medicare fraud and the corresponding cost to the taxpayer continues to go up and up.

Meanwhile, the stories we hear from States like Florida continue to horrify taxpayers. News reports have indicated that Medicare fraud is rapidly eclipsing the drug trade as Florida's most profitable and efficient criminal enterprise. With Medicare fraud, the penalties are lower and the threat of violence is nonexistent. Meanwhile, seniors who notice that their Medicare number is being used for fraudulent schemes often find themselves begging the government to do anything about it, often with no results.

The types of fraud we are seeing run the gamut from fraudulent billing schemes to the actual creation of fake storefronts to sell durable medical equipment and then bill it to Medicare. Once the criminals get their money from Medicare, they close up shop and open a new storefront in a new location and start the scam all over again.

The Administration says that additional measures are being put in place to screen Medicare providers and suppliers, and halt payments when there are credible allegations of fraud. These are good and these are necessary steps to take, but only if they work, and GAO has said that there is much more work to be done.

In 2014, the Administration's health care bill will implement massive changes. Medicare will be cut and Medicaid will expand. According to the Chief Actuary of Medicare and Medicaid, 20 million people will be dumped onto the Medicaid rolls and $575 billion will be cut from Medicare. While we are all committed to repealing this onerous law on this side, we also must do our best to end fraud before 2014. If we can't stop fraud now, how are we going to do so while simultaneously adding 20 million people to Medicaid?

We have to make sure that the focus remains on preventing fraud and abuse. Unfortunately, CMS uses a pay first, check later system. That must change. We need to check first, and pay later before taxpayers' funds are wasted. CMS needs to fix its verification system to prevent these kinds of crimes or we will never get a handle on this problem.

Every dollar that is lost to fraud is one that is not spent on medical care for those in need. Fraud raises the costs of health care for all Americans. Since Obamacare will raise those costs even further, it is absolutely necessary that we get a handle on Medicare and Medicaid fraud.

So I look forward to hearing what the Federal Government is doing to get Medicare and Medicaid fraud and abuse under control.

[The prepared statement of Mr. Stearns follows:]

PREPARED STATEMENT OF HON. CLIFF STEARNS

We convene this hearing of the Subcommittee on Oversight and Investigations today to examine the efforts of the Department of Health and Human Services and the Centers for Medicare and Medicaid to address fraud, waste, and abuse in the Medicare and Medicaid programs.

This issue is of great importance to me-during this Congress and the last I introduced the "Medicare Fraud Prevention Act", which would increase the criminal penalties for those convicted of defrauding the Medicare program. As a Representative from Florida, I have personally seen how this issue can greatly impact my State and its citizens.

Recently the Government Accountability Office (GAO) listed the Medicare and Medicaid programs in its "High Risk" report. High risk programs are identified as such due to their "greater vulnerability to fraud, waste, abuse, and mismanagement." Indeed, as much as $60 billion is lost to Medicare fraud every year. This is a massive amount of fraud, although apparently the exact number is not even known. Recently, when my staff asked the folks from the Center for Medicare and Medicaid Services how much fraud was being carried out, CMS had no idea.

It is hardly news that the Medicare and Medicaid programs are at high risk for fraud, waste, abuse, and mismanagement. GAO has listed these programs as high risk for over 20 years, beginning in 1990. Congress' interest in Medicare fraud and abuse isn't new either. Over the years, this Committee has had countless hearings on the subject. And yet, nothing seems to change. The volume of Medicare fraud, and the corresponding cost to the taxpayers, continues to go up and up and up. President Obama has repeatedly promised that he would somehow SAVE taxpayer money and fund health care reform by eliminating Medicare fraud, but in the last two years, under his watch, Medicare has remained on the GAO's list as a "high risk" program for fraud. Estimates of fraud remain in the $60 billion a year range, despite President Obama's commitment to fight Medicare fraud.

Meanwhile, the stories we hear from States like Florida continue to horrify honest taxpayers. News reports have indicated that Medicare fraud is rapidly eclipsing the drug trade as Florida's most profitable and efficient criminal enterprise. The penalties are lower and the threat of violence is nonexistent. Meanwhile, honest seniors who notice that their Medicare number is being used for fraudulent schemes often find themselves begging the government to do anything about it, often with no results.

The types of fraud we are seeing run the gamut from fraudulent billing schemes to the actual creation of fake store-fronts to allegedly sell durable medical equipment and bill it to Medicare. Once the criminals get their money from Medicare, they close up shop and open a new store-front in a new location, and start the scam all over again.

Now the Administration says that additional measures are being put in place to screen Medicare providers and suppliers, and halt payments when there are credible allegations of fraud. I agree that these are good—and necessary—steps to take, assuming that they work.

Yet, GAO found that there is still much more that can be done in both Medicare and Medicaid. Considering that Obamacare puts the federal government on the hook for 90 percent of these increased costs to Medicaid alone, I sincerely hope we move to do more to combat fraud sooner rather than later.

In 2014 massive changes will take place because of Obamacare. Medicare will face drastic cuts and Medicaid will drastically expand. According to the Chief Actuary of Medicare and Medicaid, 20 million people will be dumped onto Medicaid rolls while $575 billion will be cut from Medicare. While we are committed to repealing this onerous law, we also must do our best to end fraud before 2014.

If we can't stop fraud now, how are we going to do so while simultaneously adding 20 million people to Medicaid?

I hope the witnesses at today's hearing will help us understand the challenges CMS will face as it prepares for the full implementation of health care reform, and how it plans to combat fraud and waste in the system.

We have to make sure that the focus remains on preventing fraud and abuse before it takes place. If CMS is not setting up the right systems and checks to prevent these kinds of crimes, we are never going to get a handle on this problem.

Every dollar that is lost to fraud is one that is not spent on medical care for those who need it. Fraud raises the costs of health care in America, and since I believe that Obamacare will raise those costs even further, it is absolutely necessary that we put and end to Medicare and Medicaid fraud.

I look forward to the testimony of the witnesses today and learning what the federal government is thinking of doing to get Medicare and Medicaid fraud and abuse under control.

Mr. STEARNS. My remaining 1 minute I will give to the gentleman from Texas, Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. The easiest thing in Washington to do is talk about waste, fraud and abuse and the hardest thing in Washington to do is to actually do something about it. As Chairman Stearns just said, on both sides of the aisle we have had numerous hearings about waste, fraud and abuse in Medicare and Medicaid and yet the problem still obviously persists. We can't even get a direct answer as to what the scope of the problem is. It is an $800 billion combined program. Is it 10 percent? Ten percent would be $80 billion a year. Is it 5 percent? That would be $40 billion. Is it 1 percent? That would be $8 billion. Nobody knows.

Mr. Chairman, I hope on a bipartisan basis this subcommittee and the full committee under your leadership and under the leadership of Ranking Member Waxman and Chairman Upton in this Congress actually do something about it. With a $1.5 trillion budget deficit annually, there is no question that money spent here will be money that we get a huge return on investment.

I look forward to hearing from our witnesses and I hope that they have some solutions in addition to helping us define the scope of the problem.

With that, Mr. Chairman, I yield back.

[The prepared statement of Mr. Barton follows:]

PREPARED STATEMENT OF HON. JOE BARTON

Thank you Mr. Chairman for holding this hearing in an attempt to discuss, expose, and potentially prevent wide-spread waste, fraud, and abuse in the Medicare and Medicaid systems.

I welcome all of our witnesses and I hope they can answer the hard questions this Committee has for them. In particular, I want to know why the Centers for Medicare and Medicaid Services (CMS), a federal agency that has a budget of almost $800 billion a year and a Center dedicated to Program Integrity can not give us an estimate on how much money is lost to fraud each year.

It is frustrating that we all agree fraud is a problem, we all want to solve the problem, and yet, we still don't even know the scope of the problem. Now why is that important? I believe that if you don't know what the problem is, you can't set goals on how to solve it. So let's say it's a 10 percent problem which would be $80 billion. Maybe a reasonable goal then would be to cut that by 25 percent in a given year, which would be $20 billion. Maybe it's only a 40 billion problem a year. But if you guys can't help us determine what the problem is, it is hard for us to decide how to set goals to solve it.

This inability is deeply disappointing considering in less than three years, under the Affordable Care Act, this agency will take over much of the healthcare system and President Obama has repeatedly stated that one of the ways he plans to fund Obamacare is by saving billions of dollars by identifying and preventing this fraud.

Mr. Chairman, the hearing today highlights just one of the many flaws of expanding huge entitlement programs that are currently unmanageable, unsustainable, and highly susceptible to waste, fraud, and abuse.

Mr. STEARNS. I thank the gentleman, and I recognize the ranking member from Colorado, Ms. DeGette.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Mr. Chairman, Medicare and Medicaid fraud have been persistent problems that have plagued both Democratic and Republican Administrations, as you have said, and it costs Americans billions of dollars every year. It affects health care providers at every level in the programs themselves and also in the private sector.

Today's hearing will focus on a very worthy target of oversight: waste, fraud and abuse in these two systems. Medicare and Medicaid provide millions of people with access to medical services and so it is a vital concern to this committee that we maintain their integrity.

Fortunately, as you said, it is important to try to get a handle on Medicare and Medicaid fraud, and that is also a high priority for President Obama. Beginning in 2009, the Obama Administration made fighting fraud a priority. These efforts expanded even more after passage of the Affordable Care Act, which contains dozens of provisions designed to help fight Medicare and Medicaid fraud.

The Administration asked for and received additional funding to fight health care fraud in both 2009 and 2010. They have reorganized within HHS and they have started several new collaborations with law enforcement authorities to uncover and prevent health care fraud.

In May of 2009, HHS and DOJ announced the creation of the Health Care Fraud Prevention and Enforcement Team, or HEAT, designed to coordinate Cabinet-level agency activities to reduce fraud. Under the HEAT program, HHS and DOJ have expanded the use of dedicated strike force teams, placing law enforcement personnel in locations that are identified as health care fraud hotspots. These teams carried out the largest health care fraud takedown in U.S. history last month, netting over 100 arrests in just one day. The work undertaken by the strike force teams has led to criminal charges against 829 defendants for defrauding Medicare of almost $2 billion. There is an answer to your question about the extent of this.

The Administration's efforts have been a huge success for taxpayers, with a return on investment that would make most hedge fund managers jealous. And thanks to landmark health care reform law passed by Congress last year, HHS and law enforcement authorities now have a host of new tools and new funding to fight fraud.

The Affordable Care Act contains dozens of new provisions to fight Medicare and Medicaid fraud. The most important changes allow CMS to apply a preventative model in its antifraud efforts. For years, CMS employed, as you said, a "pay and chase" model of enforcement, simply paying fraudsters' claims, then attempting to

recover its losses. Now, CMS has new authority to keep fraudsters out of Medicare and Medicaid in the first place.

The Affordable Care Act contains stiffer enrollment requirements for all providers, mandates enhanced background checks, adds new disclosure requirements, and calls for onsite visits to verify provider information. It requires that providers create internal compliance programs, and it contains several provisions aimed directly at fighting fraud in, as you mentioned, the high-risk durable medical equipment and home health programs.

The government's ability to act once it has uncovered fraud or the possibility of fraud is also enhanced by the Affordable Care Act. The Secretary now has authority to enact moratoria on enrolling new providers if she believes that such enrollments will increase fraud risks, and she can suspend payments to providers where there is a substantiated allegation of fraud. Once fraud has been proven, the Affordable Care Act provides stiffer monetary penalties and expands the HHS Inspector General's authority to exclude violators from the Medicare and Medicaid programs.

Data sharing and collection between CMS, States, and other federal health programs are modernized under the Affordable Care Act, and the Affordable Care Act provides an estimated $500 million in increased funding over the next 5 years to fight fraud, money that will return billions of dollars to the taxpayers. This expanded authority, combined with the coordinated and focused attention of the Obama Administration, has laid the groundwork for a new era in the Federal Government's response to fraud.

Mr. Chairman, as you said, the GAO first designated Medicare a high-risk program in 1990, and Medicaid joined the high-risk list in 2003. I look forward to hearing from the GAO about why this is the case and what can be done. I am hoping that these new commitments that I just talked about can really substantially reduce fraud and ultimately produce the result that all of us want.

Mr. Chairman, if there is more than we can do to reduce waste, fraud and abuse on a bipartisan level, I would be eager to hear it and I would be happy to work with you and your colleagues on both sides of the aisle to make sure that we can do that because I think one thing we can agree on in a bipartisan way is, nobody wants to see money wasted and we certainly do not want to see fraud, waste and abuse in Medicare and Medicaid.

And with that, I yield back.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Health care fraud costs Americans billions of dollars every year. Fraud affects health care providers at all levels, in Medicare and Medicaid, and in the private sector.

Today's hearing will focus on a worthy target of oversight: waste, fraud, and abuse in the Medicare and Medicaid programs. Medicare and Medicaid provide millions of people with access to essential medical services, and the integrity of these programs is a vital concern of this Committee.

Fortunately, fighting waste, fraud, and abuse in Medicare and Medicaid is also a high priority for President Obama. Beginning in 2009, the Obama Administration made fighting fraud a priority. These efforts expanded even more after passage of the Affordable Care Act, which contained dozens of provisions designed to help fight Medicare and Medicaid fraud.

The Administration asked for and received additional funding to fight health care fraud in 2009 and 2010. They have reorganized within HHS and started several new collaborations with law enforcement authorities to uncover and prevent health care fraud.

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The Administration's efforts have been a huge success for taxpayers, with a return-on-investment that would make most hedge fund managers jealous. And thanks to the landmark health care reform law passed by Congress last year, HHS and law enforcement authorities now have a host of new tools and new funding to fight fraud.

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The most important changes allow CMS to apply a preventive model in its anti-fraud efforts. For years, CMS employed a "pay and chase" model of enforcement, simply paying fraudsters' claims, then attempting to recoup its losses. Now, CMS has new authority to keep fraudsters out of Medicare and Medicaid in the first place.

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And the Affordable Care Act provides an estimated $500 million in increased funding over the next five years to fight fraud—money that will return billions of dollars to the taxpayer.

This expanded authority, combined with the coordinated and focused attention of the Obama Administration, has laid the groundwork for a new era in the federal government's response to health care fraud.

The Government Accountability Office first designated Medicare a "high-risk" program in 1990, and Medicaid joined the "high-risk" list in 2003. For two decades, the programs have been on GAO's high priority list. We will hear today from GAO about why this is the case, and what can be done. I am hopeful that the Obama Administration's commitment to reducing fraud, and the substantial anti-fraud boost provided by the Affordable Care Act will ultimately produce the result that preceding Republican and Democratic Administrations have been unable to achieve: removal of Medicare and Medicaid from the GAO high-risk list.

Waste, fraud, and abuse in Medicare and Medicaid are bi-partisan problems, and I believe there is bi-partisan commitment to combating them. I hope there is also bi-partisan recognition of the commendable anti-fraud efforts undertaken by the Obama Administration and the vital anti-fraud authority granted by the Affordable Care Act. 5

I thank the witnesses for joining us here today and look forward to hearing their testimony on this important topic.

Mr. STEARNS. The gentleman from Texas, Mr. Burgess, is recognized for 3 minutes.

Mr. BURGESS. I thank the chairman and I thank our witnesses for being here today. I know several of you we have seen before and several of you we have seen several times before, which just under-

scores the problem that at the federal level we have really not done enough to address the issue of fraud, and as the reports that we have in front of us indicate that our Nation's government-run health care system needlessly does waste billions of dollars each year through programs that are ineffective and unfocused.

Fraud analysts and law enforcement officials estimate, and we have heard the figures already, 10 percent, as Mr. Barton did the math for us on an $800 billion public program. That is a substantial sum of money every year, and over a 10-year budget window, it is really astounding. But 10 percent of total health care expenditures are lost to fraud on an annual basis.

The point has been raised by others, I have raised it numerous times before, how much fraud is enough for us to take notice? The answer that we all expect to see in the amount of fraud is none, zero, zero tolerance, but in reality, sometimes it is even as simple as just the lack of a prosecutorial force with the background in prosecuting health care laws cripples our ability to go after the people that need to be gone after, and certainly that has been true in my communities in north Texas where repeated violations by some of the same people who have multiple provider numbers but a single post office box, you can bust someone in the morning but we are sending out payments to the same post office box under a different provider number that afternoon. Clearly, that has to stop.

Now, the Government Accountability Office has been able to identify areas where they may have made recommendations to the Centers for Medicare and Medicaid Services to prevent improper payments, some really dating back almost a decade, and they failed to fully implement them and that in fact has caused fraud to rise. If we are serious about bringing down the cost of health care and protecting the patient not just reducing but eliminating fraud, that needs to be the goal for which we strive.

Medicaid expansion under the landmark health care legislation passed last year that has already been referenced but Medicaid expansion under the Affordable Care Act is estimated to exceed $430 billion over the next 10 years. Under current standards, taxpayers would be losing over $40 billion a year to fraud.

Now, we also talk about the medical loss ratio and how we are going to control costs in the private sector but I would just simply ask, what is a more cogent indicator of medical loss ratio than dollars that are lost to fraud? Maybe we ought to include that in our calculation.

I realize the clock is misbehaving. Let me yield back to the chairman because I think he has others he wants to recognize.

Mr. STEARNS. Thank you, Mr. Burgess.

Mr. Bilbray of California is recognized for 1 minute and then Mr. Gingrey.

Mr. BILBRAY. Thank you, Mr. Chairman.

Mr. Chairman, I think there are many ways of addressing the potential or the existence of the fraud issue. I think that one of the concerns that a lot of people had when we were talking about expanding health care coverage last year was the President stood on the podium and said I assure you that those who are illegally in this country will not have access to this system, though when the bill was passed there was no requirement for verification, the same

verification required almost of every other federal program wasn't included in that expansion of health care service. I would like to make sure that we all address the fact that if you do not verify, if you do not use the check system, you cannot straight face in the American people and tell us that people who are not qualified are going to be kept out of this system. Just by saying they are not allowed to participate in the system is as logical as saying that providers will not create a fraud because we have said that they shouldn't do it. There has got to be some checks and balances here.

And just as much as need to make sure that we are on top and checking the providers of the services, we also have a responsibility, especially after the President promised the American people that they would not participate is to make sure that we check and have a verification system for those who are providing the services and those who are being provided to those services, and I think not until we are willing to do that across the board with all of our health care system can we truly have our President stand up and assure the American people with a straight face that no, we are doing everything possible to make sure we fighting fraud in this country and we make sure that every dollar spent on health care in this country is going only to those who qualify and only being provided under a legal system.

I yield back.

Mr. STEARNS. The gentleman yields back.

The gentleman from Georgia, Mr. Gingrey, is recognized for 1 minute.

Mr. GINGREY. Mr. Chairman, thank you. I am very pleased to welcome the witnesses on both the first and second panel. I look forward to hearing their testimony.

I practiced medicine for 31 years, 26 of those years in the specialty of obstetrics and gynecology, so this issue of waste, fraud and abuse, particular in our Medicare and Medicaid systems, is something that really, really gets to me, and some of the comments that I have heard already this morning, particular from the other side, you would almost think that one of the reasons for adopting Obamacare or the Affordable Care Act was so that we could succeed in combating waste, fraud and abuse. I certainly don't agree with that, and if it is true, then it will be more successful than the bill has been in lowering the cost of health care to individuals who are now uninsured. It will do more than it has done in regard to medical liability reform that was promised. It will do much more than providing a sustainable rate of reimbursement to our hard-working health care providers that was promised. So it kind of remains to be seen what is in this bill that is going to make us more successful in combating waste, fraud and abuse.

But in any regard, I look forward to hearing from the witnesses and we do need to get a handle on this problem, and I yield back.

Mr. STEARNS. I thank the gentleman, and Mr. Waxman, the ranking member of the full committee, is recognized for 5 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Well, this hearing is a very useful one already because we have the opportunity to educate two of our Republican members about the accuracy of the legislation that we just adopted. One of the reasons I am so proud of the Affordable Care Act, the historic health care reform law signed by President Obama last year, is that it contains dozens of antifraud provisions. This legislation has the most important reforms to prevent Medicare and Medicaid fraud in a generation. According to the Congressional Budget Office, these new fraud provisions will save over $7 billion for taxpayers.

The health care reform law shifts the prevailing fraud prevention philosophy from pay and chase where law enforcement authorities only identify fraud after it happens to inspect and prevent. It allows CMS to impose moratoria on enrolling new providers if the Secretary believes that such enrollments will increase fraud risk. It allows the HHS Secretary to close the barn door before the horses have left.

The new law also contains new penalties for fraudulent providers and new data-sharing provisions to catch criminals, and it provides hundreds of millions of dollars in new funding to help CMS, the Inspector General and the Department of Justice fight Medicare and Medicaid fraud, and we will hear today about how the CMS and Inspector General have already put these funds to work. I am proud of these efforts to reduce fraud.

The second thing I want to point out is that the legislation does not allow undocumented aliens to access Medicare or Medicaid or the exchanges, and it is not just on their self-affirmation that they are not here illegally, it is based on an inspection that is required under the law. That can be done in two ways. They can either check with Social Security, get all the information to be sure that the claimant is accurately stating his or her status, or they can require the birth certificates and passports and other information to be produced to show that they are not taking advantage. So these oversight hearings have a real opportunity to educate people.

I can't tell you how much I think this is an important reason for our hearing. When we have health care fraud, it robs the taxpayers of funds, affects the quality of care provided to program enrollees and saps public confidence in the Medicare and Medicaid programs. And that is why I see fighting Medicare and Medicaid fraud as a critical need and an issue where we should be able to achieve bipartisan consensus.

But I am wary of those who use the existence of fraud in these programs for the express purpose of undermining support for them. I do not believe we should attempt to exaggerate the scope of the problem just to foster ideological efforts to cut or eliminate them. When I hear estimates of the amount of Medicare and Medicaid fraud that have no basis in fact, or when members confuse Medicare and Medicaid improper payment rates that consists mostly of simple paperwork or clerical errors with the rate of intentional fraud against the programs, then I become concerned that mem-

bers are just using fraud as an excuse to bash these programs, not to improve them.

The vast majority of Medicare and Medicaid providers are compassionate and honest. The vast majority of beneficiaries of these programs desperately need the care that is provided. We need to be tough on fraud and tough on criminals who take advantage of these programs and their beneficiaries, but we cannot and should not blame the victim.

In January, every single Republican Member of Congress voted to repeal the entire Affordable Care Act, including essential antifraud provisions. In February, as part of the Continuing Resolution, every single Republican voted to ban the use of funds to implement the Affordable Care Act, including the funds needed to implement the antifraud provisions. That vote was penny-wise and pound-foolish.

We are going to hear from CMS, from the HHS Inspector General and from GAO about the new authority and new funding they have to eliminate Medicare and Medicaid fraud, thanks to the Affordable Care Act, and I hope this testimony will make some members reconsider their views. If we truly care about protecting the taxpayer, we should support, not defund, the Administration's initiatives to reduce Medicare and Medicaid fraud.

I yield back the balance of my time.

[The prepared statement of Mr. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

Mr. Chairman, I want to thank you for holding this hearing today, and for focusing on the important topic of Medicare and Medicaid fraud.

I have dedicated much of my career in Congress to improving the Medicare and Medicaid programs and the quality of care they provide and pursing waste, fraud, and abuse in government spending. This hearing combines both subjects.

Health care fraud robs taxpayers of funds, affects the quality of care provided to program enrollees, and saps public confidence in the Medicare and Medicaid programs. That's why I see fighting Medicare and Medicaid fraud as a critical need—and an issue where we should be able so achieve bipartisan consensus.

But I am wary of those who use the existence of fraud in these programs for the express purpose of undermining support for them. I do not believe we should attempt to exaggerate the scope of the problem just to foster ideological efforts to cut or eliminate them.

When I hear estimates of the amount of Medicare and Medicaid fraud that have no basis in fact . or when members confuse a Medicare and Medicaid "improper payments" rate that consists mostly of simple paperwork or clerical errors with the rate of intentional fraud against the programs . then I become concerned that members are just using fraud as an excuse to bash these programs, not to improve them.

The vast majority of Medicare and Medicaid providers are compassionate and honest. The vast majority of beneficiaries of these programs desperately need the care they provide. We need to be tough on fraud and tough on criminals who take advantage of these programs and their beneficiaries—but we can and should not blame the victim.

One of the reasons I am so proud of the Affordable Care Act, the historic health care reform law signed into law by President Obama last year, is that it contains dozens of anti-fraud provisions. The legislation has the most important reforms to prevent Medicare and Medicaid fraud in a generation. According to the Congressional Budget Office, these new fraud provisions will save over $7 billions for taxpayers.

The health care reform law shifts the prevailing fraud prevention philosophy from "pay and chase"—where law enforcement authorities only identify fraud after it happens—to "inspect and prevent."

It allows CMS to impose moratoria on enrolling new providers if the Secretary believes that such enrollments will increase fraud risks. This allows the HHS Secretary close the barn door before the horses have left.

The new law also contains new penalties for fraudulent providers and new data sharing provisions to catch criminals.

And it provides hundreds of millions of dollars in new funding to help CMS, the Inspector General, and the DOJ fight Medicare and Medicaid fraud. We will hear today about how the CMS and the Inspector General have already put these funds to work.

I am proud of these efforts to reduce fraud.

In January, every single Republican member of Congress voted to repeal the entire Affordable Care Act, including these essential anti-fraud provisions. In February, as part of the Continuing Resolution, every single Republican voted to ban the use of funds to implement the Affordable Care Act, including the funds needed to implement the anti-fraud provisions. That vote was penny-wise, pound-foolish.

We will hear today from CMS, from the HHS Inspector General, and from GAO about the new authority and new funding they have to eliminate Medicare and Medicaid fraud, thanks to the Affordable Care Act. I hope this testimony will make some members reconsider.

If we truly care about protecting the taxpayer, we should support—not defund—the Administration's initiatives to reduce Medicare and Medicaid fraud.

Mr. STEARNS. I thank the gentleman.

At this point we will go to our witnesses, and we have our witnesses at the table. The first is Kathleen King, Director of Health Care Division, Government Accountability Office. She is the director of this health care team at the U.S. Government Accountability Office, which is responsible for leading various studies of the health care system, specializing in Medicare management and prescription drug coverage. She has more than 25 years' experience in health policy and administration. She received her M.A. in government and politics from the University of Maryland.

We have John Spiegel, who is Director of Medicare Program Integrity, Centers for Medicare and Medicaid Services. He has worked in various components of the Centers for Medicare and Medicaid Services. After several years working outside the public sector, he returned to federal service in 2010 as the Director of the Medicare Program Integrity Group.

Then we have Gerald Roy, who is Deputy Inspector General for Investigations, Department of Health and Human Services. He has served in OIG since 1995. He was also instrumental in increasing OIG's civil and criminal conviction record and a 25 percent increase in OIG's monetary recoveries from $3 billion in 2008 to over $4 billion in 2009.

And then we have Omar Perez, Assistant Special Agent in Charge, Health and Human Service Office of the Inspector General, Miami Regional Office. He joined the department in July 1998 and he has been promoted to special agent in January 1999. He has led a number of successful criminal and civil investigations and orchestrated Project Ghost Rider to address fraudulent ambulance companies, Bad Medicine to address Puerto Rico's Medicaid equivalent, and the First Child Support Round in the U.S. Virgin Islands.

So I welcome our witnesses, and let me swear you in first of all.

[Witnesses sworn.]

Mr. STEARNS. Ms. King.

STATEMENTS OF KATHLEEN KING, DIRECTOR, HEALTH CARE DIVISION, GOVERNMENT ACCOUNTABILITY OFFICE; GERALD T. ROY, DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS, OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; OMAR PEREZ, ASSISTANT SPECIAL AGENT IN CHARGE, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JOHN SPIEGEL, DIRECTOR OF MEDICARE PROGRAM INTEGRITY, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF KATHLEEN KING

Ms. KING. Mr. Chairman, members of the subcommittee, thank you for inviting me today to speak about our recent high-risk report, specifically about Medicare. We have continued to designate Medicare as a high-risk program because of its complexity and susceptibility to improper payment added to its size. This has led to serious management challenges.

In 2010, Medicare covered 47 million elderly and disabled beneficiaries and had estimated outlays of $509 billion, making it the third largest federal programs in terms of spending.

Currently, Medicare remains on a path that is fiscally unsustainable in the long term. This heightens the urgency for the Centers for Medicare and Medicaid Services to address our recommendations, effectively implement new laws and guidance and improve its management in four areas. Broadly, these areas include reforming and refining payments, improving program management, enhancing program integrity and overseeing patient care and safety. Today I am going to focus my oral comments on payments and program integrity.

With regard to reforming and refining payments, CMS has implemented payment reforms such as for Medicare Advantage, inpatient hospital and home health services. It has also begun to provide feedback to physicians on their resource use, which is positive but which could benefit from additional refinement, and is developing a new payment system that accounts for the cost and quality of care. But more could be done. For example, we have recommended to CMS that they consider implementing more front-end approaches to controlling the growth of imaging services. In addition, we recently found that although payments for home oxygen have been reduced or limited several times in recent years, further savings are possible.

In regard to program integrity, Congress recently passed laws including the Improper Payments Elimination and Recovery Act, the Patient Protection and Affordable Care Act and the Small Business Job Act that provide authority and resources and impose new requirements designed to help CMS reduce improper payments.

The Administration has also issued executive memoranda including one that requires agencies to check certain databases known as the Do Not Pay List before making payments to ensure that payments are not made to individuals who are dead or entities that have been excluded from federal programs. CMS is taking steps to implement these laws and memoranda through regulations and

other agency actions. In 2010, it created a new Center for Medicare and Medicaid Program Integrity to better coordinate efforts to prevent improper payments. CMS has been tracking its improper payment rates in Medicare fee for service and Medicare Part C and has established performance goals for reducing those rates in the future. However, the agency has not reported a single error rate for Part D and has not been able to demonstrate sustained progress in lowering its improper payment rates. So continued oversight is warranted.

Having a corrective action process in place to address vulnerabilities that lead to improper payments is also important to managing them effectively. Our work on recovery auditing, which reimburses contracts on a contingency basis to uncover payments that should not have been made found that CMS had not developed an adequate process to address the vulnerabilities that had been identified by the contractors. Since it is important to address these issues going forward, we recommended that CMS develop a robust corrective action process.

Further, we issued a report in February 2009 that indicated that Medicare continued to pay some home health agencies for services that were not medically necessary or were not rendered. To address this, we made several recommendations including that CMS direct its contractors to conduct post-payment reviews on home health agencies with high rates of improper payments. CMS has not implemented this and several other recommendations to improve its program safeguards.

In conclusion, although CMS has taken many actions to improve the integrity of the Medicare program, further action is needed to ensure that payments are proper and vulnerabilities to improper payments are addressed. We are beginning new work to address some of these issues to determine if additional agency or Congressional action might be helpful.

Mr. Chairman, this concludes my statement. I would be happy to answer any questions.

[The prepared statement of Ms. King follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

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MEDICARE

Program Remains at High Risk Because of Continuing Management Challenges

Statement of Kathleen King
Director, Health Care

GAO-11-430T

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Highlights

Highlights of GAO-11-430T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

March 2, 2011

MEDICARE

Program Remains at High Risk Because of Continuing Management Challenges

Why GAO Did This Study

In the February 2011 High-Risk Series update, GAO continued designation of Medicare as a high-risk program because its complexity and susceptibility to improper payments, combined with its size, have led to serious management challenges. In 2010, Medicare covered 47 million people and had estimated outlays of $509 billion. The Centers for Medicare & Medicaid Services (CMS) has estimated fiscal year 2010 improper payments for Medicare fee-for-service and Medicare Advantage of almost $48 billion.

This statement focuses on the nature of the risk in the program, progress made, and specific actions needed. It is based on GAO work developed by using a variety of methodologies—including analyses of Medicare claims, review of policies, interviews, and site visits—and information from CMS on the status of actions to address GAO recommendations.

What Remains to Be Done

CMS needs a plan with clear measures and benchmarks for reducing Medicare's risk for improper payments, inefficient payment methods, and issues in program management and patient care and safety. Further, CMS's effective implementation of recent laws will be critical to helping reduce improper payments. CMS also needs to take action to address GAO recommendations, such as to develop an adequate corrective action process, improve controls over contracts, and refine or better manage payment for certain services.

View GAO-11-430T or key components. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov

What GAO Found

As GAO reported in its 2011 High-Risk Series update, Medicare remains on a path that is fiscally unsustainable over the long term. This fiscal pressure heightens CMS's challenges to reform and refine Medicare's payment methods to achieve efficiency and savings, and to improve its management, program integrity, and oversight of patient care and safety. CMS has made some progress in these areas, but many avenues for improvement remain.

Reforming and refining payments. Since January 2009, CMS has implemented payment reforms for Medicare Advantage and inpatient hospital and other services, and has taken other steps to improve efficiency in payments. The agency has also begun to provide feedback to physicians on their resource use, but the feedback effort could be enhanced. CMS has taken steps to ensure that some physician fees recognize efficiencies when certain services are furnished together, but the agency has not targeted the services with the greatest potential for savings. Other areas that could benefit from payment method refinements include oxygen and imaging services.

Improving program management. CMS's implementation of competitive bidding for medical equipment and supplies and its transfer of fee-for-service claims workload to new Medicare Administrative Contractors have progressed, with some delays. Of greater concern is that GAO found pervasive internal control deficiencies in CMS's management of contracts that increased the risk of improper payments. While the agency has taken actions to address some GAO recommendations for improving internal controls, it has not completely addressed recommendations related to clarifying the roles and responsibilities for implementing certain contractor oversight responsibilities, clearing a backlog of contacts that are overdue for closeout, and finishing its investigation of over $70 million in payments GAO questioned in 2007.

Enhancing program integrity. CMS has implemented a national Recovery Audit Contractors (RAC) program to analyze paid claims and identify improper overpayments for recoupment, set performance measures to reduce improper payments, issued regulations to tighten provider enrollment, and created its Center for Program Integrity. However, the agency has not developed an adequate process to address vulnerabilities to improper payments identified by RACs, nor has it addressed three other GAO recommendations designed to reduce improper payments, including one to conduct postpayment reviews of claims submitted by home health agencies with high rates of improper billing.

Overseeing patient care and safety. The agency's oversight of the quality of nursing home care has increased significantly in recent years, but weaknesses in the survey methodology and guidance for surveillance could understate care quality problems. In addition, CMS's current approach for funding state surveys of facilities participating in Medicare is ineffective. However, CMS has implemented, or is taking steps to implement, many recommendations GAO has made to improve nursing home oversight.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss GAO's 2011 High-Risk Series update on the Medicare program.[1] My testimony today will focus on information in our 2011 update on the nature of the risk in the Medicare program, progress made since our last high-risk update in 2009, and the specific actions CMS needs to take to make additional progress.

We have designated Medicare as a high-risk program because its complexity and susceptibility to improper payments, combined with its size, have led to serious management challenges. An improper payment is any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements.[2] In 2010, Medicare covered 47 million elderly and disabled beneficiaries and had estimated outlays of $509 billion. The Centers for Medicare & Medicaid Services (CMS)—the agency in the Department of Health and Human Services that administers Medicare—has estimated improper payments for Medicare of almost $48 billion for fiscal year 2010.[3] However, this improper payment estimate did not include all of the program's risk since it did not include improper payments in its Part D prescription drug benefit, for which the agency has not yet estimated a total amount.[4]

CMS is responsible for implementing payment methods that encourage efficient service delivery, managing the program to serve beneficiaries and safeguard it from loss, and overseeing patient safety and care. However, CMS faces growing challenges in coming years resolving issues that put

[1]GAO, *High-Risk Series: An Update*, GAO-11-278 (Washington, D.C.: February 2011).

[2]This definition includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except where authorized by law), and any payment that does not account for credit for applicable discounts. Pub. L. No. 111-204, § 2(e), 124 Stat. 2224, 2227 (2010) (codified at 31 U.S.C. § 3321 note).

[3]Department of Health and Human Services, *Fiscal Year 2010 Agency Financial Report*, (Washington, D.C.: November 2010).

[4]Medicare consists of four parts. Medicare Parts A and B are known as original Medicare or Medicare fee-for-service. Part A covers hospital and other inpatient stays. Medicare Part B covers hospital outpatient, physician, and other services. Part C is Medicare Advantage, under which beneficiaries receive benefits through private health plans. Part D is the Medicare prescription drug benefit.

the program at risk, given the rapid growth expected in the number of Medicare beneficiaries and program spending.

Our 2011 High-Risk Series update on Medicare is based on a body of work comprising more than 11 products that were developed by using a variety of methodologies, including analyses of Medicare claims, review of relevant policies and procedures, interviews with agency officials and other stakeholders, and site visits.[5] It also includes information CMS has provided on the status of its actions to address recommendations made in these and prior reports on Medicare. Our work was performed in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

2011 High-Risk Series Update on the Medicare Program

As we report in our 2011 High-Risk Series update, Medicare remains on a path that is fiscally unsustainable over the long term. This fiscal pressure heightens the need for CMS to reform and refine Medicare's payment methods to achieve efficiency and savings, and to improve its management, program integrity, and oversight of patient care and safety. CMS has made some progress in these areas, but many avenues for improvement remain.

Reforming and Refining Payments

Since January 2009, CMS has implemented payment reforms for Medicare Advantage (Part C) and inpatient hospital, home health, and end-stage renal disease services. The agency has also begun to provide feedback to physicians on their resource use and is developing a value-based payment method for physician services that accounts for the quality and cost of care. Efforts to provide feedback and encourage efficiency are crucial because physician influence on use of other services is estimated to account for up to 90 percent of health care spending.

[5]For more detailed information on the methodologies used in our work, please consult the list of GAO products at the end of this statement.

In addition, CMS has taken steps to ensure that some physician fees recognize efficiencies when certain services are furnished together, but the agency has not targeted the services with the greatest potential for savings. Under the budget neutrality requirement, the savings that have been generated have been redistributed to increase physician fees for other services. Therefore, we recommended in 2009 that Congress consider exempting savings from adjusting physician fees to recognize efficiencies from budget neutrality to ensure that Medicare realizes these savings.

Our examination of payment rates for home oxygen also found that although these rates have been reduced or limited several times, further savings are possible. As we reported in January 2011, if Medicare used the methodologies and payment rates of the lowest-paying private insurer of eight private insurers studied, it could have saved about $670 million of the estimated $2.15 billion it spent on home oxygen in 2009. Additionally, we found that Medicare bundles its stationary equipment rate payment for oxygen refills, but refills are required only for certain types of equipment, so a supplier may still receive payment for refills even if the equipment does not require them. Therefore, we suggested that Congress should consider reducing home oxygen payment rates and recommended that CMS remove payment for portable oxygen refills from payment for stationary equipment, and thus only pay for refills for the equipment types that require them.

Our work has also shown that payment for imaging services[6] may benefit from refinements. Specifically, CMS could add more front-end approaches to better ensure appropriate payments, such as requiring physicians to obtain prior authorization from Medicare before ordering an imaging service. CMS also has opportunities to improve the way it adjusts physician payments to account for geographical differences in the costs of providing care in different localities. We have recommended that the agency examine and revise the physician payment localities it uses for this purpose by using an approach that is uniformly applied to all states and based on the most current data. CMS agreed to consider the recommendation but was concerned about its redistributive effects. The

[6]Medical imaging is a noninvasive process used to obtain pictures of the internal anatomy or function of the anatomy using one of many different types of imaging equipment and media for creating the image. Examples of imaging services include x-rays, computed tomography, and magnetic resonance imaging scans.

agency subsequently initiated a study of physician payment locality adjustments. The study is ongoing, and CMS has not implemented any change.

Improving Program Management

CMS's implementation of competitive bidding for medical equipment and supplies and its new Medicare Administrative Contractors (MAC) have progressed, with some delays. Congress halted the first round of competitive bidding and required CMS to improve its implementation. In regard to contracting reform, because of delays resulting from bid protests filed in connection with the procurement process, CMS did not meet the target that it set for 2009 and 2010 in transferring workload to MACs. As of December 2010, CMS transferred Medicare fee-for-service claims workload to the new MACs in all but six jurisdictions. For those six jurisdictions, CMS is transferring claims workload in two jurisdictions and has ongoing procurement activity for the remainder. Some new MACs had delays in paying providers' claims, but overall, CMS's contractors continued to meet the agency's performance targets for timeliness of claims processing in 2009.

Regarding Medicare Advantage, CMS has not complied with statutory requirements to mail information on plan disenrollment to beneficiaries, but it did take steps to post this information on its Web site. In addition, the agency took enforcement actions for inappropriate marketing against at least 73 organizations that sponsored Medicare Advantage plans from January 2006 to February 2009.

Of greater concern is that we found pervasive internal control deficiencies in CMS's management of its contracting function that put billions of taxpayer dollars at risk of improper payments or waste. We recommended that CMS take actions to address them. Recently, CMS has taken several actions to address the recommendations and correct certain deficiencies we had noted, such as revising policies and procedures and developing a centralized tracking mechanism for employee training. However, CMS has not made sufficient progress to complete actions to address recommendations related to clarifying the roles and responsibilities for implementing certain contractor oversight responsibilities, clearing a backlog of contacts that are overdue for closeout, and finishing its investigation of over $70 million in payments we questioned in 2007.

Enhancing Program Integrity

New directives, implementing guidance, and legislation designed to help reduce improper payments will affect CMS's efforts over the next few years. The administration issued Executive Order 13520 on reducing improper payments in 2009 and related implementing guidance in 2010. In addition, the Improper Payments Elimination, and Recovery Act of 2010 amended the Improper Payments Information Act of 2002 and established additional requirements related to accountability, recovery auditing, compliance and noncompliance determinations, and reporting.

CMS has already taken action in some areas—for example, as required by law, it implemented a national Recovery Audit Contractors (RAC) program in 2009 to analyze paid claims and identify overpayments for recoupment. CMS has set a key performance measure to reduce improper payments for Parts A and B (fee-for-service) and Part C and is developing measures of improper payments for Part D. CMS was not able to demonstrate sustained progress at reducing its fee-for-service error rate because changes made to improve the methodology for measurement make current year estimates noncomparable to any issued before 2009. Its 2010 fee-for-service payment error rate of 10.5 percent will serve as the baseline for setting targets for future reduction efforts. However, with a 2010 Part C improper payment rate of 14.1 percent, the agency met its target to have its 2010 improper payment rate lower than 14.3 percent. For Part D, the agency is working to develop a composite improper payment rate, and for 2010 has four non-addable estimates, with the largest being $5.4 billion. Other recent CMS program integrity efforts include issuing regulations tightening provider enrollment requirements and creating its Center for Program Integrity, which is responsible for addressing program vulnerabilities leading to improper payments.

However, having corrective action processes to address the vulnerabilities that lead to improper payments is also important to effectively managing them. CMS did not develop an adequate process to address the vulnerabilities to improper payments identified by the RACs and we recommended that it do so. Further, our February 2009 report indicated that Medicare continued to pay some home health agencies for services that were not medically necessary or were not rendered. To help address the issue, we recommended that postpayment reviews be conducted on claims submitted by home health agencies with high rates of improper billing identified through prepayment review and that CMS require that physicians receive a statement of home health services that beneficiaries received based on the physicians' certification. In addition, we recommended that CMS require its contractors to develop thresholds for unexplained increases in billing by providers and use them to develop

automated prepayment controls as a way to reduce improper payments. CMS has not implemented these four recommendations. The agency indicated it had taken other actions; however, we believe these actions will not have the same effect.

CMS's oversight of Part D plan sponsors' programs to deter fraud and abuse has been limited. However, CMS has taken some actions to increase it. For example, CMS officials indicated that they had conducted expanded desk audits and were implementing an oversight strategy.

Overseeing Patient Care and Safety

CMS's oversight of the quality of nursing home care has increased significantly in recent years, but weaknesses in surveillance remain that could understate care quality problems. Under contract with CMS, states conduct surveys at nursing homes to help ensure compliance with federal quality standards, but a substantial percentage of state nursing home surveyors and state agency directors identified weaknesses in CMS's survey methodology and guidance. In addition to these methodology and guidance weaknesses, workforce shortages and insufficient training, inconsistencies in the focus and frequency of the supervisory review of deficiencies, and external pressure from the nursing home industry may lead to understatement of serious care problems. CMS established the Special Facility Focus (SFF) Program in 1998 to help address poor nursing home performance. The SFF Program is limited to 136 homes because of resource constraints, but according to our estimate, almost 4 percent (580) of the roughly 16,000 nursing homes in the United States could be considered the most poorly performing. CMS's current approach for funding state surveys of facilities participating in Medicare is ineffective, yet these surveys are meant to ensure that these facilities provide safe, high-quality care. We found serious weaknesses in CMS's ability to (1) equitably allocate more than $250 million in federal Medicare funding to states according to their workloads, (2) determine the extent to which funding or other factors affected states' ability to accomplish their workloads, and (3) guarantee appropriate state contributions. These weaknesses make assessing the adequacy of funding difficult.

However, CMS has implemented many recommendations that we have made to improve oversight of nursing home care. Of the 96 recommendations made by GAO from July 1998 through March 2010, CMS has fully implemented 45, partially implemented 4, is taking steps to implement 29, and did not implement 18. Examples of key recommendations implemented by CMS include (1) a new survey methodology to improve the quality and consistency of state nursing home

surveys and (2) new complaint and enforcement databases to better monitor state survey activities and hold nursing homes accountable for poor care.

What Remains to Be Done

When legislative and administrative actions result in significant progress toward resolving a high-risk problem, we remove the high-risk designation from the program. The five criteria for determining whether the high-risk designation can be removed are (1) a demonstrated strong commitment to, and top leadership support for, addressing problems; (2) the capacity to address problems; (3) a corrective action plan; (4) a program to monitor corrective measures; and (5) demonstrated progress in implementing corrective measures.

CMS has not met our criteria for removing Medicare from the High-Risk List—for example, the agency is still developing its Part D improper payment estimate and has not yet been able to demonstrate sustained progress in lowering its fee-for-service and Part C improper payment estimates. CMS needs a plan with clear measures and benchmarks for reducing Medicare's risk for improper payments, inefficient payment methods, and issues in program management and patient care and safety.

One important step relates to our recommendation to develop an adequate corrective action process to address vulnerabilities to improper payments. Without a corrective action process that uses information on vulnerabilities identified by the agency, its contractors, and others, CMS will not be able to effectively address its challenges related to improper payments. CMS has implemented certain recommendations of ours, such as in the area of nursing home oversight. However, further action is needed on our recommendations to improve management of key activities. To refine payment methods to encourage efficient provision of services, CMS should take action to

- ensure the implementation of an effective physician profiling system;
- better manage payments for services, such as imaging;
- systematically apply payment changes to reflect efficiencies achieved by providers when services are commonly furnished together; and
- refine the geographic adjustment of physician payments by revising the physician payment localities using an approach uniformly applied to all states and based on current data.

In addition, further action is needed by CMS to establish policies to improve contract oversight, better target review of claims for services with high rates of improper billing, and improve the monitoring of nursing homes with serious care problems.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the subcommittee may have.

Contacts and Acknowledgments

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Sheila Avruch, Assistant Director; Kelly Demots; and Roseanne Price were key contributors to this statement.

Related GAO Products

High-Risk Series: An Update. GAO-11-278. Washington, D.C.: February 2011.

Medicare Home Oxygen: Refining Payment Methodology Has Potential to Lower Program and Beneficiary Spending. GAO-11-56. Washington, D.C.: January 21, 2011.

Medicare Recovery Audit Contracting: Weaknesses Remain in Addressing Vulnerabilities to Improper Payments, Although Improvements Made to Contractor Oversight. GAO-10-143. Washington, D.C.: March 31, 2010.

Medicare Contracting Reform: Agency Has Made Progress with Implementation, but Contractors Have Not Met All Performance Standards. GAO-10-71. Washington, D.C.: March 25, 2010.

Nursing Homes: Addressing the Factors Underlying Understatement of Serious Care Problems Requires Sustained CMS and State Commitment. GAO-10-70. Washington, D.C.: November 24, 2009.

Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program. GAO-10-27. Washington, D.C.: November 6, 2009.

Centers for Medicare and Medicaid Services: Deficiencies in Contract Management Internal Control Are Pervasive. GAO-10-60. Washington, D.C.: October 23, 2009.

Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved When Services Are Provided Together. GAO-09-647. Washington, D.C.: July 31, 2009.

Medicare: Improvements Needed to Address Improper Payments in Home Health. GAO-09-185. Washington, D.C.: February 27, 2009.

Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans. GAO-09-25. Washington, D.C.: December 15, 2008.

Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices. GAO-08-452. Washington, D.C.: June 13, 2008.

Medicare: Focus on Physician Practice Patterns Can Lead to Greater Program Efficiency. GAO-07-307. Washington, D.C.: April 30, 2007.

Mr. STEARNS. Thank you.
Mr. Roy.

STATEMENT OF GERALD ROY

Mr. ROY. Good morning, Chairman Stearns, Ranking Member DeGette and distinguished members of the subcommittee. I am Gerald Roy, Deputy Inspector General for Investigations at the U.S. Department of Health and Human Services, Office of Inspector General. Today I am privileged to have with me OIG Assistant Special Agent in Charge Omar Perez of our Miami Regional Office.

OIG is an independent nonpartisan agency committed to protecting the integrity of more than 300 programs administered by HHS. The Office of Investigations employs over 450 highly skilled special agents who utilize state-of-the-art investigative technologies and a wide range of law enforcement actions including the execution of search and arrest warrants. We are the Nation's premier health care fraud law enforcement agency. Our constituents are the American people, and we work hard to ensure their money is not stolen or misspent. Over the past fiscal year, OIG investigations have resulted in over 900 criminal convictions and civil actions and over $3.7 billion in recoveries.

Today I will discuss three critical aspects of OIG's work: the Medicare fraud strike force model, corporate fraud investigations and tools employed by OIG. The Medicare fraud strike force model is a critical component of one of the Administration's signature initiatives known as HEAT. This is a joint effort by HHS and DOJ to leverage resources and expertise to prevent fraud and abuse. Strike forces concentrate antifraud efforts in geographic areas at high risk for fraud. Strike force teams consisting of OIG agents and our law enforcement partners are assigned to dedicated prosecutors. Strike force cases are data driven, which allows us to catch criminals in the act. We operate in nine locations and we plan to expand to other high-fraud areas. Last month, HEAT strike forces engaged in the largest federal health care fraud takedown in our history, arresting over 100 defendants in nine cities associated with more than $225 million in fraud. More than 300 OIG special agents led this operation. The photos you see here today show our special agents engaged in search and arrest activities.

We are also aggressively pursuing major corporations and institutions that commit health care fraud on a grand scale. Corporate fraud often involves complex kickbacks, accounting and illegal marketing schemes. Some of these companies play such a critical role in the health care delivery system that they may believe that the OIG would never exclude them. Some executives consider civil penalties and criminal fines just the cost of doing business. As long as the profit from fraud outweighs the cost, abusive corporate behavior will continue. OIG plans to alter this cost-benefit calculus of executives by more broadly employing one of the most powerful tools in our arsenal: the authority to exclude individuals and entities from participating in federal health care programs. When there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, OIG plans to exclude that executive from our programs.

Recently, we assigned a special agent to the International Criminal Police Organization, INTERPOL. INTERPOL facilitates international investigative cooperation between 188 member countries and more than 18,000 law enforcement agencies in the United States. HHS OIG is the first in the Inspector General community to have a special agent assigned to INTERPOL. We have over 170 fugitives running from health care fraud charges. We will leverage the resources of INTERPOL's worldwide partners to bring them to justice.

In February, OIG launched our most-wanted fugitive Web site. The individuals you see on our top 10 fugitive poster allegedly defrauded taxpayers of more than $136 million. We have partnered with America's Most Wanted and INTERPOL to feature our Web site and actively spread the word. We are asking the public to help us bring these fugitives to justice.

The bottom line: We are sending a clear message that fraud will not be tolerated and our success represents a prudent investment of taxpayer dollars. For every $1 spent on our health care fraud programs, we return over $6 to the Medicare trust fund.

Thank you for the opportunity to discuss our law enforcement efforts and strategies. We are committed to serving and protecting the Nation's most vulnerable citizens and the federal health care programs on which they rely.

[The prepared statement of Mr. Roy follows:]

Testimony before the United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Oversight & Investigations

"Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid"

Testimony of:

Gerald T. Roy
Deputy Inspector General for Investigations
U.S. Department of Health & Human Services

March 2, 2011
10:00AM
2322 Rayburn House Office Building

Testimony of:
Gerald T. Roy
Deputy Inspector General for Investigations
Office of Inspector General, U.S. Department of Health & Human Services

OIG'S LAW ENFORCEMENT ACTIVITIES TO COMBAT MEDICARE AND MEDICAID FRAUD

Good morning Chairman Stearns, Ranking Member DeGette, and distinguished Members of the Subcommittee. I am Gerald Roy, Deputy Inspector General for Investigations at the U.S. Department of Health & Human Services' (HHS) Office of Inspector General (OIG). Today, I am privileged to have with me OIG Assistant Special Agent in Charge Omar Perez who has served in the Miami Regional Office since 2007. We thank you for the opportunity to discuss OIG's health care anti-fraud strategy, focusing primarily on our law enforcement activities to combat Medicare and Medicaid fraud.

OIG's Role and Partners in Protecting the Integrity of Medicare and Medicaid

OIG is an independent, nonpartisan agency committed to protecting the integrity of the more than 300 programs administered by HHS. Approximately 80 percent of OIG's resources are dedicated to promoting the efficiency and effectiveness of federally funded health care programs and protecting these programs and our beneficiaries from fraud, waste, and abuse.

OIG employs more than 1,700 dedicated professionals, including a cadre of over 450 highly skilled criminal investigators trained to conduct criminal, civil, and administrative investigations of fraud, waste, and abuse related to HHS programs and operations. Our special agents have full law enforcement authority to effectuate the broad range of available law enforcement actions, including the execution of search and arrest warrants. We utilize state-of-the-art technologies and a wide range of law enforcement tools in carrying out these important responsibilities. We are the Nation's premiere health care fraud law enforcement agency.

Our constituents are the American tax payers and we work hard to ensure that their money is not stolen or misspent. Thanks to the work of our dedicated professionals, over the past fiscal year OIG opened over 1,700 health care investigations and obtained over 900 criminal convictions and civil actions. OIG investigations also have resulted in over $3.7 billion in expected criminal and civil recoveries.

Range of Investigations

Fraud, waste, and abuse in the Medicare and Medicaid programs cost taxpayers billions of dollars each year and put beneficiaries' health and welfare at risk. The impact of these losses and risks is exacerbated by the growing number of people served by these programs and the increased strain on Federal and State budgets. Health care fraud schemes commonly include purposely billing for services that were not provided or were not medically necessary, billing for

a higher level of service than what was provided, misreporting costs or other data to increase payments, paying kickbacks, illegally marketing products, and stealing providers' or beneficiaries' identities. From street gang members to corporate officers, our investigations are uncovering a wide range of individuals and entities committing health care fraud. Below are examples of fraud schemes we that have encountered.

In southern California, an individual set out to defraud the Medicare program by establishing multiple fraudulent durable medical equipment (DME) companies. The owner used members of a street gang as nominee owners of his DME companies. He paid the gang members approximately $5,000 each to establish bank accounts and fill out Medicare enrollment paperwork. The nominee owners submitted claims for reimbursement to Medicare for power wheelchairs and orthotic devices that were not medically necessary or legitimately prescribed by a physician. Nine of the gang members and associates were indicted for charges including health care fraud and providing false statements to Government agents. Of the nine defendants, eight have pled guilty and are currently serving or have completed serving jail time for their crimes. Not only is this investigation an example of one of the more prevalent fraud schemes that OIG is seeing, but it also highlights the increasing number of violent criminals entering the health care fraud arena. The criminal records for the gang members involved in this fraud ranged from assault on a peace officer to drug trafficking.

Another recent case involving violent criminals and organized criminal networks involved 73 defendants charged with various health care fraud-related crimes with more than $163 million in fraudulent billings. According to the indictments, the Armenian-American organized crime ring behind the scheme was the Mirzoyan-Terdjanian Organization, which has allegedly used violence and threats of violence to ensure payments to its leadership.

In this crime scheme, criminals allegedly stole the identities of thousands of Medicare beneficiaries from around the country, as well as the identities of doctors who were usually licensed to practice in more than one State. Other members of the syndicate allegedly leased office space, set up fraudulent clinics and opened bank accounts to receive Medicare funds—often in the name of the doctor whose identity they had stolen. Upon becoming approved Medicare providers, the crooks allegedly billed Medicare for services never provided, using the stolen beneficiary information. The funds received from Medicare were quickly withdrawn and laundered; sometimes sent overseas. Although Medicare identified and shut down several of the phony clinics, members of the criminal enterprise simply opened up more fraudulent clinics, usually in another State. The investigation uncovered at least 118 sham clinics in 25 States.

Our agents also work on investigations involving fraud committed by large corporate entities. For instance, OIG investigated the "Small Smiles" case, a horrific example of egregious health care fraud. FORBA Holdings, LLC (FORBA), a management company operating Medicaid pediatric dental clinics, recently agreed to pay $24 million plus interest and entered into a 5-year quality-of-care Corporate Integrity Agreement (CIA) to settle allegations that it performed unnecessary and often painful services on children to maximize Medicaid reimbursement. FORBA managed a chain of 68 pediatric dental clinics in 22 States and the District of Columbia commonly known as "Small Smiles Centers." The investigation revealed that among other things, FORBA allegedly caused the submission of claims for reimbursement for dental services

that either were not medically necessary or did not meet professionally recognized standards of care. Such services billed to the Medicaid programs included performing pulpotomies (baby root canals), placing multiple crowns, administering anesthesia, performing extractions, and providing fillings and sealants. This investigation involved OIG, the Federal Bureau of Investigation (FBI), and the National Association of Medicaid Fraud Control Units.

In 2009, OIG, along with our law enforcement partners, successfully completed one of the largest Federal Government settlements in history. Pfizer Inc., a drug manufacturer, and its subsidiary, Pharmacia & Upjohn Company, Inc., entered a $2.3 billion global resolution with the Federal Government and participating States. The agreement settled charges that Pfizer promoted four drugs, including its pain drug Bextra, for uses not approved by Food and Drug Administration and that the company paid kickbacks to health care professionals to induce them to prescribe Pfizer drugs. In its plea agreement, Pfizer's subsidiary admitted that it promoted Bextra for unapproved uses and at unapproved dosage levels. Pfizer also entered into a comprehensive 5-year CIA with OIG, which requires procedures and reviews to be put in place to avoid and promptly detect fraud or misconduct. Two corporate managers were charged criminally for their role in this matter.

OIG is not alone in the fight to combat fraud and protect the integrity of Federal health care programs. We work closely with the Department of Justice (DOJ); our Federal, State, and local law enforcement partners; and our colleagues at the Centers for Medicare & Medicaid Services (CMS). Additionally, commercial and private insurance entities and trade associations, such as the National Health Care Anti-Fraud Association are also involved in the identification and prevention of health care fraud. OIG conducts joint investigations with law enforcement agencies where there is concurrent jurisdiction and where sharing expertise or authority will lead to the best results possible.

OIG's partnerships extend to one of the Administration's signature initiatives, the Health Care Fraud Prevention and Enforcement Action Team (HEAT). HEAT is a joint effort by HHS and DOJ to leverage resources, expertise, and authorities to prevent fraud, waste, and abuse in Medicare and Medicaid. The HEAT initiative, established by Secretary Kathleen Sebelius and Attorney General Eric Holder in May 2009, is an unprecedented partnership that brings together senior officials from both Departments with the stated goals of sharing information, spotting fraud trends, coordinating prevention and enforcement strategies, and developing new fraud prevention tools. OIG contributes its expertise to HEAT by analyzing data for patterns of fraud; conducting investigations; supporting Federal prosecutions of providers who commit criminal and civil fraud; and pursuing administrative remedies, such as excluding providers from billing Federal health care programs. OIG also makes recommendations to HHS to remedy program vulnerabilities and prevent fraud and abuse.

Investigative Strategies

Strike Forces

A critical component of HEAT is the Medicare Fraud Strike Force. Strike Forces are collaborative efforts, combining OIG's law enforcement skills and resources with those of our partners in the FBI, Medicaid Fraud Control Units, and other State and local law enforcement agencies. The Medicare Fraud Strike Force concentrates its antifraud efforts in geographic areas at high risk for Medicare fraud and has changed the way health care fraud cases are investigated and prosecuted. Strike Force cases focus on the development and implementation of a technologically sophisticated and collaborative approach to combat fraud.

The typical Strike Force case differs from traditional health care fraud investigations. Traditional health care fraud investigations are often initiated months after the fraud has been perpetrated and rely heavily on information from individuals and dated evidence gathered by contract program integrity entities. It is often difficult to identify the perpetrator, who has dropped the "business" under investigation, and is on to the next.

In contrast, Strike Force cases are data driven to pinpoint fraud "hot spots" through the identification of unexplainable billing patterns—as they occur. Further, in traditional health care cases, the subjects of the investigations often provide some level of legitimate services. The majority of subjects in Strike Force cases are engaging in 100 percent fraud, i.e., not providing any legitimate services to beneficiaries. These differences allow Strike Force cases to be completed more quickly. Strike Force coordination has accelerated the Government's response to criminal fraud, decreasing by roughly half the average time from an investigation's start to the case's prosecution.

OIG and DOJ first launched their Strike Force efforts in 2007 in South Florida to identify, investigate, and prosecute DME suppliers and infusion clinics suspected of Medicare fraud. Building on the success in South Florida, the Strike Force model was expanded to eight additional locations—Los Angeles, Houston, Detroit, Brooklyn, Tampa, Baton Rouge, and most recently, Chicago and Dallas.

Just last month, HEAT Strike Forces engaged in the largest Federal health care fraud takedown in history. Teams across the country charged over 100 defendants in 9 cities, including doctors, nurses, health care company owners, and executives for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing. More than 300 OIG special agents participated in partnership with other Federal and State agencies. The defendants charged as a part of the operation are accused of various health care-related crimes ranging from violating the anti-kickback statute to money laundering to aggravated identity theft.

As of February 28, 2011, OIG's Strike Force efforts nationwide have charged over 800 defendants, of which 390 have been convicted and sentenced, resulting in over $376 million in court-ordered restitutions, fines, and penalties.

Corporate Fraud

Health care fraud is not limited to blatant fraud by career criminals and sham providers. Major corporations and institutions, such as pharmaceutical and device manufacturers, hospitals and nursing facilities also commit fraud, often on a grand scale. These corporate and institutional frauds often involve complex kickbacks, accounting schemes, illegal marketing, and physician self-referral schemes. These cases necessitate different, and often more laborious, investigative techniques to unravel the complex fraud schemes and build strong cases.

Investigations of large corporations are often initiated after a "whistleblower" files a law suit on behalf of the Government, known as a "qui tam," alleging wrongdoing by the company. The allegations include information that the company engaged in illegal activities that violated the False Claims Act. In doing so, the companies cause false claims to be submitted to Federal health care programs for payment. The investigations involve coordination among many Federal Government departments and agencies whose programs are alleged to have been harmed.

Investigative techniques utilized in these multi-year, complex corporate investigations include reviewing voluminous paper and electronic documents obtained via subpoenas, interviewing witnesses, and analyzing diagnosis and claims data. We now use cutting-edge electronic discovery tools to maximize investigative efficiency in the processing and review of voluminous electronic evidence. Notably, our office was the first Federal law enforcement agency to implement such technology. This technology enables OIG to analyze large quantities of email or other electronic documents quickly, and to associate or link emails contained in multiple accounts based on content and data.

OIG often negotiates compliance obligations, known as CIAs, such as those discussed earlier in the FORBA and Pfizer investigations, with health care providers and other corporate entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. The typical term of a comprehensive CIA is 5 years. This compliance measure seeks to ensure the integrity of corporate activities and the Federal health care program claims submitted by providers. While many CIAs have common elements, each agreement addresses, in part, the specific facts of the conduct at issue.

I will now address OIG's strategy to counter through our exclusion authority the fraud schemes discussed above and discuss additional high impact tools we employ in our fight against health care fraud.

Employing Effective Fraud-Fighting Tools

The effectiveness of our fraud-fighting efforts is enhanced by our use of several tools. We continuously implement and evaluate these new tools to ensure we are maximizing our impact on health care fraud.

Exclusion

Once we determine that an individual or entity is engaged in fraud, waste, abuse, or the provision of substandard care, OIG can use one of the most powerful tools in our arsenal: exclusion from participating in Federal health care programs. Program exclusions bolster our fraud fighting efforts by removing from the Federal health care programs those who pose the greatest risk to programs and beneficiaries.

There are many grounds for exclusion. Some are mandatory and imposed for a minimum of 5 years. These include a conviction related to the Medicare or Medicaid program and a conviction related to patient abuse. Other exclusions are imposed at OIG's discretion. There are a significant number of such exclusions, including actions based on a sanction taken by a State licensing authority or conduct that could trigger False Claims Act liability.

No program payment may be made for any item or service that an excluded person or entity furnishes, orders, or prescribes. This payment prohibition applies regardless of whether the excluded person is paid directly by the programs (like a physician) or whether the payment is made from the program to another person (such as payments to a hospital for services by its employed nurses and other staff, or payments to a pharmacy for drugs manufactured by a pharmaceutical company). Those who employ the services of an excluded individual or entity for the provision of items or services reimbursable by Medicare or Medicaid may be subject to monetary penalties and program exclusion. Because of its scope and effect, the risk of exclusion creates a strong incentive to comply with the programs' rules and requirements.

In imposing discretionary exclusions, OIG must weigh the fraud and abuse risks to the programs and beneficiaries against the impact on patient access to care if the provider or entity is excluded from the Federal health care programs. Some hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the care delivery system that they may believe that they are "too big to fire" and thus OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries. We are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business. As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue. For example, some major pharmaceutical corporations have been convicted of crimes and paid hundreds of millions of dollars in False Claims Act settlements and yet continue to participate in the Federal health care programs.

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk. For example, in 2008, we excluded three former executive officers of the pharmaceutical company Purdue Frederick based on their convictions for misbranding of the painkiller OxyContin. Each of the executives was convicted based on his status as a responsible corporate officer.

OIG also has the discretionary authority to exclude certain owners, officers, and managing employees of a sanctioned entity (i.e., an entity that has been convicted of certain offenses or excluded from participation in the Federal health care programs) even if the executive has not been convicted of a crime. This authority, section 1128(b)(15) of the Social Security Act, allows OIG to hold responsible individuals accountable for corporate misconduct. OIG has used this exclusion authority in over 30 cases since it was added to the statute in 1996. But until recently, we had typically applied this exclusion authority to individuals who controlled smaller companies, such as pharmacies, billing services, and DME companies and not to executives of large complex organizations like a drug or device manufacturer.

We intend to use this essential fraud-fighting tool in a broader range of circumstances. For example, in addition to the Purdue Frederick executives, we recently excluded an owner (and former executive) of Ethex Corporation under our section (b)(15) exclusion authority. Ethex operated manufacturing facilities in St. Louis. In March of last year, Ethex pled guilty to felony criminal charges after it failed to inform the FDA about manufacturing problems that led to the production of oversized tablets of two prescription drugs. The owner was excluded for a period of 20 years.

We are mindful of our obligation to exercise this authority judiciously, and we do not propose to exclude all officers and managing employees of a company that is convicted of a health care-related offense. However, when there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization, OIG will operate with a presumption in favor of exclusion of that executive. We have published guidance on our Web site that sets out factors we will consider when evaluating whether a section (b)(15) exclusion should be imposed in a particular case.[1] This guidance alerts health care providers and executives to the standards of ethical conduct and responsibility to which they will be held accountable by OIG. Even if we decide exclusion of a major health care entity is not in the best interests of Federal health care programs and their beneficiaries, we may decide that executives in positions of responsibility at the time of the fraud should no longer hold such positions with entities that do business with the programs.

Payment Suspension

We work closely with CMS to suspend payments to the perpetrators of these schemes and in other cases where we have credible evidence of fraud. For example, during a July 2010 Strike Force operation, OIG worked with CMS to initiate payment suspensions and pre-pay edits on 18 providers and suppliers targeted by the investigation. The prompt action taken by OIG and CMS stopped the potential loss of over $1.3 million in claims submitted by the defendants. During the February Strike Force operations discussed above, OIG and CMS worked to impose payment suspensions that immediately prevented a loss of over a quarter million dollars in claims submitted by Strike Force targets.

[1] Available online at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf.

Data Access

Better access to, and use of, CMS claims data is critical to the Strike Force model and for all health care fraud detection and enforcement activities. To be most effective, it is essential that law enforcement have access to robust, "real time" claims data – data that are available as soon as claims are submitted to Medicare. Timely data is also essential to our ability to respond with agility as criminals shift their schemes and locations to avoid detection. We have made important strides in obtaining data more quickly and efficiently. We have obtained limited law enforcement access to real-time data, and OIG and DOJ are working with CMS to expand this access.

The Strike Force approach also uses data analysis and a collaborative approach to focus enforcement resources in geographic areas at high risk for fraud. Strike Force cases are data driven to pinpoint fraud hot spots through the identification of suspicious billing patterns as they occur. To support this approach, OIG established a team of data experts comprised of OIG special agents, statisticians, programmers, and auditors. Together, the team brings a wealth of experience in utilizing sophisticated data analysis tools combined with criminal intelligence gathered directly from special agents in the field to identify more quickly ongoing health care fraud schemes and trends. To expand the coalition of data experts focused on this effort, OIG has garnered the support and participation of our law enforcement partners at DOJ and FBI.

Mutual Assistance

OIG recently worked with the Council of the Inspectors General on Integrity and Efficiency and the U.S. Department of Justice to establish assistance agreements within the Inspector General community to leverage law enforcement resources, maximize efficiency, and reduce operational costs. As a result, special agents in the IG community can assist each other on law enforcement operations, limited in time and scope. Before, when a local OIG office lacked the resources to serve multiple search and arrest warrants, special agents traveled from other locations at considerable cost to assist. Now, OIG special agents from various OIG offices can assist each other. This mutual assistance agreement was used with great success during last month's major Strike Force operation. Special agents from seven OIG offices assisted us in our historic takedown. In Miami, for example, those agents knew the geographic areas and were familiar with the local communities and customs. Most of those who assisted us spoke Spanish, they language spoken almost exclusively in many South Florida communities. Knowledge of local environment, ability to speak a common language, and familiarity of local customs results in a safer environment in which OIG special agents can operate and conduct law enforcement activities. As a result of leveraging the resources of the IG community, we saved in excess of $40,000. These funds will be put towards future operations and investigations.

Interpol

Recently, we assigned a special agent to INTERPOL Washington, the U.S. National Central Bureau (USNCB). USNCB is the official U.S. representative to the International Criminal Police Organization (INTERPOL) as designated by the U.S. Attorney General. The USNCB

serves as the national point of contact for INTERPOL matters and coordinates international investigative cooperation between INTERPOL's 188 member countries and the more than 18,000 Federal, State, local and tribal law enforcement agencies in the United States. HHS OIG is the first in the Inspector General community to have a special agent detailed to INTERPOL. We have over 200 fugitives from our investigative efforts, more than 170 of which are the result of health care fraud investigations. We will leverage the resources and relationships of INTERPOL's, 18,000 law enforcement partners worldwide to bring perpetrators of health care fraud to justice.

OIG's Fugitive Web site

Recently, OIG established a fugitive Web site to assist in locating fugitives running from health care fraud charges. We have posted on our website the list of the most-wanted health care fraud fugitives, including photographs and details on the fugitives and their fraud schemes.[2] Our current most-wanted list includes 10 individuals who have allegedly defrauded taxpayers of approximately $136 million. We have partnered with "America's Most Wanted" and INTERPOL to feature our Web site and actively engaged the media to spread the word that we are searching for these fugitives. We are asking the public to help us bring these fugitives to justice by reporting any information about their whereabouts to our Web site or fugitive hotline (1-888-476-4453).

Conclusion

OIG's efforts that I have discussed today are critical aspects of a multi-agency effort to protect the vitality, integrity and finite resources of the Federal health care programs. We are committed to investing in program integrity efforts in order to send a clear message that fraud in our Federal health care programs will not be tolerated.

By attacking fraud vigorously, wherever it exists, we all stand to benefit. Medicare Trust Fund resources will be protected and remain available for their intended purposes. Medicare dollars that have gone to fraudulent providers will instead be available to serve the critical health care needs of our program beneficiaries. And most importantly, we can ensure that our seniors and persons with disabilities receive the necessary services and care they need to stay healthy, so as to enjoy enhanced well-being and quality of life.

Finally, our anti-fraud efforts represent a prudent investment of taxpayer dollars. Over the past 3 years, for every $1 spent on the health care fraud and abuse control program, an average of $6.80 has been returned to the Government.

Thank you for the opportunity to discuss our law enforcement efforts and strategies used to protect the integrity of Federal health care programs.

[2] Available at http://oig.hhs.gov/fugitives/.

Mr. STEARNS. Thank you.
Mr. Perez, welcome.

STATEMENT OF OMAR PEREZ

Mr. PEREZ. Good morning, Chairman Stearns, Ranking Member DeGette and distinguished members of the subcommittee. I am Omar Perez, Assistant Special Agent in Charge with Human and Health Services Office of Inspector General. I am stationed in Miami and currently supervise agents assigned to the Medicare strike force, and prior to assuming my position, I was a member of one of the strike force teams. I am honored for the invitation and opportunity to discuss our efforts in combating health care fraud.

This morning, I am here to tell you what our agents and I experience as criminal investigators on the front line in this fight against health care fraud. Although the vast majority of Medicare providers are honest, my job and our job is to focus on those intent on stealing from the program. My squad is actively engaged in criminal investigations, testifying before grand juries, executing search and arrest warrants and seizing bank accounts.

Medicare fraud is discussed openly on the streets of south Florida because it is accepted as a safe and even way to get rich quick. Now, the money involved in staggering. We see high school dropouts making anywhere from $100,000 to millions a year. Typically, we see business owners, health care providers, doctors and Medicare patients participate in the fraud but now we see drug dealers and organized criminal enterprises joining in.

Today I will describe the typical fraud scheme, highlight Miami's investigative model, share success stories, and finally discuss the evolution of fraud in south Florida.

Now, prior to the state of the strike force, Miami was riddled with sham DME companies whose owners had one idea in mind: steal from the program. In order to perpetrate the fraud, nominee owners were recruited to place their names on corporate documents, lease agreements and corporate bank accounts, and in exchange were paid between $10,000 to $20,000. Stolen patient information was obtained from corrupt employees at hospitals, clinics and doctors' offices. They also obtained lists of stolen physician identifiers, and with these two key pieces of information submitted fraudulent claims to Medicare for equipment that was never provided. Once the money was deposited into the account, it was withdrawn within days. The idea was to deplete the account so that by the time Medicare even realized that there was a fraud, there was no money left to recover.

These schemes are executed within a matter of months so we developed a streamlined investigative approach to HEAT investigations. The model includes the following steps to help identify our targets: quickly obtain and analyze Medicare claims, identify and obtain banking information, obtain the corporate documents, and identify the medical billing agent.

Now, the following examples highlight the successes of our model. Two months ago, one of our agents received information from a confidential source that a DME company was submitting fraudulent claims. Through data analysis, we saw that $1.5 million was billed in just 3 weeks after a corporate change of ownership.

Further data analysis showed that this company and another that we had under investigation was billing for about the same 100 patients, so within 30 days the agents corroborated that fraud was taking place and we were able to arrest the target. Using this model, he got zero money. When we arrested him, we found a fake driver's license and learned that he was about to purchase yet another company under this assumed identity.

In another example, a source alleged a corporation owning several community mental health centers was paying patients to allow them to bill for services they were not receiving. Data analysis and other investigative techniques led to five individuals being indicted and arrested and seven search warrants being executed simultaneously. Now, 2 weeks ago, we indicted and arrested another 20 individuals associated with this corrupt corporation and those arrested included center directors, physicians, therapists, patient recruiters and money launderers. The photographs you see are of the lavish estate of a patient recruiter who also laundered money for the corrupt corporation. We are finding that criminals have migrated to other services within the Medicare program including home health, community mental health centers, physical and occupational therapy. Historically, Medicare patients and doctors were not involved but now we are finding that in many cases both are getting paid to participate in the fraud.

Additionally, not only are we seeing criminals migrate to other parts of the State but we know that they have migrated to States adjacent to Florida and other parts of the country like Georgia, North Carolina, Tennessee, West Virginia and Michigan.

Thank you very much for the opportunity to discuss strike force operations in the south Florida and the investigative model that we utilize to protect the taxpayers interest, and I certainly welcome the opportunity to address any questions the panel has.

[The prepared statement of Mr. Perez follows:]

Testimony before the United States House of Representatives

Committee on Energy and Commerce

Subcommittee on Oversight & Investigations

"Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid"

Testimony of:

Omar Perez
Assistant Special Agent in Charge
Office of Inspector General
U.S. Department of Health & Human Services

March 2, 2011
10:00AM
2322 Rayburn House Office Building

Testimony of:
Omar Perez
Assistant Special Agent in Charge
Office of Inspector General
U.S. Department of Health & Human Services

Good morning Chairman Stearns, Ranking Member DeGette, and distinguished members of the Subcommittee. I am Omar Perez, an Assistant Special Agent in Charge (ASAC) with the U.S. Department of Health & Human Services' (HHS) Office of Inspector General (OIG). I am stationed in the Miami Regional Office, and currently supervise Agents assigned to the Medicare Fraud Strike Force. I was formerly a member of one of the Strike Force teams prior to my assuming the position of ASAC. I am honored to have the opportunity to discuss OIG's efforts in combating Medicare and Medicaid fraud.

I am here this morning to tell you what our agents experience as criminal investigators on the front-line in the fight against health care fraud. Although the vast majority of Medicare providers are honest, my job is to focus on those who steal from the program. My squad is actively engaged in investigating criminal health care fraud, executing search and arrest warrants, seizing bank accounts, and providing Grand Jury testimony in the pursuit of criminal indictments.

In South Florida, Medicare fraud is not only perpetrated by independent, scattered groups, but also by competitive, organized businesses complete with hierarchies and opportunities for advancement. Medicare fraud is discussed openly on the streets and is accepted as a safe and easy way to get rich quick.

Who commits this fraud? People from all walks of life—they say it's easy money and it's safer than dealing drugs. I see people who never finished high school living lavish lifestyles, making anywhere from $100,000 to millions of dollars a year by committing Medicare fraud. The money involved is staggering. We see business owners, health care providers and suppliers, doctors, and Medicare beneficiaries participating in the fraud. We also see drug dealers and organized criminal enterprises defrauding the system.

How much money is involved? Way too much! As an example, I will tell you a little later about an investigation I supervise in which over $200 million was billed to Medicare in just 2 years.

In my testimony today, I will describe a typical Medicare fraud scheme that we investigate in Miami. I will then provide an overview of the Miami Strike Force investigative approach from an agent's perspective. I will share examples of Miami Strike Force success stories. Finally, I will discuss the evolution of fraud in South Florida.

COMMON DURABLE MEDICAL EQUIPMENT FRAUD SCHEMES PRE-STRIKE FORCE

Prior to the start of the Strike Force, South Florida was riddled with sham durable medical equipment (DME) companies. Some of these companies started out as legitimate operations with a Medicare billing number; however, they were unsuccessful as the market was saturated with illegitimate DME companies. As a result, these companies were sold and, all too often, their new owner(s) had one idea in mind: steal from Medicare.

Once in the hands of criminals, these companies no longer provided legitimate services. In order to perpetrate the fraud, "nominee owners"[1] were recruited. The names of these nominee owners were placed on corporate documents, lease agreements, and corporate bank accounts. Those perpetrating the fraud then obtained lists of stolen Medicare beneficiary information which were compiled by individuals with access to patient information, such as employees of hospitals, clinics, and physicians' offices. The criminals also obtained lists of stolen Unique Physician Identification Numbers (UPIN) assigned to physicians by the Centers for Medicare & Medicaid Services (CMS). UPINs are essential to the completion of a Medicare claim for reimbursement. With these two key pieces of information, the nominee owners would submit fraudulent claims to Medicare for DME that was never provided. The types of equipment ranged from nebulizers and corresponding medications, to incontinence supplies, to motorized wheelchairs.

Once CMS paid the claims and deposited money into the company's bank account, it was withdrawn within days using multiple check cashers. The idea was to deplete the account so that once Medicare discovered the fraudulent billing, which could take 6 months to 1 year, there would be no money in the account.

MIAMI STRIKE FORCE APPROACH TO COMBATING FRAUD

The DME fraud schemes described above were executed within a matter of months. After billing Medicare for millions of dollars, companies would change ownership, bill Medicare again for millions of dollars, close, and simply take over another company and repeat the process in another location. By the time traditional investigative referral methods came to fruition, criminals had absconded with millions of taxpayer dollars.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, established by Secretary Kathleen Sebelius and Attorney General Eric Holder in May 2009, is a joint effort by HHS and DOJ to leverage resources and expertise to prevent fraud, waste, and abuse in Medicare and Medicaid. A critical component of HEAT is the Medicare Fraud Strike Force.

[1] A nominee owner is an individual who is recruited and paid by the true owner to be the owner of record for a DME company. This process occurs to protect the identity of the true owner.

A streamlined investigative approach was created for Strike Force investigations. The Strike Force model is a collaborative effort between the Department of Justice (DOJ) and HHS. Each Strike Force team includes agents from HHS OIG and the Federal Bureau of Investigation, as well as attorneys from DOJ. The teams are supported by Investigative Analysts, as well as CMS program experts and contractors. Miami has 10 Strike Force teams dedicated to investigating the wide array of Medicare fraud such as HIV infusion therapy, physical and occupational therapy, DME, home health agencies, and Community Mental Health Centers to name a few.

The individual investigations generally follow a model that has proved highly successful in these fraud schemes. The model includes the following steps: (1) analyze and evaluate claims data; (2) obtain the Medicare enrollment application; (3) identify the medical biller; (4) identify and obtain bank information; and (5) identify the "true" owner of the Medicare provider that is under investigation.

Analyze and Evaluate Claims Data

We now have the ability to stop the payment of a significant amount of money and catch the criminals before they and the money disappear. Strike Force team members receive Medicare billing data gleaned from a wide variety of CMS data systems. We analyze the data to identify aberrant billing patterns. Before Strike Force teams were initiated, the referrals we received contained billing data that were typically between 6 months to 1 year old. Today, the data we receive provide billing information that is only 2 to 3 weeks old. In South Florida, as elsewhere, criminals can receive several hundred thousand dollars in fraudulent payments within a matter of weeks. The ability to retrieve recent data allows us to potentially obtain evidence immediately to substantiate fraudulent activity. The claims data can help us identify important information in assessing whether a fraudulent scheme is underway, including:

- total amount paid
- dates of service
- referring/ordering physicians
- beneficiaries
- claim dates
- types of procedures billed
- place of service
- provider banking information, and
- ownership status.

This process is called developing an investigative snapshot[2] of the suspected fraudulent activity.

[2] "Snapshot" refers to an excerpt of a provider's or supplier's billing history that includes total amount billed and paid, claims denied, patient name, referring physicians, procedural codes billed, dates of service and place of service.

Obtain the Medicare Enrollment Application and Other Data

Obtaining the Medicare enrollment application is extremely important because it identifies the registered owner, his or her financial institution, and the authorized medical billing representative. For investigators, this information can generate countless leads to other co-conspirators involved in the fraudulent activity.

Identify the Medicare Medical Biller

The Medicare billing process begins when the medical biller electronically submits the patient's information to a Medicare claims contractor for processing and reimbursement. The medical biller could be an employee of the fraudulent company and/or a contracted third party. It is important for investigators to interview the medical biller to determine his or her level of complicity, if any, and identify who provided the billing information.

Identify the Bank Account and Financial Institution of the Fraudulent Business

A critical investigative step is determining the true owner of the fraudulent provider's bank account. In many instances, the true owner is not the individual who opened the bank account, withdrew or transferred funds, and/or cashed the Medicare checks. It is a significant step for investigators to identify and interview all individuals with signatory control over these accounts.

Identify the "true" owner of the clinic and/or DME company

Strike Force members utilize commercial databases, bank account data, and informants in an effort to identify the true owners of the company. Once the true owner is identified, Strike Force members will attempt to interview the true owner.

Typically, a nominee owner is paid $10,000 to $20,000 for his or her role. Our sources have told us that nominee owners have been recruited in other countries and travel to South Florida solely for this purpose. After being paid, they return to their native countries.

MIAMI STRIKE FORCE SUCCESS STORIES

I offer the following examples that highlight the successes of our streamlined investigative strategy:

One of our Agents received information from a confidential source that a DME company was submitting fraudulent claims. Through data analysis, we saw that there was an aberrant billing spike just after a corporate change of ownership took place: $1.5 million billed in just 3 weeks. Further data analysis showed that this company was billing for about 100 patients that another company we have under investigation was also billing for.

With a few interviews, the Agents corroborated that fraud was taking place, and within 30 days we were able to arrest our target. Using this approach, we were able to prevent any Medicare funds from reaching the subject's hands. After the arrest, the Agents learned that he was using a false identity and was about to purchase yet another company. The investigation continues.

In another example, OIG Agents received information from a confidential source that a corporation owning several Community Mental Health Centers (CMHC) was billing Medicare for services that patients were not receiving or did not qualify for to the tune of $200 million. The owner and managers of this corporation offered and paid kickbacks and bribes to patient recruiters to recruit Medicare beneficiaries to attend the corporation's CMHCs and allow Medicare to be billed for services purportedly provided to them. The patients in turn were paid by the patient recruiters. Data queries were performed, interviews conducted, and within 45 days we secured a criminal indictment charging the center's owner and managers with health care fraud. In October of last year, we executed five arrest warrants and seven search warrants.

The information obtained in the CMHC investigation led to another indictment this year. In February, our enforcement operation resulted in the arrest of 20 individuals ranging from physicians, therapists, clinic directors, patient recruiters, and money launderers. Physicians purportedly falsified medical records, and clinic directors allegedly directed the patient recruiters and money launderers. As part of this operation, we reached out to seven other OIGs to assist in the arrest operation using the mutual assistance program previously mentioned by Deputy Inspector General for Investigations Roy. Utilizing this collaborative and cost-efficient approach, we were able to arrest 60 subjects in Miami connected to stealing millions of dollars from the Medicare trust fund. This investigation is ongoing.

THE EVOLUTION OF FRAUD IN SOUTH FLORIDA

In many instances, criminals have shifted their schemes from purchasing legitimate DME companies to instead establishing storefront shams. The storefronts are set up by criminals who have the required equipment to pass Medicare onsite inspections. Once the Medicare provider number has been issued, the individuals pick up their equipment and all that remains is an empty storefront.

Some criminals create additional layers to shield the true owners to counter Strike Force tactics. Prior to Strike Force operations, the true owner was most likely an associate of the nominee owner. Now there are many levels to their criminal enterprises; each level operating independently of the others but controlled by the same person(s).

We found that criminals are now migrating to other services within the Medicare program to perpetrate their fraud. Other services impacted include home health, community mental health, and physical and occupational therapy. OIG is aggressively addressing these areas. Historically, Medicare beneficiaries and physicians were not

typically involved in these types of criminal enterprise. Now we know that in more and more cases both are getting paid to participate in fraud.

CONCLUSION

The investigative approach and success stories referenced today represent the dedication and commitment of all OIG Special Agents and our collaborative partners in the fight against fraud within the Medicare and Medicaid insurance programs. The HEAT initiative illustrates how combined resources, technology, and collaboration can be synthesized to combat health care fraud to protect vulnerable Americans.

Thank you for the opportunity to discuss Strike Force operations in South Florida, and the strategies and investigative methods utilized to protect the interest of all taxpayers. I would be happy to answer any questions that the Subcommittee may have.

Mr. STEARNS. Thank you, Mr. Perez.
Mr. Spiegel.

STATEMENT OF JOHN SPIEGEL

Mr. SPIEGEL. Thank you. Chairman Stearns, Ranking Member DeGette and members of the subcommittee, thank you very much for the invitation to discuss the Centers for Medicare and Medicaid Services' efforts to reduce fraud, waste and abuse in the Medicare, Medicaid and Children's Health Insurance programs and the new tools and authorities provided in the Affordable Care Act. I am happy to be here today appearing on behalf of Peter Buddetti, who is the Director of the Center for Program Integrity where I work as the Director of the Medicare Program Integrity Group.

Dr. Buddetti said from the beginning of the time on his job that people are asking two questions repeatedly: why do you let the perps into Medicare and Medicaid and why do you continue to pay fraudulent claims? Well, I can tell you that with the new authorities provided in the recent laws and the commitment of the Administration in fighting fraud, we are making progress on both fronts. Our approach will be keeping people who don't belong in the programs out and we will be kicking out fraudulent claims before they are paid. We now have the flexibility to tailor resources to address the most serious problems and quickly initiate activities in a transformative way.

Under the leadership of Secretary Sebelius, CMS has taken a number of administrative steps to better meet emerging needs and challenging in fighting fraud and abuse. For example, CMS consolidated the Medicare and Medicaid Program Integrity Groups under a unified Center for Program Integrity to pursue a more strategic and coordinated set of program integrity policies and activities across both programs. This change in structure and focus served our program integrity well and has facilitated collaboration on antifraud initiatives with our law enforcement partners in the HHS Office of Inspector General and in the Department of Justice and State Medicaid fraud control units as well. And just last week we restructured the center to provide some additional concentrated focus on the new initiatives that I will be talking about in a little bit, some examples being increased focus on data development and uses of analytics that will help bolster our work.

The Affordable Care Act enhanced this organizational change by providing an opportunity to develop policies across all of our programs jointly. The act's division such as enhanced screening requirements for new providers and suppliers apply across all the programs, not just for Medicare and not just for Medicaid. They are uniform across the board. This ensures consistency obviously as one of the goals that we try to pursue in our fraud and abuse activities.

So many might argue that just rearranging the boxes doesn't have much of a value but we think that having created a Center for Program Integrity, it is on a par with other major operating components within CMS. It sends a powerful message that the Administration is seriously committed to fighting fraud and it puts the bad actors on notice, and because most success in anything comes from clarity of purpose, we have made certain that our

sights are firmly fixed on the goal of ensuring correct payments are made to legitimate providers for covered, reasonable and appropriate services for eligible beneficiaries.

I would like to take a little time today to explain how we have been transforming our fraud detection and prevention work through the new approach on the poster over there. So first, central to our goal is the shift away from identifying fraud before it happens. We want to prevent things from taking shape. We want to move away from "pay and chase" that we have relied on so heavily in the past. Second, we don't want to be limited to a monolithic approach to fighting fraud. Instead, we want to focus our efforts on the bad actors who pose elevated risk. Third, we are taking advantage of innovation and technology as we move quickly to take action focused on prevention when possible. And fourth, consistent with the Administration's commitment to being transparent, we are developing performance measures that will specify our targets for improvement. We are actively engaging public and private partners from across the spectrum because there is obviously much to learn from others who engaged in the same endeavor of fighting fraud. We know the private sector is victimized by the same schemes we see in public programs in collaboration and communication among all parties. And finally, we are committed to coordination and integration of our activities across all the programs in CMS based on best practices and lessons learned.

So as we move away from the old ways to more modern and sophisticated successful approaches, we are continuing to concentrate our actions——

Mr. STEARNS. Just if you can, sum up. Your time is over.

Mr. SPIEGEL. OK. Sorry.

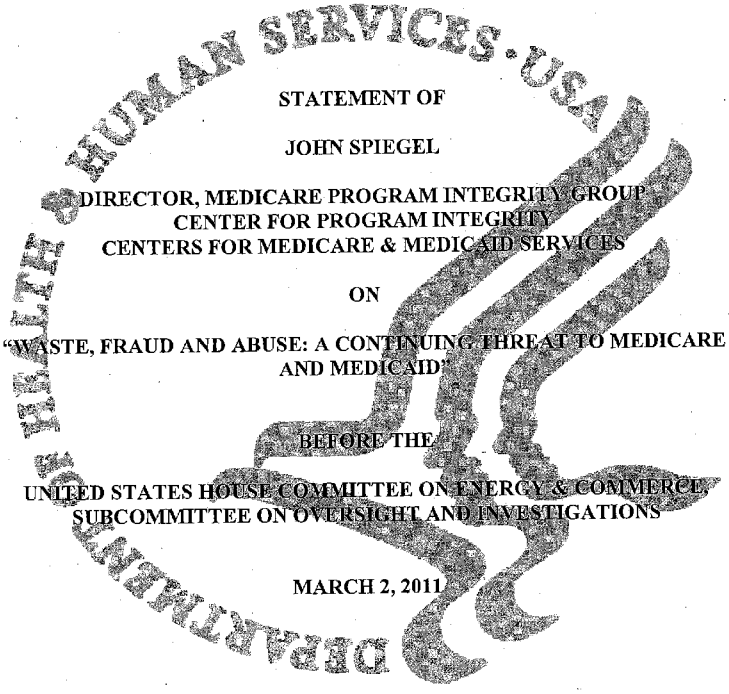
Mr. STEARNS. Thank you.

Mr. SPIEGEL. Let me just get through this one particular part and I will be finished.

Mr. STEARNS. Can you just summarize?

Mr. SPIEGEL. Sure. We want to do a better job of keeping people out before they get in. We want to move quickly when we see those who have gotten in that are potentially improper bills and take steps to reduce claims payment error by 50 percent and get people out who don't belong.

[The prepared statement of Mr. Spiegel follows:]



STATEMENT OF

JOHN SPIEGEL

DIRECTOR, MEDICARE PROGRAM INTEGRITY GROUP
CENTER FOR PROGRAM INTEGRITY
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

"WASTE, FRAUD AND ABUSE: A CONTINUING THREAT TO MEDICARE AND MEDICAID"

BEFORE THE

UNITED STATES HOUSE COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

MARCH 2, 2011

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

U.S. House Committee on Energy & Commerce,
Subcommittee on Oversight and Investigations
Hearing on "Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid"
March 2, 2011

Chairman Stearns, Ranking Member DeGette, and Members of the Subcommittee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to reduce fraud, waste, and abuse in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) and the new tools and authorities provided in the Affordable Care Act.

As CMS implements the new authorities in the Affordable Care Act, we have a significant opportunity to enhance our existing efforts to combat fraud, waste, and abuse in Federal health care programs. These new authorities offer more front-end protections to keep those who are intent on committing fraud out of the programs and new tools for deterring wasteful and fiscally abusive practices, identifying and addressing fraudulent payment issues promptly, and ensuring the integrity of Medicare, Medicaid, and CHIP. CMS is pursuing an aggressive program integrity strategy that seeks to prevent payment of fraudulent claims, rather than chasing fraudulent providers after a payment has been made. CMS now has the flexibility to proactively tailor resources and quickly initiate activities in a transformative way. We believe the Affordable Care Act provisions will greatly support the effectiveness of our work. This historic moment also presents CMS with a valuable opportunity to partner with the private sector and collaborate on fraud detection efforts based on tools and methods that are already succeeding in other sectors.

CMS recognizes the importance of having strong program integrity initiatives that will deter and end criminal activity that attempts to defraud Federal health care programs. I share your commitment to ensuring taxpayer dollars are being spent on legitimate items and services, which is at the forefront of our program integrity mission.

Bringing Activities Together into the Center for Program Integrity

CMS has taken several administrative steps to better meet the Agency's future needs and challenges. CMS realigned its internal organizational structure last year, consolidating the Medicare and Medicaid program integrity groups under a unified Center for Program Integrity (CPI). This centralized approach has enabled CMS to pursue a more strategic and coordinated set of program integrity policies and activities across the Federal health care programs and has formed a bridge that facilitates collaboration on anti-fraud initiatives with our law enforcement partners, such as the Health and Human Services Office of Inspector General (OIG), the Department of Justice (DOJ), and State Medicaid Fraud Control Units. We are also working closely with our colleagues in the Office of the Secretary at HHS, as they implement the Secretary's program integrity initiative across the department. We are actively sharing best practices and lessons learned as we move forward together.

The Affordable Care Act enhances this organizational change by providing CMS with the ability to improve and streamline its program integrity capabilities by providing us with an opportunity to jointly develop Medicare, Medicaid and CHIP policy on these new authorities. For example, many Affordable Care Act provisions, such as enhanced screening requirements for new providers and suppliers, apply across the programs. The new integrated operation of program integrity activities within CMS ensures that there is better consistency in CMS' approach to fraud prevention across all of our programs.

Strategic Principles for Program Integrity Operations

As we continue the process of implementing these authorities and strengthening the integrity of the Federal health care programs, we are mindful of the impact our new rules have on health care providers and suppliers, who are our partners in caring for beneficiaries and have the awareness needed to assist us in continuing to protect beneficiary access to necessary health care services, supplies or medication. CMS is committed to improving care for our beneficiaries and engaging States and law-abiding providers and suppliers to ensure our activities reflect their interests. As we seek to reduce fraud, waste, and abuse in Medicare, Medicaid, and CHIP, we are mindful of

striking the right balance between preventing fraud and other improper payments without impeding the delivery of critical health care services to beneficiaries. At their core, Federal health care programs are designed to provide affordable health care to families in need, people with disabilities, and aging Americans. Additionally, the vast majority of health care providers are honest people who abide by their legal and professional duties and provide critical health care services to millions of CMS beneficiaries every day. CMS is committed to providing health care services to beneficiaries, while reducing the burden on legitimate providers, targeting fraudsters and saving taxpayer dollars.

This Administration is committed to minimizing fraud, waste, and abuse in Federal health care programs. While improper payments are not necessarily indicative of fraud, CMS is committed to reducing all waste within our programs. In order to focus on the prevention of improper payments while remaining vigilant in detecting and pursuing problems when they occur, we have increased provider education on proper documentation and are reexamining our claims payment and enrollment systems. With these efforts and others, we are confident that we will meet the President's goal to reduce the Medicare fee-for-service error rate in half by 2012. Moreover, we are implementing a number of measures that will shift our enforcement and administrative actions from a "pay and chase" mode to the prevention of fraudulent and other improper payments. This shift involves many different activities, which we are carrying out with the powerful new anti-fraud tools provided to CMS and our law enforcement partners under the Affordable Care Act.

We are steadily working to incorporate targeted screening and prevention activities into our claims and enrollment processes where appropriate. Our goal is to keep those individuals and companies that intend to defraud Medicare, Medicaid, and CHIP out of these programs in the first place, not to pay fraudulent claims when they are submitted, and to remove such individuals and companies from our programs if they do get in. The first step to preventing fraud in the Federal health care programs is to appropriately screen providers and suppliers who are enrolling or revalidating their enrollment to verify that only legitimate providers and suppliers who meet our stringent enrollment standards are providing care to program beneficiaries.

CMS' Efforts to Implement the Affordable Care Act

New Actions – Medicare, Medicaid, and CHIP Screening and Fraud Prevention Rule (CMS-6028-FC)

On January 24, 2011, HHS and CMS announced rules that implement new Affordable Care Act tools to fight fraud, strengthen Federal health care programs, and protect taxpayer dollars. This rule puts in place prevention safeguards that will help CMS move beyond the "pay and chase" approach to fighting fraud.

Enhanced Screening and Enrollment Protections: The Affordable Care Act requires providers and suppliers who wish to enroll in the Medicare, Medicaid, or CHIP programs to undergo a level of screening tied to the level of risk of fraud, waste, or abuse such providers and suppliers present to the programs. This new rule will require high-risk providers and suppliers, including newly enrolling suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and home health agencies, to undergo a higher level of scrutiny based on CMS' and law enforcement's experience with these provider and supplier types. CMS has also established certain triggers that would move a provider or supplier into the highest screening level.

In addition, CMS-6028-FC implements the Affordable Care Act provision that authorizes CMS to require that providers who order and refer certain items or services for Medicaid beneficiaries be enrolled in the State's Medicaid program; this is similar to the new Medicare requirement included in an interim final rule published this past spring, CMS-6010-IFC, described in more detail below.

This new rule implements the statutory authority for CMS to impose a temporary enrollment moratorium if the Secretary determines such a moratorium is necessary to prevent or combat fraud, waste, or abuse. We will assess the impact of any proposed moratorium on beneficiary access and take this into consideration. We will publish a notice of the moratorium including a rationale for the moratorium in the *Federal Register*. Other preventive measures include new levels of coordination between

Medicare and State Medicaid agencies. For example, State Medicaid programs are now required to terminate a provider that has been terminated for cause by Medicare or another State Medicaid agency.

Stopping Payment of Suspect Claims: CMS-6028-FC allows Medicare payments to be suspended from providers or suppliers if there is a credible allegation of fraud pending an investigation or final action. The law also requires States to suspend payments to Medicaid providers where there is a credible allegation of fraud. This enhanced authority will help prevent taxpayer dollars from being used to pay fraudulent providers and suppliers.

New Resources to Strengthen Program Integrity: The Affordable Care Act provides an additional $350 million over 10 years, plus an inflation adjustment, to ramp up program integrity efforts in HHS' Health Care Fraud and Abuse Control program (HCFAC) account, including the Medicare Integrity Program, as well as the Medicaid Integrity Program. These dedicated Affordable Care Act funds provide important financial resources for government-wide health care fraud and abuse efforts for the next decade, which will be used along with discretionary funding sought in the President's Budget to pursue critical new prevention-focused activities, place more "feet on the street" by hiring more law enforcement agents, and facilitate other efforts to reduce improper payments and address emerging fraud schemes in the health care system.

Other Implementation Steps – CMS-6010-IFC

CMS published an interim final rule with comment period (CMS-6010-IFC) in the *Federal Register* on May 5, 2010 that implemented some new anti-fraud authorities and provisions of the Affordable Care Act. This rule, which took effect July 6, 2010, requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in Federal health care programs and to also include their NPI on all claims for payment submitted to Medicare and Medicaid. CMS-6010-IFC also requires that physicians and eligible professionals who order or refer home health services or most Medicare Part B-

covered items and services for Medicare fee-for-service beneficiaries be enrolled in Medicare. In addition, it adds requirements for providers, physicians, and suppliers participating in the Medicare program to provide access and maintain documentation on orders or requests for payments for items or services at high risk of fraud, waste, and abuse, such as DMEPOS, home health services, and certain other items or services as specified by the Secretary.

Other Affordable Care Act Authorities

There are many other Affordable Care Act program integrity provisions that we will also be busy implementing this year. For example, CMS will be issuing additional surety bond requirements under the Affordable Care Act for DMEPOS suppliers and home health agencies and potentially for certain other providers of services and supplies. These surety bonds are a condition of enrollment and may help ensure that DMEPOS suppliers and home health agencies, and potentially certain other providers of services and supplies, are legitimate and financially solvent.

In addition, providers and suppliers will be required to establish compliance plans that contain certain anti-fraud requirements and reflect good governance practices. Such plans will help ensure that providers and suppliers have incorporated anti-fraud protections into their operations. Other preventive measures focus on certain categories of providers and suppliers that historically have presented concerns to our program including DMEPOS suppliers, home health agencies, and Community Mental Health Centers (CMHCs). For example, as an additional safeguard to address longstanding concerns with CMHCs, such facilities will be required to provide at least 40 percent of their items and services to non-Medicare beneficiaries.

Expanded Use of Recovery Audit Contractors

CMS is drawing from the lessons learned from the Medicare Fee-For-Service (FFS) Recovery Audit Contractor (RAC) Program to implement the new statutory authority given in the Affordable Care Act to expand the program to Medicare Parts C and D and Medicaid. In order to address the fundamental differences in payment structure between

FFS, Medicare Part C(managed care), Medicare Part D and State-run Medicaid programs, CMS has taken a multi-pronged approach to implementation of the new Affordable Care Act authorities. In January, CMS awarded a contract to identify incorrect payments and recoup overpayments in Medicare Part D. Additionally, we are seeking public comment through a solicitation issued on December 27, 2010 in the Federal Register on innovative strategies for review of additional Medicare Parts C and D data, including the effectiveness of sponsors' anti-fraud plans.

In the Medicaid program, CMS issued a State Medicaid Director letter in October 2010 that offered initial guidance on the implementation of the Medicaid RAC requirements and published a Notice of Proposed Rulemaking on November 10, 2010. CMS has provided significant technical assistance to States through all-State calls and webinars and has begun the coordination with States that have RAC contracts in place, as required by the statute. CMS will also work to ensure that States and their Medicaid RACs coordinate recovery audits with other entities to minimize the likelihood of overlapping audits. On February 17, CMS launched a Medicaid RACs At-A-Glance web page on the CMS website. The page provides basic State RAC information to the public and interested stakeholders about each State's RAC program. As States fully implement their programs and additional elements are added to the site in the future, the site will help States to monitor the performance of their own RAC program and find information on other States' programs that may assist them.

Increased Flexibility in Medicaid Recovery Rules

CMS issued a State Medicaid Director letter in July 2010, providing initial guidance on the recovery of Medicaid overpayments as required by the Affordable Care Act. States now have up to one year from the date of discovery of an overpayment in Medicaid to recover, or attempt to recover, such overpayment before being required to refund the Federal share of the overpayment. Prior to passage of the Affordable Care Act, States were allowed only up to 60 days from the date of discovery of an overpayment to recover such overpayment before making the adjustment to the Federal share. CMS appreciates this new flexibility for States. The additional time provided under the Affordable Care

Act will enable States to more thoroughly root out fraud and overpayments. However, for overpayments resulting from fraud, if an ongoing administrative or judicial process prevents a State from recovering an overpayment within one year of discovery, the State has an additional 30 days after a final judgment is made to recover the overpayment before making the adjustment to the Federal share.

Guidance on Self-Disclosure of Actual or Potential Violations of Physician Self-Referral Statute

In September 2010, CMS published the Voluntary Self-Referral Disclosure Protocol (SRDP) on its website to enable providers and suppliers to disclose actual or potential violations of the physician self-referral statute (Section 1877 of the Social Security Act). The SRDP contains instructions for providers and suppliers who make self-disclosures, and advises that the Affordable Care Act gives the Secretary the discretion to reduce the amount due and owing for a violation of the physician self-referral statute. The SRDP states the factors CMS may consider in reducing the amounts due and owing, including: (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party.

Fraud Detection and Reporting

CMS has improved the processes for fraud detection by our contractors and for reporting, analyzing, and investigating complaints of potential fraud from beneficiaries.

In order to take a more holistic approach to detecting and addressing fraud, CMS has worked to integrate the activities of the Program Safeguard Contractors (PSCs) into more comprehensive Zone Program Integrity Contractors (ZPICs). Before these reforms, each PSC focused on benefit integrity in limited parts of the Medicare program, making it possible for providers and suppliers to continue to submit fraudulent claims to one part of the Medicare program even after questionable claims had been identified in another part of the program. Instead, CMS is currently in the process of contracting with one ZPIC in

each of seven separate geographic zones, with an emphasis on designated high fraud areas. Unlike PSCs, ZPICs perform program integrity functions for all parts of Medicare. These contracting reforms have allowed CMS to break down silos in program integrity work and better identify potentially fraudulent behavior across all parts of the Medicare program.

Another of these fraud detection improvements involves modifications to the 1-800-MEDICARE call center procedures. In the past, if a caller reported that they did not recognize a provider or did not receive the service documented on their Medicare Summary Notice form, they were asked to follow up with the provider prior to filing a fraud complaint. However, now 1-800-MEDICARE will review the beneficiary's claims records with them and if the discrepancy is not resolved, we will take action and file a complaint immediately, regardless of whether the caller has attempted to contact the provider. Also, CMS is using the information from beneficiaries' complaints in new ways. For instance, CMS is generating weekly "fraud complaint frequency analysis reports" that compile provider-specific complaints and flag providers who have been the subject of multiple fraud complaints for a closer review. This is just one example of CMS shifting our use of available data in more intuitive ways.

As part of our commitment to applying innovative analytics to existing data sources to prevent fraud, CMS has developed the capability to map shifts and trends in fraud allegations reported to 1-800-MEDICARE over time using geospatial maps and sophisticated data tools. These tools will allow CMS to gather more information from 1-800-MEDICARE calls for data analysis. The various parameters include claim type, geographic location, and fraud type. CMS is also exploring new options for streamlining the process and timeframe for investigating fraud complaints, while seeking to preserve the efficiencies and cost-effectiveness of a single call center like 1-800-MEDICARE.

Fiscal Year 2012 Budget Request

To continue the Administration's focus on fraud prevention and to build on the new authorities and resources provided by the Affordable Care Act, the President's Fiscal

Year 2012 Budget Request includes a package of program integrity legislative proposals across Medicare, Medicaid and CHIP that will save $32.3 billion over 10 years. These proposals, if enacted, would provide CMS with additional tools to reduce and prevent improper payments and ensure that those committing fraud are held responsible and cannot easily discharge their debts or reenter our programs to commit additional offenses.

In addition, the FY 2012 Budget Request also includes a little over $1.85 billion for the HCFAC account, including mandatory and discretionary sources, divided between CMS' programs and our law enforcement partners at the OIG and DOJ. The FY 2012 discretionary HCFAC request is $581 million, a $270 million increase over the FY 2010 enacted level. Described in more detail below, these new HCFAC resources would support and advance the goals of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, a joint Cabinet-level effort established by the President and led by Secretary Sebelius and Attorney General Holder. The Budget Request is necessary to continue expanding the Medicare Fraud Strike Force—an integral part of HEAT, described below—to as many as 20 areas, as well as civil health care fraud enforcement activities. Further, if provided by Congress, this discretionary HCFAC funding will allow us to expand prevention and detection activities and work to reduce improper payments with aggressive pre-payment review, increased provider education, and the development of a national pre-payment edit module.

HCFAC Program Successes

HCFAC has been steadily growing since it began in 1997 and, as shown in the recently released FY 2010 HCFAC report, this investment in fraud fighting resources is paying dividends. The HCFAC report demonstrates the value of this program; since its inception and through FY 2010, HCFAC has resulted in the return of $18 billion to the Medicare trust funds. In FY 2010 alone, $2.8 billion was returned to the Medicare trust funds and $683 million was returned to the Federal Treasury from Medicaid recoveries. The HCFAC return-on-investment (ROI) is currently the highest it has ever been; the 3 year rolling ROI (FY 2008- FY 2010) averaging all HCFAC activities is $6.8 to $1; this is

$1.9 more than the historical average. Additionally, the ROI for the Medicare Integrity Program's activities is 14 to 1.

HCFAC funds support HEAT and many complementary anti-fraud initiatives, including:

- **DOJ-FBI-HHS-OIG-Medicare Strike Forces:** This coordinated effort is needed in order to focus enforcement resources in geographic areas at high risk for fraud. Strike Force cases are data driven, using technology to pinpoint fraud hot spots through the identification of unusual billing patterns as they occur.
- **Increased Prevention and Detection: CMS** is committed to working with law enforcement to efficiently use existing systems and collaborate on future improvements, and has provided numerous training sessions for law enforcement personnel on CMS data analytic systems. Further, CMS will do rapid response projects as well as long-term in-depth studies.
- **Expanded Law Enforcement Strategies:** HCFAC will further expand existing criminal and civil health care fraud investigations and prosecutions, particularly related to fraud schemes in areas such as pharmaceutical services, medical devices, and durable medical equipment, as well as newly emerging schemes. It will allow the use of cutting-edge technology in the analysis of electronic evidence to better target and accelerate enforcement actions. Finally, the increase will expand Medicare and Medicaid audits and OIG's enforcement, investigative, and oversight activities.
- **Oversight:** HCFAC will help to further strengthen oversight in Medicare, Medicaid, and CHIP.

We are excited about the tools and resources available to CMS through HCFAC. In particular, because of changes in the Affordable Care Act, we will now have flexibility to utilize HCFAC funds to enhance our own expertise for pursuing fraud, waste, and abuse in Medicare.

Engaging Our Beneficiaries and Partners

Meanwhile, HHS and CMS continue to work with and rely on our beneficiaries and collaborate with our partners to reduce fraud, waste, and abuse in Medicare, Medicaid and CHIP. The Senior Medicare Patrol (SMP) program, led by the Administration on Aging (AoA), empowers seniors to identify and fight fraud through increased awareness and understanding of Federal health care programs. This knowledge helps seniors protect themselves from the economic and health-related consequences of Medicare and Medicaid fraud, waste, and abuse. In partnership with State and national fraud control/consumer protection entities, including Medicare contractors, State Medicaid Fraud Control Units, State Attorneys General, the HHS OIG, and CMS, SMP projects also work to resolve beneficiary complaints of potential fraud. Since the program's inception, the program has educated over 3.84 million beneficiaries in group or one-on-one counseling sessions and has reached almost 24 million people through community education outreach events. CMS is partnering with AoA to expand the size of the SMP program and put more people in the community to assist in the fight against fraud.

In addition to working with AoA on expanding the SMPs, CMS is implementing a number of new mechanisms to better engage beneficiaries in identifying and preventing fraud. As part of that effort, CMS encourages its beneficiaries to check their Medicare claims summaries thoroughly. Medicare Summary Notices (MSNs) are sent to beneficiaries every 90 days; CMS is working with beneficiaries to redesign the MSNs to make them easier to understand so beneficiaries can spot potential fraud or overpayments on claims submitted for their care. Additionally, some 10 million beneficiaries are enrolled into www.mymedicare.gov, a secure website, and can now check their claims within 24 hours of the processing date. This information is also available through the 1-800-MEDICARE automated system. A fact sheet and informational card have been developed to educate and encourage beneficiaries or caregivers to check their claims frequently and to report any suspicious claims activity to Medicare. These materials are being used at the regional fraud prevention summits (described below) and have been shared with both State Health Insurance Plans (SHIPs) and SMPs.

Further, CMS is implementing a number of new educational and awareness initiatives in identifying and preventing fraud among those Americans who receive services under the Medicaid program.

Collaborating with Law Enforcement Partners

CMS is committed to working with our law enforcement partners, who take a lead role in investigating and prosecuting alleged fraud. CMS provides support and resources to the Strike Forces, which investigate and track down individuals and entities defrauding Medicare and other government health care programs. Strike Force prosecutions are "data driven" and target individuals and groups actively involved in ongoing fraud schemes. These efforts started in Miami in 2007and expanded to Los Angeles in 2008. In 2009 and 2010 under the HEAT initiative, we continued expanding the Strike Force to Detroit, Houston, Brooklyn, Tampa and Baton Rouge using the additional discretionary funding that Congress provided in response to the President's budget requests. On February 17, 2011, we announced further expansion of Medicare Fraud Strike Force operations to Dallas and Chicago. HEAT has enhanced coordination of anti-fraud efforts of DOJ's Civil and Criminal Divisions and U.S. Attorneys' Offices, FBI, HHS/OIG and CMS. The HEAT task force is working to identify new enforcement initiatives and areas for increased oversight and prevention, including how to increase efficiency in pharmaceutical and device investigations.

The Strike Force model has been very successful. Since its inception, Strike Force operations in nine cities have charged more than 990 individuals who collectively have falsely billed the Medicare program for more than $2.3 billion. This figure includes the Medicare Strike Force's latest successes, announced on February 17, 2011, charging 111 individuals with more than $225 million in false Medicare billing.

Sharing information and performance metrics broadly and engaging internal and external stakeholders requires establishing new partnerships with government and private sector groups. Because the public and private sectors have common challenges in fighting fraud and keeping fraudulent providers at bay, it makes sense that we should work together to

develop common solutions. In addition to the HEAT initiative, agencies including HHS, CMS, OIG, and DOJ have co-hosted a series of regional summits on health care fraud prevention.

Building on the momentum generated by the National Health Care Fraud Summit in January 2010, regional health care fraud prevention summits have been held across the country. These summits, held to date in Miami, Los Angeles, New York, and Boston with plans for additional cities, brought together Federal and State officials, law enforcement experts, private insurers, beneficiaries, caregivers, and health care providers to discuss innovative ways to eliminate fraud within the nation's health care system. These summits also featured educational panels that discussed best practices for providers, beneficiaries and law enforcement in preventing health care fraud. The panels included law enforcement officials, consumer experts, providers and representatives of key government agencies. CMS looks forward to continuing these summits in 2011 as well as more opportunities to bring these stakeholder communities together in other cities to continue this important dialogue and strengthen our cooperative efforts across the Federal government and with the private sector.

Data Analytics

The Affordable Care Act also requires increased data sharing between Federal entities to monitor and assess high risk program areas and better identify potential sources of fraud. CMS is expanding its Integrated Data Repository (IDR) which is currently populated with five years of historical Part A, Part B and Part D paid claims, to include near real time pre-payment stage claims data; this additional data will provide the opportunity to analyze previously undetected indicators of aberrant activity throughout the claims processing cycle. CMS intends to develop shared data models and is pursuing data sharing and matching agreements with the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential waste, fraud, and abuse throughout Federal health care programs. Also, the Affordable Care Act requirement that States report an expanded set of data elements from their Medicaid Management Information System (MMIS) will

strengthen CMS' program integrity work both within State Medicaid programs and across CMS. This robust State data set will be harmonized with Medicare claims data in the IDR to detect potential fraud, waste and abuse across multiple payers.

CMS will implement an innovative risk scoring technology that applies effective predictive models to Medicare. Innovative risk scoring technology applies a combination of behavioral analyses, network analyses, and predictive analyses that are proven to effectively identify complex patterns of fraud and improper claims and billing schemes. CMS is integrating the advanced technology as part of an end-to-end solution that triggers effective, timely administrative actions by CMS as well as referrals to law enforcement when appropriate. Prior to applying predictive models to claims prepayment, CMS will rigorously test the algorithms to ensure a low rate of false positives, allowing payment of claims to legitimate providers without disruption or additional costs to honest providers; confirm that the algorithms do not diminish access to care for legitimate beneficiaries; and identify the most efficient analytics in order to appropriately target resources to the highest risk claims or providers. Given the changing landscape of health care fraud, any successful technology will need to be nimble and flexible, identifying and adjusting to new schemes as they appear.

As we pursue and test new technology, CMS is working to involve the private sector and State partners to incorporate strategies that have already proven successful. As the first phase of partnership building with private sector entities, CMS held an industry day in October 2010 that was attended by approximately 300 industry representatives. This event highlighted CMS' strategic goals, priorities, and objectives in the use of information technology solutions for fraud prevention in our programs and provided an opportunity for attendees to determine whether their firm's services, methods and products fit with CMS' mission and vision. In December 2010, CPI issued a Request for Information asking vendors to identify their capabilities in the areas of provider screening/enrollment and data integration. CMS will review the responses and incorporate innovative ideas into the strategy for integrated, automated, providers screening and data integration.

Further, the Small Business Jobs Act of 2010 provided $100 million, beginning in FY 2011 to phase-in the implementation of predictive analytics in Medicare FFS, Medicaid, and CHIP over four years. The new predictive modeling technology will incorporate lessons learned through pilot projects. For example, in one pilot, CMS partnered with the Federal Recovery Accountability and Transparency Board (RATB) to investigate a group of high-risk providers. By linking public data found on the Internet with other information, like fraud alerts from other payers and court records, we uncovered a potentially fraudulent scheme. The scheme involved opening multiple companies at the same location on the same day using provider numbers of physicians in other states. The data confirmed several suspect providers who were already under investigation and, through linkage analysis, identified affiliated providers who are now also under investigation.

Delivery System Reforms

Beyond the traditional program integrity initiatives, the delivery system reforms created by the Affordable Care Act will further help to deter and prevent fraudulent activities within Medicare. When there are large disparities between the cost of goods and services, as compared to the allowed reimbursement, we know that these excessive payments often make Medicare a more attractive and lucrative target for those attempting to commit fraud. For instance, OIG, the Government Accountability Office (GAO), and other independent analysts have repeatedly highlighted that the fee schedule prices paid by Medicare for many DMEPOS items are excessive, as much as three or four times the retail prices and amounts paid by commercial insurers or cash customers. These inflated prices in turn increase the potential profits of those intending to defraud the Medicare program. To that end, CMS implemented supplier contracts and new payment rates based on the Round 1 rebid of DMEPOS competitive bidding on January 1, 2011 in nine Metropolitan Statistical Areas. The Office of the Actuary estimates that once fully implemented this program is projected to save more than $17 billion in Medicare expenditures over ten years. Outside of DMEPOS, CMS is working to redesign our Medicare payment systems and institute delivery system reforms that will realign

Medicare payments with market prices and thereby reduce the incentive for "bad-actors" to target Medicare.

All of these new authorities and analytical tools will help move CMS beyond its historical "pay and chase" mode to a prevention-oriented approach with strong fraud deterrents and increased enrollment screenings, new disclosure and transparency guidelines, and early identification of high-risk providers and suppliers.

Conclusion

Health care fraud and improper payments undermine the integrity of Federal health care programs. Taxpayer dollars lost to fraud, waste, and abuse harm multiple parties, particularly some of our most vulnerable seniors, not just the Federal government. Eliminating the problem requires a long-term, sustainable approach that brings together beneficiaries, health care providers, the private sector, and Federal, State, and local governments and law enforcement agencies, in a collaborative partnership to develop and implement long-term solutions. New authorities in the Affordable Care Act offer additional front-end protections to keep those who intend to commit fraud out of Federal health care programs, as well as new tools for deterring wasteful and fiscally abusive practices, and promptly identifying and addressing fraudulent payment issues, which will ensure the integrity of Medicare, Medicaid and CHIP.

This Administration has made a firm commitment to rein in fraud and wasteful spending, and with the Affordable Care Act, we have more tools than ever before to implement important and strategic changes. CMS thanks the Congress for providing us with these new authorities and resources, and looks forward to working with you in the future as we continue to make improvements in protecting the integrity of Federal health care programs and safeguarding taxpayer resources.

Center for Program Integrity
Current State
New Approach
1
Pay and Chase
Prevention and Detection
2
"One Size Fits All"
Risk-Based Approach
3
Legacy Processes
Innovation
4
Inward Focused Communications
Transparent and Accountable
5
Government Centric
Engaged Public/Private Partners
6
Stand Alone PI Programs
Coordinated & Integrated PI Programs
CMS

Mr. STEARNS. Thank you. With that, I will open up with questions. Let me start with you, Mr. Spiegel. When I looked at your résumé, it looks like you have been on the job less than a year. You started June 2010. So you have really been the man who is Director of Medicare Program Integrity for less than one year. Is that correct?

Mr. SPIEGEL. That is correct.

Mr. STEARNS. And you came from the private sector?

Mr. SPIEGEL. Most immediately.

Mr. STEARNS. OK. You might not have a handle on this, but how much money, in your opinion, is lost to fraud each year in the Medicare program precisely?

Mr. SPIEGEL. Well——

Mr. STEARNS. Just precisely.

Mr. SPIEGEL. I would have to answer that question and say that there is no actual one number——

Mr. STEARNS. So you don't know? Is that fair enough?

Mr. SPIEGEL. That is correct.

Mr. STEARNS. Now, 60 Minutes in September had an exposé on Medicare, and they indicated it was $60 billion, and they had one witness who indicated it would be $90 billion. Do you think it is fair to say that it is anywhere from $60 billion to $90 billion based on what 60 Minutes said?

Mr. SPIEGEL. Like all of us, I have heard the estimates that have come from private groups as well as government——

Mr. STEARNS. Why is it so difficult to understand what the figure is? If 60 Minutes has come up with it and witnesses have come up with it, we had the Justice Department give an estimate, why is it that you are the man in charge of Medicare Program Integrity, why can't you give us an estimate of what it is, approximately?

Mr. SPIEGEL. Well, because a lot of the estimates that you cite and others cite contain information that deals with things that aren't necessarily fraud. Some of them turn out to be improper payments, things we want to know about but they are really not fraud and it is not necessarily——

Mr. STEARNS. All right. Mr. Waxman indicated in his opening statement that these new requirements that are in the Obamacare prevention will save us $7 billion. Do you think that is an accurate statement?

Mr. SPIEGEL. I believe Mr. Waxman cited CBO estimates.

Mr. STEARNS. OK. Now, the problem is, it is a $650 billion program and they are saving $7 billion. That is probably about less than 1 percent. How can you effectuate eliminating waste, fraud and abuse when you cut the program $550 billion like Obamacare does? So it is a question for Ms. King. If you are actually cutting Medicare program, wouldn't that make it difficult to prevent waste, fraud and abuse just by axiomatic? Wouldn't it be self evident that you can't cut a program that amount of money and still reduce waste, fraud and abuse?

Ms. KING. Mr. Chairman, I think that the reductions in Medicare spending are reductions off the rate of growth and not overall reductions in the size of the——

Mr. STEARNS. Well, that is not how we understand it. But Mr. Spiegel, let us go to Medicaid. How much is lost to Medicaid, not

Medicare, because you say you don't know. What about Medicaid? What is the loss to fraud?

Mr. SPIEGEL. Well, it is the same issues that surround trying to come up with a number for fraud in Medicare.

Mr. STEARNS. So you have no idea, not even approximate? OK.

Now, Ms. King, they are expanding Medicaid by another 20 million people they are going to add, and so if you are going to expand and increase it, and Medicaid has a lot of fraud, wouldn't that indicate that you are going to have increased fraud?

Ms. KING. I think it depends on what happens with the new authorities that CMS was given in the Affordable Care Act and how they are implemented.

Mr. STEARNS. Let me say, the Republicans on this side would be very glad to vote for any legislative measure to prevent fraud. Any fraud measures, we would be glad to implement. It is just we are worried about some of the things I mentioned about.

So Mr. Spiegel, my concern is, before we expand Medicare and Medicaid, we still don't know how much we lost to fraud and you are the man in charge less than a year, so you are saying at this point we just have no idea how much it is, how much fraud, waste and abuse. So it seems to me that if you don't even have a handle on what the amount is, it is going to be very difficult to penetrate it down.

Let me ask a question to Mr. Roy and Mr. Perez. I appreciate, Mr. Perez, I said in my opening statement, I just said that Medicare fraud is rapidly eclipsing the drug trade as far as most profitable and efficient criminal enterprise system. This was comments based on the 60 Minutes exposé. Do you think that is true?

Mr. PEREZ. Well, we certainly have seen some of our investigations that individuals that used to participate in the drug trade are now certainly involved in health care fraud.

Mr. STEARNS. Have you seen a lot of organized crime involved in Medicare and Medicaid fraud, Mr. Roy?

Mr. ROY. Yes, sir. We are seeing——

Mr. STEARNS. Just bring the mic just a little closer to you, if you don't mind.

Mr. ROY. My apologies. We are seeing an uptick in organized crime elements engaging in health care fraud, whether it is in structured organizations like Eurasian organized crime that we see out in Los Angeles to more loose—knit organizations that we see in Texas and the Miami, Florida, area.

Mr. STEARNS. Mr. Roy, this is probably putting you on the spot but do you or Mr. Perez and your colleagues, have you come up with what is a figure of how much fraud? Would you venture a guess?

Mr. ROY. No, sir, I cannot.

Mr. STEARNS. Would you venture a guess it is more than $7 billion a year?

Mr. ROY. Yes, sir, I would.

Mr. STEARNS. And Mr. Perez, would you venture a guess that the fraud in Medicare is more than $7 billion a year?

Mr. PEREZ. I know we recovered $3.7 billion, so certainly I think——

Mr. STEARNS. So what I am trying to say, Mr. Spiegel, is here you have no idea what the fraud figure is and the people to your right, one has indicated that he has found just in Florida $3.5 billion, so you have—it is just incomprehensible to me how you can come here this morning and say you have no idea how much the fraud when the man to your right has indicated that he can track $3.5 billion himself and so I think when Mr. Waxman mentioned $7 billion, that is just the tip of the bucket. That is just the tip, and there is so much more there and I think Mr. Roy and Mr. Perez have confirmed that.

My time is expired. I will turn to the ranking member, Ms. DeGette.

Ms. DEGETTE. Thank you so much, Mr. Chairman.

Let me follow up on that, Mr. Spiegel, with you. I believe the CBO estimated that the provisions of the Affordable Care Act will save the taxpayers $7 billion over the next 10 years. Is that correct?

Mr. SPIEGEL. I believe that is what it says.

Ms. DEGETTE. Is that the only money that the Administration intends to save on fraud in Medicare and Medicaid?

Mr. SPIEGEL. No.

Ms. DEGETTE. Could you explain, please, why that is not the—I don't want this to be misinterpreted that the Administration, that these are the only efforts that are going to be made. What other efforts are being undertaken to eliminate fraud, waste and abuse, briefly?

Mr. SPIEGEL. First of all, however much the number is for fraud that is going on is too much.

Ms. DEGETTE. Right. What other efforts are being undertaken to avoid fraud, waste and abuse, briefly?

Mr. SPIEGEL. So we are implementing the new provisions of the Affordable Care Act that allow us to do a better job——

Ms. DEGETTE. OK. What other—Mr. Perez, do you have an answer? Oh, you are just trying to move the mic.

Mr. SPIEGEL. I mean——

Ms. DEGETTE. What I am saying is, the provisions of the Affordable Care Act are not the only provisions of law that help——

Mr. SPIEGEL. Right. That is true.

Ms. DEGETTE [continuing]. Us to avoid waste, fraud and abuse. What other provisions in law that may be separate and apart from the $7 billion are going to help us avoid fraud, waste and abuse?

Mr. SPIEGEL. OK. So in addition to the things that I was talking about with regard to provider screening, we have a whole range of activities that we do now and that we are going to do to oversee proper payments——

Ms. DEGETTE. OK. If you can supplement your answer in writing, that would be helpful.

Mr. SPIEGEL. I would be happy to do so.

Ms. DEGETTE. But in essence, what you are saying is, the $7 billion is in addition to efforts that are being currently made?

Mr. SPIEGEL. That is right.

Ms. DEGETTE. Now, Mr. Perez, the efforts that you are undertaking, those are being undertaken under current law, right? Be-

cause the Affordable Care Act hadn't been implemented yet, correct?

Mr. PEREZ. Yes, ma'am.

Ms. DEGETTE. OK. Now, Mr. Spiegel, perhaps you can talk about the enrollment screening requirements in the Affordable Care Act. Will they work to prevent enrollment by fraudulent providers?

Mr. SPIEGEL. Yes.

Ms. DEGETTE. And how are they different than previous requirements?

Mr. SPIEGEL. Well, the new enrollment screening provisions allow us to focus on providers based on the risk that they pose, the risk of fraud that they pose. We have new and enhanced screening that we would be applying to those that pose the greatest risk like criminal background checks, database checks, fingerprinting for those that are posing the greatest risk. We have new approaches to consolidating our data and sharing data across Medicare and Medicaid so that both programs have access to information about, for example, providers that have been terminated from Medicaid that may be terminated from Medicare as well and vice versa. The particular provision that—one of the particular provisions in the provider screening rule we just published that may have the most effect is the Secretary's authority to impose temporary enrollment moratoria when she determines that there is a need to do that to combat fraud, waste and abuse.

Ms. DEGETTE. Ms. King, do you believe that some of these new provisions that we have talked about today will add to our arsenal in being able to target waste, fraud and abuse and to eliminate it?

Ms. KING. Yes, we do. We have previously identified several areas where increased enforcement and action would be helpful. One of those is enrollment. One is them is in prepayment edits. One is in postpayment edits, contractor oversight, and the other is, the last is a robust process for corrective action, and the Affordable Care Act has provisions in several of these areas designed to enhance CMS's ability, and some of the key ones I think are on the enrollment side because preventing fraud is a lot better and easier than chasing after it when it has been committed so——

Ms. DEGETTE. Correct, and these are new tools.

Ms. KING. Yes, they are.

Ms. DEGETTE. But would you agree that some of the existing tools that CMS has could also be used in a robust way?

Ms. KING. Yes. Congress starting in 1997 in HIPAA created a program, a Medicare integrity program that was designed to focus on reducing improper payments and fraud and abuse, and that is what some of these activities that have been discussed today are funded from——

Ms. DEGETTE. Thank you.

Ms. KING [continuing]. Before the Affordable Care Act.

Ms. DEGETTE. I yield back.

Mr. STEARNS. The gentlelady's time is expired. The gentleman from Texas, Mr. Barton, is recognized for 5 minutes.

Mr. BARTON. Well, thank you, Mr. Chairman.

Let us start off by saying that everybody on the dais here is anti fraud and abuse. John Dingell is anti fraud and abuse. Jan Schakowsky is anti fraud and abuse. Diana DeGette is anti fraud

and abuse. The chairman is anti fraud and abuse. All of our freshmen down here in the front row are anti fraud and abuse on the Republican side. Dr. Murphy is anti fraud and abuse. I mean, we are all anti fraud and abuse, so this is not a partisan issue. But we are very frustrated. I have chaired hearings on this, John Dingell has chaired hearings on this, Diana DeGette has chaired hearings on this, Waxman has chaired hearings on this. I mean, it is so frustrating that we all agree it is a problem, we all want to solve the problem, and yet we still don't even know the scope of the problem.

Now, why is that important? I believe that if you don't know what the problem is, you can't set goals on how to solve it. So let us say it is a 10 percent problem, which would be $80 billion. Maybe a reasonable goal then would be to cut that by 25 percent in a given year, which would be $16 billion or $20 billion. Maybe it is only a $40 billion a year. But if you guys can't help us determine what the problem is, it is hard for us to decide how to set goals to solve it.

So I am going to go through a series of questions here and they are kind of sophomore 101 questions, and hopefully you have got great answers to every one of them. My first question is—and I am going to ask Mr. Perez because you seem to be the guy at the table that actually can do something about it, not just study it or whatever but you can actually make things happen. Do you have the ability to seize assets of folks that you arrest and accuse of Medicare and Medicaid fraud?

Mr. PEREZ. Well, first, Congressman, thank you very much for the vote of confidence. I certainly appreciate that. And the department does not have, or OIG does not have seizure authority but we do work in tandem with the Federal Bureau of Investigation or other entities that do you have the seizure authority.

Mr. BARTON. Does anybody within HHS have the ability to go out and actually seize physical assets, seize cash, seize equipment, or do you have to go to the FBI to do that?

Mr. PEREZ. Currently, we have to use the FBI unless it is a civil proceeding.

Mr. BARTON. Would you like to have the authority, if Congress gave you the authority to seize assets?

Mr. ROY. Sir, if I could respond to that? We would be more than happy to have that authority, but you have to understand that the size of our organization, taking on full seizure authority entails taking on a tremendous amount of additional assets to be able to seize that and care for that property and then liquidate that property. It is a tremendous undertaking that is probably——

Mr. BARTON. Right now I just want to know if you want to have the authority. Mr. Perez seems to think he would like it. You seem to think it is more trouble than it is worth.

Mr. ROY. Well, Mr. Perez is in lockstep here. We will take any additional authority that comes our way and utilize——

Mr. BARTON. I only have another minute and 25 seconds. Are there currently under existing programs taxpayer hotlines where people can phone in or mail in or Internet in tips on people they think are defrauding the government on billing claims? Do you have that?

Mr. ROY. Yes, sir. OIG has 1–800–HHS–TIPS as our hotline.

Mr. BARTON. What about my friend here, Mr. Spiegel? Do you have those hotlines?

Mr. SPIEGEL. We do. We have 1–800–Medicare. We have special hotlines in south Florida.

Mr. BARTON. Do you pay bonuses or some sort of a cash payment if the tip is followed up and actually proves to be correct?

Mr. SPIEGEL. We have a set of rules around that, and yes, we have.

Mr. BARTON. How often is that used?

Mr. SPIEGEL. It depends. Well, there is a number of criteria that define it. It hasn't been used all that often but it has been just recently actually.

Mr. BARTON. Do you have within your agency the ability to check internally for people that are employees that are part of scams in terms of credentialing people that shouldn't be or checking for folks that are paying bills that they shouldn't pay? Is there an internal ability to check within the system?

Mr. SPIEGEL. There are. There is a number of contracting requirements in place to make sure that the people who actually make decisions on our behalf are following the rules.

Mr. BARTON. My last question. If it is not proprietary, how often does that type of investigation actually produce fraudulent activity within the system? In other words, 10 percent of the time that you check?

Mr. SPIEGEL. I don't know the exact number. I would be glad to get back to you with that, though.

Mr. BARTON. OK. Thank you, Mr. Chairman. And I will have some questions for the record.

Mr. STEARNS. Thank you, and recognize the chairman emeritus, Mr. Dingell from Michigan, for 5 minutes.

Mr. DINGELL. Mr. Chairman, I thank you and commend for this hearing. It is a very important matter, and I would note, I was one of the people who went with our very fine investigators when they were conducting the nine community raids on these malefactors that we are discussing today, and I want to commend you down there for the work that you are doing on this matter. I also want to commend the people from the Inspector General's Office, from the GAO and our friend, Dr. Spiegel.

I would like to observe one thing very quickly. No environmental impact statements are filed by these criminals and they don't file any 10Ks or 10Qs so we can know what they are up to, and I want to say, Mr. Chairman, I commend you for having this hearing because moving this process forward is extremely important and there is a lot of money in the recent health care reform legislation which will make available to us the ability to make significant savings. I am not about to criticize our witnesses today or anybody else for not having the cost of these things. These criminals don't operate by the clear light of day.

These questions are to Dr. Spiegel and to Ms. King. Dr. Spiegel and Ms. King, do you believe that the new tools included in the Affordable Care Act will help CMS to meet its goal? Yes or no.

Ms. KING. Yes, if they are implemented properly.

Mr. SPIEGEL. Yes.

Mr. DINGELL. Again, if you please, funding for the health care fraud and abuse control program includes mandatory and discretionary funding. It is divided by CMS's integrity programs and law enforcement programs at the Office of the Inspector General and DOJ. The President's 2012 discretionary request is $581 million. If this funding is not provided, will CMS be able to hire the personnel necessary to implement the antifraud provisions included in the Affordable Care Act? Yes or no.

Mr. SPIEGEL. Until we find out exactly how much would in fact be appropriated, we won't know exactly what we would be able to do but we know that are limited in our ability to plan right now.

Mr. DINGELL. If you don't get the money, you can't plan and you can't hire——

Mr. SPIEGEL. And we wouldn't be able to——

Mr. DINGELL [continuing]. People to support the program work?

Mr. SPIEGEL. We would have to ratchet back.

Mr. DINGELL. All right. Now, the Affordable Care Act requires high-risk providers and suppliers who want to enroll in Medicare, Medicaid CHIP to undergo a higher level of screening. This increases scrutiny will be critical in rooting out fraud, waste and abuse in susceptible programs. If the requested discretionary funding is not provided, will CMS be able to fully implement and utilize enhanced screening? Yes or no.

Mr. SPIEGEL. Again, it would depend on the levels of funding that ended up——

Mr. DINGELL. The simple fact of the matter is, if you don't get that, you aren't going to be able to move forward. You aren't going to be able to move forward until you know that you are going to get it, and until you get it, you aren't going to be able to do the hiring and the other things that are necessary to bring your enforcement program up to date. Isn't that right?

Mr. SPIEGEL. It would have a severe effect on that, yes.

Mr. DINGELL. Very good. Now, again, Dr. Spiegel, the Affordable Care Act requires data sharing among federal agencies to monitor and assess risk levels in program areas that improve identification of fraud. If the requested discretionary funding is not provided, will CMS be able to implement full data-sharing technology needed to coordinate monitoring and identifying sources of fraud across the federal agencies? Yes or no.

Mr. SPIEGEL. No.

Mr. DINGELL. Now, again, Doctor, the goal of the antifraud provisions in the Affordable Care Act is to move CMS away from that wonderful practice of "pay and chase" and preventing improper payments from happening in the beginning. While some improper payments may be due to honest mistakes, many, many criminals have made Medicare and Medicaid their targets and also the other programs of this character. CMS has already begun testing risk-scoring technology to predict and prevent fraud. If the requested discretionary funding is not provided, will CMS be able to fully test and pursue the technology? Yes or no.

Mr. SPIEGEL. No.

Mr. DINGELL. This to Deputy Inspector General Roy. This last summer, as I had mentioned, I was fortunate enough to attend a ride-along with the Detroit Medicare's fraud strike force. That is

nine communities. And I saw some of the most extraordinary practices by the criminals in making money at the expense of Medicare that you could ever believe possible. And so as the first Member to ever join Medicare strike force on a ride-along, I have enormous respect for the fine work that the strike forces are doing. They have the difficult task of not only rooting out fraud in our health system but protecting our neediest populations, the poor, the elderly and the sick, from the criminals seeking to make money from the most vulnerable. Do you believe that the Medicare strike forces have the staffing resources they need to be effective? Yes or no.

Mr. ROY. Yes, I do.

Mr. DINGELL. You believe they do now?

Mr. ROY. Sir, right now in the cities we are operating, yes. If we want to expand, I will need additional funding.

Mr. DINGELL. So your answer is that they don't have the resources and you are hoping to get them. Is that right?

Mr. ROY. Absolutely.

Mr. DINGELL. Now, do you agree on that, Ms. King?

Ms. KING. I don't have the basis of evidence to answer that question.

Mr. DINGELL. Any other witness like to make a comment on that? Very well.

This goes to you again, Inspector General Roy. If the requested discretionary funding for the health care fraud and abuse control program is not provided, will the health care fraud prevention and enforcement action team be able to expand the Medicare strike force? Yes or no.

Mr. ROY. No, sir.

Mr. DINGELL. All right. Now, I guess that completes my time and I thank you for your kindness and generosity, Mr. Chairman.

Mr. STEARNS. I thank the gentleman.

Mr. Burgess, the gentleman from Texas, is recognized for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Spiegel, so I don't get lost in all the numbers that we are hearing this morning, let me walk through some things and you tell me if the thinking is generally correct. Now, if I understand correctly, the Congressional Budget Office score for the entirety of the Patient Protection and Affordable Care Act that the provisions in that act would save about $8 billion over the 10-year budgetary cycle. Is that correct?

Mr. SPIEGEL. That is my understanding.

Mr. BURGESS. And the HHS estimate of the error rate in the payments, the payment error rate, is just under 10 percent at 9.4 percent a year. Is that correct?

Mr. SPIEGEL. Yes.

Mr. BURGESS. Now, Medicaid expenditures are going to increase of necessity under the Patient Protection and Affordable Care Act. The number I calculate for that is about $430 billion over 10 years. Does that sound about right?

Mr. SPIEGEL. I am not an expert on that Medicaid budget.

Mr. BURGESS. Does GAO have an opinion on the amount that we are going to spend additionally in Medicaid over the life cycle of the 10-year budgetary window?

Ms. KING. I actually don't have that number off the top, either.
Mr. BURGESS. Well, it is——
Ms. KING. But it certainly——
Mr. BURGESS [continuing]. A part of the GAO report that we have that the cost of Medicaid expansion is estimated to exceed $430 billion over the next 10 years. So I am going to assume the answer from GAO is yes.

So just in Medicaid, just in the expansion of the Medicaid system that we are doing, we have an error rate that will lose $43 billion over the 10-year budgetary cycle but we have safeguards in the act that are going to save us $8 billion, so we are not netting out very much in that exchange, are we? And that is your division of CMS, right? I mean, that is what you are going to fix, right?

Mr. SPIEGEL. I am in the Medicare Program Integrity Group, and yes, we are focused keenly on preventing fraud, waste and abuse in our program.

Mr. BURGESS. But in fact, the numbers just don't add up. I mean, this is going to cost us a tremendous—I am all for the antifraud provisions that are in the Patient Protection and Affordable Care Act but there is no way in the world they are going to pay for the expansion that is occurring even just in the Medicaid part of this, let alone other areas.

In my area in Dallas-Fort Worth, we have got a very aggressive—Mr. Roy and Mr. Perez, I am basically directing this question to you. We have got a very aggressive investigative reporter. She is very, very good. Becky Oliver is her name, and you just never know when she is going to walk up behind you and put a microphone 2 centimeters away from your face and ask a very, very tough question, and most of those tough questions have to do with Medicare and Medicaid fraud, and I referenced some of that in my opening statement. It almost seems as if organized crime and organizations from outside the continental United States, offshore organizations, are getting involved. This business is so lucrative and so easy and the risks are so slight that they are really going after this money aggressively. And she was the one that pointed out to me that there was a Nigerian national who had several home health agencies opened under various provider numbers and a single post office box. I guess she wants to be cost-effective so she wasn't spending much on overhead, a single post office box, and yet after one of our provider numbers was busted, CMS keeps sending payments to the same post office box. I mean, you say you are doing stuff with the electronics and getting better at this, but oh, my God, that is the sort of stuff, the American people look at and they just don't understand. Is there a way to get at that?

Mr. ROY. Well, first and foremost, that is the scheme, to have multiple provider numbers and set those up.

Mr. BURGESS. So you know that, right?

Mr. ROY. Yes, sir. We are addressing it. In your city of Dallas, that is our brand-new strike force city and we are bringing the resources to there to adopt that model to address this issue.

Mr. BURGESS. I am going to run out of time. I referenced in my opening statement about the prosecutorial force. You guys are doing the job we asked you to do and we are grateful for that, but when you bring these folks to light, are we able to actually get jus-

tice on these criminals or do they end up back out on the street to sin again?

Mr. ROY. Now more than ever, I am seeing sentences and people go to jail that is more than I have seen before in the past. People are being prosecuted. They are going to federal prison for stealing from Medicare.

Mr. BURGESS. How comfortable are you with the prosecutorial manpower, the strength of the prosecutorial force that is available to prosecute this?

Mr. ROY. Getting better all of the time. In your particular city, the resources coming from the Department of Justice are some of the best health care fraud prosecutors in our country.

Mr. BURGESS. Well, I appreciate that, and of course, I have had several meetings with HHS and the Department of Justice on this issue after being asked the tough questions by Becky Oliver, so I credit her with having put some pressure on that, but I have to tell you, we have got to do a lot more in this. It is going to overwhelm the system.

Thank you, Mr. Chairman. I will yield back.

Mr. STEARNS. I thank the gentleman.

Ms. Schakowsky from Illinois is recognized for 5 minutes.

Ms. SCHAKOWSKY. Thank you.

Do you have a strike force in Chicago, Mr. Roy?

Mr. ROY. Yes, ma'am, we do.

Ms. SCHAKOWSKY. Can I go on a ride-along?

Mr. ROY. Yes, ma'am, you can.

Ms. SCHAKOWSKY. Thank you. The Affordable Care Act increased mandatory funding for the health care fraud and abuse control fund by about $350 million, and indexed funding for the health care fraud and abuse control fund and the Medicare and Medicaid integrity programs to make sure that funds keep up with inflammation. Overall funding to fight fraud will increase by about $500 million over the next 5 years. The House Republicans voted to repeal the health care reform bill, and that would cut off the funds the law provided for antifraud activities, so I do want to ask you, Mr. Roy, could you describe the impact of cutting off this funding and what it would do to antifraud initiatives that the Administration is implementing under the Affordable Care Act?

Mr. ROY. Well, right now, as I stated, from the perspective of strike force, we were in nine cities. I would ultimately like to expand that using data to justify and find our hotspots. I will say without additional funding at this point in time, I don't think I am going to be in a position to open up additional strike force locations. I need the resources. I need the additional bodies to put in fraud hotspots across the country.

Ms. SCHAKOWSKY. Thank you.

Mr. Spiegel, would you want to answer that?

Mr. SPIEGEL. Sure. I mean, we had planned to expand the strike force locations from where they were to a total of 20 because they are so effective in what they do, and we are obviously not going to be able to go there with the adequate resources to do that.

Ms. SCHAKOWSKY. Thank you.

Ms. King, the Affordable Care Act includes provisions to provide more transparency in nursing home ownership and operating struc-

tures and to require training, compliance and ethics. Ensuring that we have complete and accurate information on ownership allows not just more transparency but provides tools to allow regulators to hold any wrongdoers accountable. How important is it to have this data, in your view, or in GAO's view?

Ms. KING. I think that we believe it is always important to have good data about the people who are participating in the program so that you can track what is going on.

Ms. SCHAKOWSKY. Mr. Roy, you had mentioned the importance in your written testimony, I didn't hear it orally necessarily but of whistleblowers in identifying possible wrongdoing. Last month, a Florida long-term-care ombudsman asked for information on nursing home structure, the same information that will be required in the Affordable Care Act, and was subsequently fired by Governor Scott. Without getting into the specifics of the case, do we need to provide whistleblower protections for long-term-care ombudsmen and others who seek information about fraud and abuse? And in the nursing home area, do we need to look at special protections for long-term-care ombudsmen?

Mr. ROY. I am certainly in favor of some type of protection for all our whistleblowers. I am not familiar too in-depth with the matter you are speaking about.

Ms. SCHAKOWSKY. Mr. Perez, are you, being in Florida now?

Mr. PEREZ. No, ma'am.

Ms. SCHAKOWSKY. And so the protection for whistleblowers, is that an important source for you?

Mr. ROY. It is, specifically with corporate fraud. Whistleblowers often file what we refer to as qui tam lawsuits, which are lawsuits on behalf of the Federal Government. They are usually corporate insiders with in-depth knowledge of corporate fraud. From a corporate standpoint, they are essential to our work.

Ms. SCHAKOWSKY. And do we have those protections in the new act? Are we going to do better to make sure we protect those people?

Mr. ROY. In the new act, I do not—I am not familiar with anything that would point toward whistleblower protection but I am certainly not an expert on everything in that Affordable Care Act.

Ms. SCHAKOWSKY. OK. Thank you very much. I yield back.

Mr. STEARNS. The gentleman from Nebraska, Mr. Terry, is recognized for 5 minutes.

Mr. TERRY. Thank you, Mr. Chairman.

I like the strike force, or HEAT. It seems to be a common theme on both sides of the aisle probably because it is positive news of success. I am trying to get my arms around what resources CMS has right now to fight fraud and abuse. Under the PPACA, I understand there will be an additional $35 million per year, as Dr. Burgess said, that won't even come close to what will fight fraud and abuse from the expansion of Medicare, but that is the CBO number. I don't know what the base is right now. What does CMS set aside per year for investigating and prosecuting fraud and abuse? Do you know that number?

Mr. SPIEGEL. I don't know right offhand but the investigating and the prosecuting takes place to my right.

Mr. TERRY. All right.

Mr. SPIEGEL. But the identification and the looking for in dealing with the improper payments and fraud at the front end would be us, and it is——

Mr. TERRY. Will you please provide that number to the committee, please?

Mr. SPIEGEL. Yes.

Mr. TERRY. And why I wanted that is so I can get a picture of what percentage of your budget is being used for policing purposes, and then I would like the opportunity to compare that to private sector health insurance who seems to be able to do a lot better job in weeding out and finding insurance fraud and abuse and what they spend in policing. I think that is a good opportunity to figure out if you have enough resources or not. Obviously I would say you don't have enough resources.

Mr. SPIEGEL. Well, one of the things about the way the private sector does things versus the way we do it is, they have different——

Mr. TERRY. I didn't ask that, and I only have 2 minutes.

Mr. SPIEGEL. Sorry.

Mr. TERRY. But I am curious about it.

Let me talk to Mr. Roy. With your strike forces and the work with Justice in being able to prosecute these, if you had the perfect world and Congress came to you and CMS came to you and said what do you need to get $50 billion a year recovered, what would you need?

Mr. ROY. It would have to be a joint effort between us and Department of Justice. I can hire as many agents as possible to address the fraud but I also need prosecutors to prosecute that case. The perfect world is that we utilize the models we are using now, looking at data to find these hotspots and then have the ability to put agents in those particular hotspots and the prosecutors to prosecute the cases as well.

Mr. TERRY. Would you be able to provide us information if we set a goal of $50 billion per year? And by the way, I think it was the testimony, I don't know if it was you or Mr. Perez said you already have 300 agents working in HEAT and these strike forces.

Mr. ROY. That was just the agents—I do not have 300 agents assigned to strike force locations. When we did that operation 2 weeks ago, I took 300 out of my 420-plus agents and detailed them if they weren't already on the ground to the cities where we had strike force operations take place.

Mr. TERRY. Can I assume that not all 420 of your agents are dedicated to fighting CMS fraud and abuse?

Mr. ROY. That is correct, sir. Eighty percent of our time is spent in the realm of health care fraud but we over see the 300-plus programs of the department, and I am certainly engaged in oversight activities, criminal activities in those other departments as well.

Mr. TERRY. Mr. Perez, being on the streets and getting information, it sounds like fighting drug distribution on the streets. What do we need in communities and on the streets to be able to obtain this? The gentlelady from Illinois mentioned whistleblowers. I think that is probably an important part of this. How much of it, and how much of it comes from just hearing on the street?

Mr. PEREZ. I unable to quantify exactly how much we get from the street but I think one of the things, to underline your question or at least answer it, is one of the things that I think we would like to see in the field, at least as agents, are two things, one, an ability to access the claims data directly, in other words, be able to have—sit outside of a business who we believe fits all the mold of a fraudulently run company and actually open up a laptop, log on and actually to be able to see whether or not a claim is being submitted by that company now, whether or not there are any payments that are on the payment floor, if they have already submitted claims, and we can make phone calls and actually start doing the investigation from right outside of the parking lot. That would be helpful.

Mr. TERRY. And that is not available to you today?

Mr. PEREZ. Not today.

Mr. TERRY. Thank you.

Mr. STEARNS. The gentleman from Texas, Mr. Gonzalez, is recognized for 5 minutes.

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

My question will be to Mr. Spiegel and Mr. Roy. I am trying to get at percentages of fraud. I know GAO did a study on Medicare and CMS estimated that it could be as much as $48 billion in improper payments. What I don't follow here is equating fraud, waste and abuse with improper payment.

Mr. STEARNS. Does the gentleman have your speaker on?

Mr. GONZALEZ. Thank you very much, Mr. Chairman.

I do not want to equate fraud, waste and abuse to improper payment, which may be a billing error or a good-faith mistake. So can you—taking that into consideration, and I think that Dr. Burgess asked if it was an accurate—I think he quoted a percentage of 10 percent of payments on Medicaid can be attributed to fraud, but that wouldn't be accurate. Is that correct? I think it was Mr. Roy or Mr. Spiegel may have responded to Dr. Burgess's question.

Mr. SPIEGEL. That is—what you said is accurate. It is not fraud, it is improper payments, and it is important to make that distinction as we try and calculate what the elusive number is that everybody is going after. Some of the numbers tend to have a lot of improper payments or just billing errors or things that aren't anything more than a mistake included in them. They are not fraudulent. And so we are reluctant to say things like that but the Medicaid number is improper payments.

Mr. GONZALEZ. Mr. Roy, obviously you are not going to go and prosecute and seek some sort of legal action against someone who made a good-faith mistake, yet that number is going to be taken into consideration when we are trying to look at payments, overpayments and so on. What I am saying is, it is not all criminal activity so that when you take Jan out there in your car and you are making all the big busts, you are not going to be going to providers that have simply made a good-faith mistake on a billing statement?

Mr. ROY. That is correct, sir. In the strike force model for the most part, these providers that we are going after are involved in almost 100 if not 100 percent fraud.

Mr. GONZALEZ. But you have limited resources, and I understand that, and you are going after the true wrongdoers and such, be-

cause I think there are some participants out there that make good-faith mistakes. I don't want to make excuses for anybody out there that is billing the government again fraudulently and so on and no one is for that, and my colleague from Texas, Mr. Barton, pointed that out.

What about the private sector? Let me ask Mr. Roy and even Ms. King, has there ever been a comparison—or Mr. Spiegel—as far as what is happening when it comes to fraud, waste and abuse with the private sector? What is the percentage there that is being suffered as a result of the same actors or similar actions by individuals that are defrauding obviously the private sector? Do we have numbers there? Is there a percentage that we can estimate, guesstimate as to how much is the private sector suffering as a result of fraud or criminal activity?

Ms. KING. To my knowledge, there is not a number out there about that and one of the difficulties I think on fraud is that you don't know what you don't know, and part of the reason I think that Medicare doesn't know the number about fraud or we don't know about that, if someone does something fraudulently, for example, they submit a claim on behalf of a beneficiary who is deceased or they buy a beneficiary's number and they submit a clean claim, that claim is paid and that is not going to show up as fraud or improper payments because it slipped through the system, so that is part of the difficulty about estimating a number on fraud.

Mr. GONZALEZ. And I appreciate that. Whether it is in the private sector or public sector, you are still faced with the same dilemma, and I think that is important to point out rather than saying that this is something distinct and unique to Medicaid or to Medicare.

Mr. Roy, I am just curious, and I have got about 32 seconds but quickly, what is the State's obligation when it comes to Medicaid fraud? Because we had an incident in Texas—I don't know if you are familiar—that the governor did relieve the doctor that basically was managing or the head of looking at the Medicaid contracts with providers as well as the attorney that was charged with prosecuting. Are you familiar with that case?

Mr. ROY. No, sir. I believe this might be a question that is probably better posed to Mr. Spiegel than myself.

Mr. GONZALEZ. Mr. Spiegel, what is the role of the State government?

Mr. SPIEGEL. Well, the State government has a responsibility to have fraud control, a Medicaid fraud control unit, and they do and they look at instances where they can take action to both identify and prevent fraud. There is data systems in place in most—and again, I am not an expert on this but there are data systems in place in most all State Medicaid programs that allow a fairly robust analysis of things that appear to be aberrant or improper. They have——

Mr. GONZALEZ. You can complete your answer, Mr. Spiegel.

Mr. SPIEGEL. Sorry. That are similar to the way we do things in Medicare where they make sure that they are paying for people who are properly enrolled in Medicaid in a proper amount for a provider that is eligible to provide the service.

Mr. GONZALEZ. Thank you, Mr. Spiegel. So that is a shared responsibility then?

Mr. SPIEGEL. Yes.

Mr. GONZALEZ. Thank you.

Mr. Chairman, thank you for your indulgence.

Mr. STEARNS. Thank you.

Mr. Gingrey from Georgia is recognized for 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you.

I want to go back to Ms. King in a follow-up on the question that Mr. Gonzalez from Texas just asked you, because I think it is a real important, pertinent question. Ms. King, you are director of the Health Care Division of GAO and if you don't have this information here today, you ought to be able to get it for the committee, and the question that he asked in regard to comparing the amount of waste, fraud and abuse in the private sector versus the government sector, and primarily we are discussing Medicare and Medicaid, I think is of paramount importance and I want, Mr. Chairman, to ask Ms. King, maybe she can answer that right now and I will gladly give you the opportunity to do so.

Ms. KING. You know, we would be happy to look into it and see if we could get an answer to it, but as a practical matter, we don't have a right of information from the private sector so we would have to ask them to provide that information to us as opposed to on the government side where we have a right to information.

Mr. GINGREY. Well, yes, and I appreciate that and certainly I think that you ought to use every tool that you do have available to get that information because quite honestly, a lot of us feel that the big government and the bigger it gets, the more expansive it gets, and 15 million additional people on the Medicaid program and we have got 47 million now on the Medicare program of aged and disabled, and that number is just going to grow as all the Baby Boomers are maturing, and, you know, you expand this Obamacare program, another entitlement program, in fact.

Let me ask you a specific question about that. On July 30, 2009, President Obama stated that his health plan—that is why I refer to it as Obamacare—was funded by eliminating the waste that is being paid out of the Medicare trust fund, and then on September 10, 2009, Speaker Pelosi said that Congress will pay for half of Obamacare, $500 billion, by squeezing Medicare and Medicaid to wring out the waste, fraud and abuse, and I will ask you, Mr. Spiegel, as well, was cutting $137 billion out of the Medicare Advantage program in any way, shape or form cutting out waste, fraud or abuse?

Ms. KING. I don't have the exact numbers off the top of my head but we in MedPAC have done work that has shown that payments to Medicare Advantage plans are higher than those that are made in fee for service.

Mr. GINGREY. Well, Ms. King we know that. We understand that. It is 112 percent. That is not an arguable—the point is, you overpaid them. That is not waste, fraud and abuse. It may be waste but it is certainly not fraud and abuse.

Ms. KING. It is not fraud and abuse but it could be considered waste by some.

Mr. GINGREY. Mr. Spiegel, any comment on that?

Mr. SPIEGEL. I am just trying to identify and prevent fraud in my job. You know, to respond to the questions about——

Mr. GINGREY. You are going too slow for me. I am going to give you a pass.

Let me go to Mr. Perez and Mr. Roy. Can you tell us what you are seeing in terms of organized crime involvement in Medicare and Medicaid fraud? That poster over there, I keep looking at it. It looks like Murderers Row. But you know, what is going on in Miami and is organized crime involved heavily in Medicare and Medicaid fraud and abuse, and why?

Mr. ROY. I will answer the first portion of that question about the overall scope of organized crime because it is geographical in nature. For instance, in the Los Angeles area you are seeing very organized criminal structures, in essence Eurasian organized crime entities heavily involved in Medicare fraud. They are involved in many street-level crimes as well. They are also involved in things such as credit card fraud and identity theft but what we are seeing is that in order to get to the upper echelons of these organized criminal elements, you have to go through health care fraud. That is where they make their money and that is different from what we would in Texas and in Miami, and with respect to what we see in Miami, I will turn that over to ASAC Perez and he will give you an idea of what is going on there.

Mr. GINGREY. Mr. Perez, thank you.

Mr. PEREZ. Thank you for the question. A lot of the things that we are seeing are a group or groups of individual that have tiers underneath them and for all intents and purposes there is even another subset of cells that work underneath that second tier and one cell won't necessarily know what the other cell is doing but they all kind of report to the same few folks in the top.

Mr. GINGREY. I see my time has expired, Mr. Chairman, and thank you, panelists, for your response, and I yield back.

Mr. STEARNS. I thank the gentleman.

Mr. Scalise, the gentleman is recognized for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. I appreciate the panelists for coming.

We are talking about waste, fraud and abuse. I want to first go back to something I saw in our State and ask you to comment on some of the things that we saw and how it is being dealt with at the federal level. In 1996 when I started in our State legislature, our governor appointed a 24-year-old to run our health department. At the time it was the largest department in State government, and there was a lot of waste, fraud and abuse and the governor made it a priority. And we talk about zero tolerance against waste, fraud and abuse, it is an attitude. It can't just be rhetoric. It has got to be followed by real action. And so the governor set out on a mission to root out that waste, fraud and abuse. He appointed, as I said, back in 1996 a 24-year-old to run that department and to go and seek it out, and in fact, that new head of our department was very aggressive. People went to jail. They shut down programs. There were Medicare mills, a lot of things that were going on that got rooted out. We cut out almost a billion dollars in waste, fraud and abuse in our department. I say that to make a point, that person that 24 years old at the time is now called the Governor Bobby

Jindal. He is now the governor of our State, but he was very aggressive then as the head of our Department of Health and Hospitals in rooting out that waste, fraud and abuse and he is still aggressive today.

I want to know, what coordination do you all have with our governors who are aggressive in rooting out whether you find Medicare fraud or Medicaid fraud, if you are finding Medicare care by a provider that is maybe doing business in other States and Medicaid, how do you coordinate those things with the States who are specifically dealing with Medicaid because they do have real jurisdiction there? I will you all kind of down the list. Ms. King.

Ms. KING. There is one provision in the Affordable Care Act that gives CMS the authority to revoke Medicare enrollment if Medicaid enrollment has been revoked in a State, so if someone is a bad actor in Medicaid and they are excluded from Medicaid, Medicare can follow the lead on that, and that is a new authority.

Mr. SPIEGEL. And that is addressed in our most recently published final rule with the new screening authorities.

Mr. SCALISE. Do you coordinate with the governors when you do find—let's say you find Medicare fraud or even, you are working on Medicaid fraud, are you all coordinating with those governors in those States who maybe have some enforcement that they are trying to do as well?

Mr. ROY. Sir, from a law enforcement perspective, we are working very closely with our Medicaid fraud control units, which obviously the governor, that would be their representative from a fraud level. We are doing great work there. Over the last 3 years we have probably increased our joint cases with the Medicaid fraud control units by upwards of 25 percent.

Mr. SCALISE. Thanks. And I need to move because we are limited on time. I apologize.

One of the components we really haven't talked about a lot is the waste component of waste, fraud and abuse, and you know, when you talk to doctors, and I have talked to a lot of doctors, especially over the last few years since I have been in Congress and we have been working on ways to actually reform health care as opposed to what I think President Obama did, doctors will tell you the biggest area of, you can call it waste—I would—the biggest area of work that they do that doesn't really relate to improving patients' health but it is defensive medicine. They run tests that everybody knows they don't have to run but they do it because they are afraid of frivolous lawsuits. In many cases they have had to fight frivolous lawsuits but it costs them a lot of money so it is just something that every doctor will tell you they do. Do you all consider—first of all, do you all consider defensive medicine to be part of waste in the definition that we are discussing today, Ms. King? Yes or no.

Ms. KING. I don't know. I don't honestly know the answer.

Mr. SCALISE. Have you done any kind of research to know how much this does cost?

Ms. KING. Defensive medicine? We have not done any direct work on that.

Mr. SCALISE. Mr. Roy or Mr. Perez?

Mr. ROY. I don't have a direct comment to that but I want to say that we are putting people in jail that are committing fraud, not necessarily involved in——

Mr. SCALISE. Mr. Spiegel?

Mr. SPIEGEL. I don't know the answer to that.

Mr. SCALISE. I can't believe that, you know, especially Mr. Spiegel and Ms. King, would say that you don't know the answer to what doctors will tell you is the biggest area of unnecessary spending but something they have to do because they will get sued if they don't run the test but they will tell you probably a third of those tests are done not because they think it is in the best decision for care of the patient but because they are afraid of getting frivolous lawsuits, and in fact, the President's bill does absolutely nothing to address that problem, and doctors will tell you that people in the medical profession across the board will tell you that topic was completely ignored, the topic that doctors will tell you is probably the biggest cause of waste in health care. And so when we talk about adding another 20 million onto the Medicaid rolls, at least, I would hope you all would go back and look at just how much more we are going to waste in making these doctors run these tests, because in our bill, in our real reform bill after we have done repeal, we are including medical liability reform where you get dramatic savings in waste in health care. But I would ask if both Ms. King and Mr. Spiegel would go back and include defensive medicine and come back to us with some real costs. Will you get the committee that information on what you estimate are the costs that it adds to the system to have these defensive medicine practices that weren't addressed in the President's bill?

Ms. KING. We can certainly look into it. I think it is a difficult question because what someone considers defensive medicine may be, you know, an unnecessary test on someone's part——

Mr. SCALISE. But you can estimate the cost of that?

Ms. KING. Well, there is a lot of variability in how physicians practice medicine.

Mr. SCALISE. As there is with anything that you give estimates on.

Mr. Spiegel?

Mr. SPIEGEL. I mean, I would say the same thing Ms. King said. We could look into it but the definitions of what falls into the category that you are trying to get a handle on vary, depending upon to whom you are speaking.

Mr. SCALISE. Thank you. I yield back.

Mr. STEARNS. The gentleman's time has expired.

Mr. Griffith from Virginia is recognized for 5 minutes.

Mr. GRIFFITH. Mr. Spiegel, how many claims does CMS get a day? Do you know?

Mr. SPIEGEL. I don't.

Mr. GRIFFITH. But it would be millions, would it not?

Mr. SPIEGEL. It would.

Mr. GRIFFITH. And do you have any idea what percentage of them you are able to review before payment is made?

Mr. SPIEGEL. Well, we do a substantial amount of review on virtually all of them before they get paid.

Mr. GRIFFITH. And I saw somewhere, I know that there was some testimony earlier that there was some indication that we didn't really know what the private sector's rate was but I had seen somewhere or have information that their rate is about 1–1/2 percent lost to fraud, and I am just wondering if you have seen that, A, and B, if you have studied what the private sector is doing to eliminate fraud so you could see maybe if there are better ways for eliminating or preventing Medicare fraud.

Mr. SPIEGEL. Sure. I have seen some numbers for the private sector, and we did look into what it is about them that makes them different from us in the way they approach this. So in the private sector, they have a different approach to how they deal with approval of services that we don't do in Medicare because we are designed as a program to get beneficiaries needed services and not to impose restrictions at the point of service. But private insurance can have prior authorization for a whole range of things that we don't, and so they can eliminate things that may have an impact on someone's need for services or at least impose a barrier there that we don't operate that way.

Mr. GRIFFITH. Since there appears to be some intent to pay for all of this new health care by getting rid of this fraud, have you all considered going to a preapproval process?

Mr. SPIEGEL. Well, we have had discussions about that among ourselves but right now it is not consistent with I guess our statutory authorities to be doing that.

Mr. GRIFFITH. And let me switch——

Ms. KING. Sir?

Mr. GRIFFITH. I am sorry.

Ms. KING. If I might point out something else that is a key difference between the private sector and Medicare is that Medicare is an "any willing provider" program so the private sector has much more ability to restrict the providers who are coming into the program than Medicare does. Now, with some of the new authorities in the ACA, CMS is going to have more authority to take a closer look at providers and keep out providers who are not good actors.

Mr. GRIFFITH. Let me claim back my time. Let me ask, switching, something that is kind of interesting, it is my understanding that the Medicare number, and I don't care whether it is Ms. King or Mr. Spiegel, but the Medicare number is the same as your Social Security number. Is that correct?

Ms. KING. That is correct.

Mr. GRIFFITH. And then if somebody steals your identity, you can't just go out and change your Social Security number. Wouldn't it be a better policy to have each patient have a separate Medicare number and then when somebody steals that number the patient can get a new number just like you do with your credit card if you lose it or it is stolen by somebody?

Ms. KING. Certainly there have been proposals made to that effect.

Mr. SPIEGEL. And we are doing a substantial amount of work right now to eliminate all the compromised numbers that we have identified through both providers and suppliers as well as beneficiaries.

Mr. GRIFFITH. Doesn't that have the impact on the one hand of making it very difficult for the patient and then I guess I would ask, what is your opinion of that? You said it had been talked about but what do you think? Don't you think that would be a better policy, Ms. King?

Ms. KING. I think it probably would be. There would be a question, I think, in our minds about what it would cost to effect that transition and how long that would take and what would be involved with that because you have every living beneficiary and then new beneficiaries as they come on the rolls.

Mr. SPIEGEL. And we agree with that.

Mr. GRIFFITH. New ones would be a lot easier. That wouldn't probably very much at all.

Ms. KING. Yes, they would.

Mr. GRIFFITH. But anyway. All right. I yield back my time, Mr. Chairman.

Mr. STEARNS. The gentleman yields back his time. The gentlelady, Ms. Myrick, is recognized for 5 minutes.

Mrs. MYRICK. Thank you, Mr. Chairman. Thanks to all of you for being here and thank you, you two who do the investigative work for what you are doing and the way you are going about it.

My question I guess is to Mr. Spiegel. I am not real sure. On States, is there a requirement that States report fraud to you, to CMS? Because I understand that maybe half the States don't even report data.

Mr. SPIEGEL. I don't know what the requirement is for——

Mrs. MYRICK. Would you mind finding out and getting back? Because I would like to know.

Mr. SPIEGEL. Sure.

Mrs. MYRICK. And then the next question is relative to States, do they have their counties report? Does it individually vary by State to State? In North Carolina, counties are responsible for reporting the fraud to the State. Is that something that happens across the country? You know, when you get right down to the local level where they have better control on it maybe than the whole State does. It is more efficient?

Mr. SPIEGEL. I don't know about the efficiencies, and it would really depend on how each State is set up its operational structure.

Mrs. MYRICK. So each State is in control of how they report that?

Mr. SPIEGEL. I would think so.

Mrs. MYRICK. But why do some States not report? Do you know?

Mr. SPIEGEL. I don't know the extent to which they don't. I mean, I know we have fraud investigation databases and we collect information from States, and I think we—what I was trying to say before is, I didn't know what the requirement was. I know we get reporting from States about the fraud cases that they uncover and I am sure they coordinate closely with——

Mrs. MYRICK. I would be curious to know.

And then the second part of that, are there any minimum standards that States have to meet relative to, you know, the waste, fraud and abuse, whatever you want to call it, to receive their FMAP?

Mr. SPIEGEL. Well, again, I am not a Medicaid expert but there are requirements that States have to meet, you know, to have a

proper State plan in place, they have certain administrative requirements they have to meet. They have to have a single State agency with authority. They have to have Medicaid fraud control units and things.

Mrs. MYRICK. And is there a follow-up on that to make sure that gets done? And I guess that goes back to my first question, do the States all report? Anyway, if you don't know——

Mr. SPIEGEL. Well, I know there is follow-up on how the States organize themselves and there is constant interaction between the folks in CMS who oversee Medicaid around that.

Mrs. MYRICK. But all of you pretty much agree that there needs to be more of an effort on this relative to dollars that come from what you said before to the different people and you have all responded that if there were more dollars into the program for what you are doing, you would have a better ability to do it, particularly with the two in the middle and what you do with the inspection work.

Mr. SPIEGEL. We have found that for every dollar we are spending, we are getting a substantial return on investment, 6.8 percent, I believe.

Mrs. MYRICK. But yet in the new health care bill, there is only, in my understanding, $350 million in there for any fraud activities, which, if that is divided up across all the agencies, you know, it is less than one-tenth of 1 percent of what we are spending on the health care bill. So it seems like it is a very small amount that is being dedicated to what really is getting at the crux of so much of the waste that everybody talks about is going to pay for all this. It just doesn't seem to make sense. It seems like there should be more effort put into what you are doing from the standpoint that you are actually seeing results and you are getting to the bottom of the issue.

Mr. SPIEGEL. I mean, I guess we would welcome the opportunity to have more resources to do more of the things that we have embarked on.

Mrs. MYRICK. But I know Mr. Terry asked a question about actually if we could do this what would it take type thing, so you all are going to get back to him with that?

Mr. SPIEGEL. Yes, ma'am.

Mrs. MYRICK. I appreciate it. No more questions.

Mr. STEARNS. The gentleman, Mr. Murphy from Pennsylvania, is recognized for 5 minutes.

Mr. MURPHY. Thank you.

I want to go over this list here and I wonder if you can tell me if you have any idea where these fugitives are. Carlos Benitez, do you know where he might be? Do we know what country he is in?

Mr. ROY. Sir, I may indeed know the general whereabouts of some of these individuals but——

Mr. MURPHY. Cuba?

Mr. ROY. Probably not, sir.

Mr. MURPHY. Are any of these folks in Cuba?

Mr. ROY. Probably not.

Mr. MURPHY. I understand that some of them actually may be.

Mr. ROY. Sir, I correct myself. There may be several of those that are in Cuba, yes.

Mr. MURPHY. Because my understanding is there may be as many as six, and the question is what the Cuban government is involved in here. According to some reports, "In a discussion with a high-level former intelligence official with the Cuban government who asked to remain unnamed," and this is from University of Miami report. He states, "There are indeed strong indications that the Cuban government is directing some of these Medicare frauds as part of a desperate attempt to obtain hard currency." The source notes that the Cuban government is also assisting and directing other instances of Medicare fraud providing perpetrators with information with which to commit fraud. They go on to say in the instance where the Cuban government is not directing or facilitating the fraud——

Ms. DEGETTE. Mr. Chairman?

Mr. MURPHY [continuing]. It does provide Cuba as a place for fugitives to flee. This gives the Castro regime a convenient and carefree way to raise hard currency. Are we doing anything about that?

Mr. ROY. I have actually inquired before about what are the ties to Cuba, and nothing has been brought to my attention that would substantiate what you are saying. I am more than happy to take a name and a number or if you can get me in touch with that individual to follow up on that.

Mr. MURPHY. This was a report——

Ms. DEGETTE. Mr. Chairman, will the gentleman just yield briefly?

Mr. MURPHY. Not on my time.

Ms. DEGETTE. I would like to make——

Mr. MURPHY. I didn't yield yet, because I really only have a couple of minutes——

Mr. STEARNS. Does the gentlelady request a personal privilege or a point of order?

Ms. DEGETTE. I just want to make sure——

Mr. STEARNS. Is this a request for a point of order?

Ms. DEGETTE. It is a request for a point of order.

Mr. STEARNS. OK. The gentlelady is recognized.

Ms. DEGETTE. I just want to make sure, and I know that you are not intending to ask Mr. Roy any information that would in any way undermine an ongoing investigation.

Mr. MURPHY. Absolutely.

Ms. DEGETTE. I just wanted to clarify that. Thank you.

Mr. MURPHY. Absolutely.

Ms. DEGETTE. He looked a little uncomfortable when you asked that question.

Mr. MURPHY. I am just asking if——

Ms. DEGETTE. Thank you very much.

Mr. MURPHY. Thank you. I appreciate that.

This is a report from the University of Miami. I would be glad to let you read that. It is just something I wanted to bring attention because it does bring to light there has also been concerns about how things happen by other countries where they may be doing this as part of an organized-crime issue, recognizing the ability to have false claims with Medicare actually may be easier, less risk and lower penalties than it would be, for example, with cocaine trafficking where you have long mandatory sentences. And so

I am wondering along these lines if you are also looking to see-I mean, I appreciate the work you are doing. This is great. I am glad you are pursuing this. The American people appreciate that. As Mr. Barton talked before, we are all in favor of this. I just want to make sure we are also looking at this as a mechanism to see if you think we need more enforcement, do you need more funding, do you need more personnel, or do we need stiffer penalties, or all of the above?

Mr. ROY. We need all of the above, sir.

Mr. MURPHY. Do you think the level of penalties is a factor in terms of people are willing to risk the risk and consider jail time as the price of doing business?

Mr. ROY. Well, I certainly felt that way probably 5 to 10 years ago but in the recent years I have seen across the board sentencing guidelines go up and I have seen perpetrators of health care fraud go to federal prison for longer periods of time. If I had my way, they would go there longer but that is not the perfect world but I see a movement toward the punishment fitting the crime, sir.

Mr. MURPHY. Thank you. Anybody else want to comment on that, Mr. Perez or Mr. Spiegel?

What additional tools then do you think that Congress can give all of you with regard to helping investigate Medicare and Medicaid fraud and abuse cases? Are there any other tools you want from us?

Mr. ROY. First and foremost, the funding aspect of it. The funding has to be continuous. It has to be long term to ensure that I can keep bodies on the ground. It can't be a one shot in the arm type of a situation. Our organization is human resource driven, and the more agents I have in the field and the more support staff I have, the better job I am going to be able to do.

Mr. MURPHY. I appreciate that. Anyone want to comment? Yes, Mr. Perez.

Mr. PEREZ. Just from an investigative standpoint, and I mentioned this earlier. I apologize if I am repeating myself at least to you. But we certainly would like to have real-time data access so that we can see the claims as they are hitting them. We currently don't have that. And there is another system that is out there that we would also like access to that actually gives us the profile of the providers that are in so that we know once they are in, all of the makeup of that particular provider and then we can initiate investigations.

Mr. MURPHY. Do you have that profile access now or that is something you are asking for in addition?

Mr. PEREZ. We do not have it now.

Mr. MURPHY. So to be able to get that profile information on the providers and the real-time data so you could I guess more or less profile as people are submitting claims that there are things that appear to not match standard billing procedures with durable medical equipment or services, that would show up and you could hit on that right away, would that help you?

Mr. PEREZ. I think that certainly would help us, yes.

Mr. MURPHY. Mr. Spiegel, do you have a comment on that?

Mr. SPIEGEL. Sure. And what I would say is, the President's budget has laid out a number of things that we would want to do

in 2012, and for now, we need to have a little bit of time to gauge the impact of all the things that we started doing in the last year to refocus our efforts on the front end and to take prompt action on the folks who need to have action taken against them.

Mr. MURPHY. Thank you. I think if any of you had any other details of how that work would out to let the committee know. Thank you so much.

Mr. STEARNS. The gentleman's time has expired. The gentleman, Mr. Gardner, from Colorado is recognized for 5 minutes.

Mr. GARDNER. Thank you, Mr. Chairman, and thank you to the witnesses for being here today. I appreciate your work on something that obviously everybody is concerned about.

In Colorado, we were able to do a couple of things to detect fraud, to fight back against those who would abuse the system. We passed legislation that would freeze—you know, pair up benefits, the public pension fund. If it was a public employee that was involved, it allowed the board to freeze those assets. We also tried to pass legislation that said if you were a contractor, a provider that had been convicted of fraud elsewhere, that after a certain point you were barred from dealing with the State of Colorado and so I want to get into that a little bit for a couple of questions.

Mr. Spiegel, I wanted to follow up on one of your responses to Mr. Griffith. I believe Medicare receives about 4.5 million claims a day, and you substantially review every single one of those claims?

Mr. SPIEGEL. In some way. We verify that the person who sends in the bill, for example, is enrolled in Medicare and that the person who received the services is an eligible beneficiary. I mean, there are automated claims edits that are in place that look at that.

Mr. GARDNER. How many would you say you substantially review that you are actually able to really look at? Because that is all automated. I mean, what percentage are you able to actually look at to detect——

Mr. SPIEGEL. If what you are talking about is do we take an opportunity to collect medical records and make a judgment about the clinical conditions that were present and things like that, I don't know the exact percent. I could get back to you with that.

Mr. GARDNER. That would be great if you would get back to me on that. Thank you.

And then Mr. Spiegel, we have heard that in terms of both durable medical equipment and home health, both are highly susceptible to fraud. What other areas lose a substantial amount to fraud?

Mr. SPIEGEL. Well, in our recent screening rule, the ones that we put in the high-level-risk category were newly enrolling suppliers and newly enrolling home health agencies and those individuals or entities that hit some of the triggers that we put in the rule. There are examples of other provider and supplier types that we have uncovered and that the Inspector General's work has identified that maybe not as a class but as individuals have had some problems.

Mr. GARDNER. And I see in your testimony where you talk about delivery system reform, you talk about inflated prices that could lead to increased fraud but you have only made reforms in, I believe it was nine areas. Why did you just add those reforms in nine

areas? If you are overpaying somebody, shouldn't we reform them all?

Mr. SPIEGEL. The nine areas were in statute.

Mr. GARDNER. So if they are being overpaid and it is causing fraud, do you have an ability to add to those nine areas?

Mr. SPIEGEL. I don't know the answer to that. Over time we have an opportunity to add to that based on what we learn from our work.

Mr. GARDNER. And the President's budget 2012 said we are going to recover about $32 billion in fraud. Is that how much fraud there is? What percentage of fraud total are we recovering?

Mr. SPIEGEL. Well, as I mentioned before, we don't know the exact number because the estimates that we have all seen contain things that are in addition to fraud. They contain improper payments, they contain administrative errors, they contain both public and private sector estimates. Until we can get to one number that identifies fraud, which is in a sense a legal determination, we are not going to be able to——

Mr. GARDNER. At what point is a provider barred from doing business with a Medicare and Medicaid provider?

Mr. SPIEGEL. Well, it would depend on the circumstances.

Mr. GARDNER. After one time they have been found fraudulent?

Mr. SPIEGEL. Well, it would depend on, you know—we don't determine fraud at CMS. That is a law enforcement decision. And if somebody has been convicted of fraud, the Inspector General has the opportunity to exclude them from the program for a period of time.

Mr. GARDNER. So if somebody is convicted of fraud, are they automatically barred?

Mr. SPIEGEL. Sir, yes, they are.

Mr. GARDNER. And then are States using that then to bar them from their Medicaid programs?

Mr. SPIEGEL. We are working on that issue right now. I am not sure how in depth the State goes with respect to who they exclude from their programs.

Mr. ROY. We have provisions in our recently published rule to implement that so that when someone is excluded from Medicare, States will be doing the same thing as well as States excluding from Medicaid entities or individuals that have been excluded by other State Medicaid programs.

Mr. GARDNER. What happens to the money that you are recovering from fraud? Does that go back into fraud-fighting efforts?

Mr. ROY. By law, the money that we recover goes right back in the Medicare trust fund.

Mr. GARDNER. So it does not go into additional fraud prevention?

Mr. ROY. No, sir.

Mr. GARDNER. I yield back my time.

Mr. STEARNS. I thank the gentleman, and I thank the first panel for their indulgence and forbearance here.

Ms. DEGETTE. Mr. Chairman?

Mr. STEARNS. Just let me finish and I will be glad to recognize you.

There was a question, Mr. Spiegel, that was asked of you and you did not know the answer concerning the claims per day. I

thought I would put in the record that Health and Human Services' Bill Corr testified in front of the Senate Finance Committee in October 2009 that CMS gets 4.4 million claims a day with a requirement to pay within 14 to 30 days and they are only able to review 3 percent of the prepayment.

The gentlelady from——

Ms. DEGETTE. I would just ask unanimous consent to follow up on one question.

Mr. STEARNS. Sure. Go ahead.

Ms. DEGETTE. Mr. Perez, someone asked you if you needed more powers and you said you would like to be able to access claims data directly when you are on these investigations. Do you need—is this a matter of more authority to be given to you by Congress or is it just the procedures that your office is using?

Mr. PEREZ. I believe it may be an internal issue with the department working with CMS and allowing OIG then to have direct access to that.

Ms. DEGETTE. If you need more powers, let us know because it would seem to us to be good information for you to be able to access. Thank you.

Mr. STEARNS. I thank the gentlelady. We have another member who has joined us. The gentleman from California, Mr. Bilbray, is recognized for 5 minutes.

Mr. BILBRAY. Thank you.

Mr. Perez, we were talking about the ability to impound. IRS has been given that power to impound so why wouldn't we—if we are as serious about making sure that taxpayer funds are going out inappropriately, wouldn't we at least give you the authority that we give to the people who make sure that revenue comes in to the Federal Government appropriately?

Mr. ROY. If I could, sir?

Mr. BILBRAY. Go ahead.

Mr. ROY. I am more than willing and happy to look at that particular issue in terms of the ability to impound. We do seize bank accounts. It is more in the matter of physical assets but I am more than willing to take any additional resources that come my way.

Mr. BILBRAY. I am just concerned, because you see the disconnect that we take income of the revenue very seriously but traditionally we haven't put as much weight on reviewing and oversight and recapturing of assets coming back.

Ms. King, I appreciate your kind words about the wrongful payment bill. I was one of the authors of that bill, one of the few bipartisan bills that got passed last year, but I don't think that weight has been traditionally applied and I would like to make sure that we do it.

Speaking of the IRS, the fact is, a lot of these people are engaged in fraud and abuse. I have to believe as a former tax consultant that once they get in the habit of filling out applications for revenue from Medicare and Medicaid inappropriately, I have to believe there has got to be more opportunity in there to engage the IRS to be able to be involved with this. Remember, it wasn't the FBI that got Al Capone, right?

Mr. ROY. Sir, you are correct. We work joint cases with IRS/CID all the time just for that purpose.

Mr. BILBRAY. Mr. Spiegel, I have a concern with something you said. I know that this is waste, fraud and abuse in here but you appear to take wrongful payments as being sort of separate and apart from waste, fraud and abuse.

Mr. SPIEGEL. Well, from fraud.

Mr. BILBRAY. From fraud? OK. And that is why I want to clarify because you will admit the impact to the taxpayer and to the federal family is financially the same between wrongful payment and fraud.

Mr. SPIEGEL. We are against all of us. We are against improper payments and fraud and waste and abuse.

Mr. BILBRAY. OK. So the fact is, is that we need to fast-track those items and get it there.

One of the items that has been brought up is the fact of the use of false documentation, identify theft. Now, we usually talk about identify theft in different fields, and we have gone around with individual the use of identify fraud to falsify employment opportunities, illegal presence in the country and everything else. But the identity fraud issue that we have seen here with your enforcement of the ability of somebody to get a driver's license, get a document and use it fraudulently, that has been documented in your enforcement as a vehicle that organized crime or these bad guys are using in implementing their fraud to the health care system.

Mr. PEREZ. Certainly, and in Miami I know that in those instances where we are able to prove that beyond reasonable doubt, we certainly are including those in——

Mr. BILBRAY. Has Florida implemented the REAL ID bill yet? Do you know?

Mr. PEREZ. That I do not know, sir.

Mr. BILBRAY. Mr. Chairman, I just think we need to point out that that is one bill that we passed how long ago which was basically the number one request of the 9/11 Commission, but we still have States that are looking at dragging their feet about using biometrics, and biometrics is one way we could catch these guys. You have biometrics through a driver's license under one name, you do the other. Anybody who watches NCIS knows that, you know, we have got that computer technology. We have had it in California since 1978. That they will get busted coming in, one guy coming in as Smith, another guy coming in as Martinez, and we cross-reference those biometrics. So I just want to point out that I think that the federal bureaucracy needs to be sensitive that the States are the people that provide the IDs in lieu of a federal ID, that REAL ID is a way we can secure the system without having to have a federal ID and make sure—you know, there is one reason why we have got to be serious as federal agents to push that the States have to do their part down the line.

And maybe, Mr. Chairman, our committee can recommend to Homeland Security that before we send money to States for homeland security projects that we require that the first priority that if States haven't implemented REAL ID and secured this identification issue that should be the first project used with federal funds on Homeland Security, and with that, I yield back, unless anybody has a comment on that.

Mr. STEARNS. All right. I thank the gentleman. That could be your piece of legislation.

So I want to thank the first panel again. We will move to our second panel and ask the Hon. Alex Acosta to come up and Mr. Craig H. Smith and Ms. Sara Rosenbaum, and I invite all my members to stay for the second panel.

The Hon. R. Alex Acosta is a native of Miami and the current Dean of the College of Law at Florida International University. He received his law degree from Harvard. He served as a law clerk to Justice Samuel Alito, then a judge on the U.S. Court of Appeals for the 3rd Circuit. He has been the longest serving U.S. attorney in south Florida since 1970, sitting as a Senate-confirmed United States Attorney for the Southern District of Florida.

Our second panelist is Craig Smith. He is a partner of Hogan and Lovells. He rejoined the firm in 2008 after serving as General Counsel for the Florida Agency for Health Care Administration. While serving as the chief legal officer of one of the Nation's largest Medicaid programs, he coordinated frequently with the federal officials at the Centers for Medicare and Medicaid Services and the Department of Justice.

Our third panelist is Sara Rosenbaum, who received her J.D. from Boston University Law School. She has played a major role in design of national health policy in areas such as Medicare and Medicaid, private health insurance and employee health benefits, access to health care from medically underserved persons, maternal and child health, civil rights in health care and public health. She also worked for the White House Domestic Policy Council.

So I thank all three of you, and we welcome the Hon. Mr. Acosta for your opening statement of 5 minutes. Thank you for staying with us.

STATEMENT OF R. ALEX ACOSTA, DEAN, FLORIDA INTERNATIONAL UNIVERSITY COLLEGE OF LAW; CRAIG H. SMITH, PARTNER, HOGAN LOVELLS, LLP; AND SARA ROSENBAUM, HIRSH PROFESSOR AND CHAIR, DEPARTMENT OF HEALTH POLICY, SCHOOL OF PUBLIC HEALTH AND HEALTH SERVICES, THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER

STATEMENT OF R. ALEX ACOSTA

Mr. ACOSTA. Thank you, Mr. Chairman, Ranking Member DeGette and distinguished members of the committee. I appreciate the opportunity to appear before you to discuss waste, fraud and abuse in Medicare and Medicaid. As the chairman mentioned——

Mr. STEARNS. Let me just swear you in. If you don't mind, please stand and raise your right hand.

[Witnesses sworn.]

Mr. STEARNS. Sorry. Go ahead.

Mr. ACOSTA. As the chairman mentioned, I served as the United States Attorney for the Southern District of Florida from 2005 to 2009.

Early in my term, I made the prosecution of health care fraud a top priority in my district. I organized in 2006 the South Florida Health Care Fraud Initiative. As a result, we became home to the

first Medicare fraud strike force in the Nation. The results were spectacular but they were also very sad. By 2008, we accounted for 32 percent of the Nation's health care fraud prosecutions.

From fiscal year 2006 through May 2009, we charged more than 700 individuals responsible for more than $2 billion in fraud. That is actual fraud charged in criminal indictments. I have heard this morning that figure now stands at 3.5 billion. Put differently, those $2 billion, which is sometimes hard to imagine so I put it in per-beneficiary terms. That is $1,900-plus per beneficiary in south Florida.

Numbers alone, though, don't tell the story. I was very happy to hear that some Members are going to do ride-alongs. I wish more Members could visit the strike forces. If I was U.S. Attorney and if you visited south Florida, I would take you to our facility. There we have a wheelchair that we have shown to other interested individuals. That wheelchair was billed again and again and again, the same wheelchair not used by patients. We call it the million-dollar wheelchair because it was billed that many times. We have boxes after boxes of evidence. We have pictures of a pharmacy, and that pharmacy is billing thousands, perhaps millions of dollars in expensive brand-name inhalation products. In fact, the pharmacy was a broom closet and there was nothing there.

That level of fraud should absolutely disgust each and every one of us. We enjoy one of the world's best health care systems but we often hear of the skyrocketing costs of health care and we worry that one day we will not be able to afford quality care. Reducing fraud, as you have already mentioned, is, in public parlance, a no-brainer. It should be a bipartisan effort.

Now, let me say I am proud of the work we did in south Florida prosecuting fraud but prosecution is not the solution. We need to prevent fraud from happening in the first place. Prosecutions have limited deterrence. The sentences, while increasing, are not sufficient. Prosecutions are resource-intensive. Prosecutions rarely recover taxpayer dollars wrongfully paid out in fraudsters. The fraudsters for the most part spend the money or send the money overseas. Prevention is the preferred approach.

Think of this as perhaps, analogize fraud to a busy intersection. How do you prevent accidents at a busy intersection? Do you post a police officer at that intersection and ticket cars after they commit accidents or do you put a red light at that intersection and prevent accidents in the first place? In the same way, we need to prevent fraud in the first place. Prosecutions are not the solution.

Now, effective prevention requires a lot more than front-end screening. Effective prevention requires continuous and proactive efforts to identify and stop fraud as it happens. The gentleman from Virginia, Mr. Griffith, mentioned the issue of unique IDs. Well, Mr. Chairman, Ranking Member DeGette, I assume both of you have credit cards. Imagine if you call—you use that credit card and you call American Express and you say I just lost my card and they say thank you very much, we can't issue a new card with a new number; when you get fraudulent charges, let us know and continue to let us know in the future because we cannot cancel your card. How long would American Express stay in business? But that is the system that Medicare uses. Your Medicare number is

your Social Security number, a number that is easily found and a number that can then be used to bill in your name and that number cannot be changed.

Effective predictive modeling is another tool that can assist with fraud prevention. An example of how effective this can be comes out of south Florida. South Florida in one year was responsible for $92 million in Budesonide billings. This is an expensive inhalation drug, and inhalation drugs are a large problem in south Florida. Well, the Office of Inspector General did a study to look at these billings. Seventy-four percent of the beneficiaries for this drug submitted claims that exceeded the 90-day coverage maximum. Any private insurance company would say if you exceed a coverage maximum, we are not going to pay. Sixty-two percent of those that allegedly submitted claims for these drugs in fact hadn't seen a prescribing physician in 3 years. Ten doctors in south Florida were responsible for more prescriptions for this drug than all the doctors in Chicago combined. Chicago is the next highest billing city.

These are the kinds of issues that predictive modeling can catch. These are the kinds of issues that should be caught. Experience shows that prepayment prevention computer models that identify billing patterns that stop payments when you see spikes like this are the preferable approach. Post-payment pay and chase does not work.

Now, I have heard this morning that CMS is moving away from pay and chase, and I think that is a wonderful idea. It is an important issue because we need to catch this before it happens. After the fact my former colleagues and good friends at OIG can prosecute with DOJ but that is not going to solve the problem. Thank you.

[The prepared statement of Mr. Acosta follows:]

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FLORIDA INTERNATIONAL UNIVERSITY

STATEMENT OF

THE HON. R. ALEXANDER ACOSTA

DEAN OF THE COLLEGE OF LAW
FLORIDA INTERNATIONAL UNIVERSITY

FORMER U.S. ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

BEFORE THE

UNITED STATES CONGRESS
ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HEARING ENTITLED
"WASTE, FRAUD AND ABUSE: A CONTINUING THREAT TO MEDICARE AND MEDICAID."

MARCH 2, 2011

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Mr. Chairman, Ranking Member DeGette and distinguished Members of the Committee:

I have been asked to provide testimony regarding (i) my efforts, as U.S. Attorney, to combat Medicare fraud and (ii) my thoughts, based on these experiences, on how we can reduce – and hopefully prevent – fraud in the future. I appreciate the opportunity to appear before you to address this critical issue.

I can think of few more pressing issues than that of health care fraud. Americans enjoy one of the world's best health care systems. We hear often, however, of the skyrocketing cost of health care and we worry that one day we will be unable to afford quality care. Reducing fraud cuts costs without impacting quality. Reducing fraud is, in common parlance, "a no-brainer."

I served as the United States Attorney for the Southern District of Florida ("SDFL") from 2005 to June 2009. Early in my term, I made the prosecution of health care fraud a top priority in my District. The results were spectacular, yet sad. From FY2006 through May 2009, my District charged more than 700 individuals responsible for submitting more than $2 billion in fraudulent bills to Medicare. Put differently, we prosecuted more than $1,900 in Medicare fraud per senior citizen living in South Florida and the Treasure Coast.[1]

Admittedly, this $1,900 per capita figure both underestimates and overestimates the scope of health care fraud. On the one hand, the actual per capita figure for South Florida is much higher, as only a small percentage of fraudulent billings are identified and prosecuted. On the other hand, this per capita fraud figure, when applied nationally, may be lower as South Florida's popularity with Medicare beneficiaries makes it particularly vulnerable to fraud. (I reject the loose allegations, which I have sometimes heard, that label South Florida a "fraud capital." Although fraud in South

[1] The U.S. Census estimated the South Florida and Treasure Coast population, as of July 1, 2008, to be 6,114,069. The South Florida Regional Planning Council estimated that 17.2% of this population was 65 years or older, yielding 1,051,620 senior citizens, or $1903 per capita. The Southern District of Florida also includes Okeechobee and Highlands Counties, which are excluded from these figures as they are not part of the South Florida / Treasure Coast Population Areas.

Florida is high, it is comparable to other major metropolitan areas with similar demographics.)[2]

Imagine the impact of saving even a fraction of $1900 per Medicare beneficiary. This would go a long way toward improving Medicare without impacting the quality of care, and toward improving our budget deficit.

Despite our success prosecuting Medicare fraud in South Florida, I believe that increased prosecutions are not the answer to reducing Medicare waste, fraud and abuse. I want to make clear that I am proud of the work we did in South Florida, and want to thank the prosecutors, agents and staff of the Southern District of Florida law enforcement agencies for their incredible efforts to combat Medicare fraud. I want to thank, and to commend, in particular, my successors, my former First Assistant and later U.S. Attorney Jeffrey Sloman, and the now U.S. Attorney, Wilfredo Ferrer, for continuing and expanding the District's anti-fraud efforts. Nonetheless, prosecutions are not the solution.

We need to prevent fraud from happening in the first place. Prosecutions have limited deterrence. Prosecutions are resource intensive. Prosecutions rarely recover the taxpayer dollars wrongfully paid out to fraudsters. Prevention is the preferred approach. Think, if you will, of anti-fraud efforts as analogous to efforts to reduce traffic accidents at a busy intersection. What is a better way to reduce accidents at this intersetion: to spend resources to station a police officer at that busy intersection to ticket cars (and prosecute drivers) that cause traffic accidents, or to place a traffic light at the intersection to prevent accidents in the first place?

I urge you to carefully review the various HHS Office of Inspector General ("HHS-OIG") recommendations regarding Medicare and Medicaid, and to investigate needed reforms to prevent fraud on these important public programs.

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[2] Media reports that reference South Florida as having the highest level of fraud overlook a simple fact. From 2006 until today, SDFL has prosecuted more cases than any other District in the nation. As a result, SDFL identifies and reports more fraud. This does not imply that there is substantially more fraud, any more than an increased incidence of speeding tickets implies that more drivers break traffic laws. Rather, the higher numbers are explained in part by our increased incidence of enforcement. Reference to pre-2006 figures supports this, as prior to our 2006 South Florida Health Care Fraud Initiative, reported measures of fraud in South Florida were substantially lower.

I.

Early in my tenure as U.S. Attorney, the SDFL chief of economic crimes, Eric Bustillo, provided me data regarding the breadth and depth of the Medicare fraud problem. Subsequent investigations confirmed the concerns that he raised with me. For example:

- In 2006, HHS-OIG agents conducted site visits of all 1,581 durable medical suppliers ("DMEs") registered in South Florida. They inspected the DMEs for compliance with five standards, including whether they: (i) maintained a physical facilility and (ii) were opened and staffed during business hours. A total of 491 (31%) failed to maintain a physical facility or were not open during reasonable or posted business hours. Indeed, instead of medical equipment businesses, agents often found empty offices with "for rent" signs, abandoned offices with mail stacked outside the door, and sometimes even other businesses such as a florist shop, and a real estate company. These 491 suppliers billed Medicare approximately $237 million ($97 million paid) from January 1 to November 30, 2006.[3]

- In 2006, eight percent of Medicare beneficiaries with HIV / AIDS lived in South Florida. By contrast, South Florida providers accounted for 79% of the amount of drugs billed nationally by Medicare beneficiaries with HIV / AIDS. With respect to non-oral HIV / AIDS related drugs, South Florida providers submitted bills of more than $2.2 billion ($568 million paid), about 22 times the $100 million submitted ($42 million paid) in the rest of the nation.[4]

- In 2007, about two percent of Medicare beneficiaries lived in South Florida. Nonetheless, South Florida accounted for 17% of Medicare spending on inhalation drugs. On a per capita basis, Medicare spent approximately $4400 per South Florida

[3] *See* HHS Office of Inspector General, *South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visit.*
[4] *See* HHS Office of Inspector General, *Aberrant Billing in South Florida for Beneficiaries with HIV / AIDS.*

beneficiary receiving inhalation drugs compared with a national average of $815 per beneficiary.[5]

In 2006, in response to Mr. Bustillo's presentation, I organized the South Florida Health Care Fraud Initiative. Our initiative created more than a working group; it brought a different approach to health care fraud enforcement. First, to augment the cooperation between lawyers and investigators, we co-located SDFL prosecutors and federal agents in a fusion center modeled after similar arrangements more traditionally, and successfully, used in drug and organized crime prosecutions. To make clear that the agents and prosecutors must operate as a team, we cross-designated agents who held law degrees as Special Assistant United States Attorneys, to help with the prosecutions.

Second, the initiative streamlined criminal health care fraud prosecutions. Traditionally, white collar fraud cases rely on historical evidence of past billing records. Reconstructing years of records consumes time and resources. The South Florida quick-hit squad, and later the Strike Force, instead focused on present fraud, limiting criminal charges to the more recent fraudulent billings and thus avoiding the need to reconstruct years of data. Again, this resembled similar practices traditionally used in drug prosecutions: an individual found dealing illegal drugs is typically charged with that single, present act, and prosecutors do not spend additional resources recreating past history of drug sales absent a compelling reason.

Third, South Florida became the first District in which prosecutors worked with agents to review near real-time data to identify aberrant billing patterns. This use of advance data analysis techniques permitted our teams to identify and pro-actively investigate individuals while they were still engaged in fraudulent billing. Particular credit for these efforts goes to a licensed nurse, whom we employed, who reviewed and identified medically unrealistic data trends.

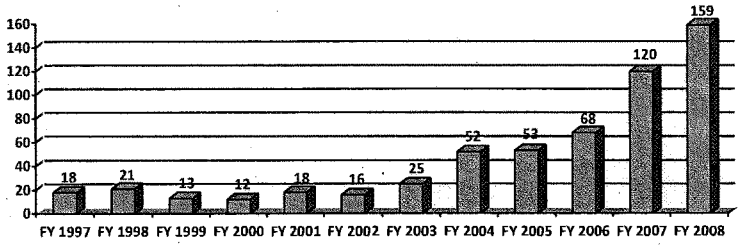
In 2007, our efforts were substantially energized as the Criminal Division's Fraud Section contributed its attorneys, expertise and resources through a Health Care Fraud Strike Force. Attorneys from Washington D.C. spent weeks co-located in our facilities. They integrated fairly seamlessly with SDFL prosecutors and agents, and they deserve credit for working to

[5] *See* HHS Office of Inspector General, *Aberrant Claim Patters for Inhalation Drugs in South Florida.*.

avoid the bureaucratic squabbles that often impede these multi-office team approaches. South Florida owes much to their expertise, their contributions and their teamwork.

Our efforts resulted in a substantial increase in health care fraud prosecutions in South Florida. Indeed by FY 2008, SDFL was prosecuting 32% (159 of 502) of the nation's health care fraud matters.

Health Care Fraud Cases Prosecuted in SDFL



The fraudulent Medicare claims associated with these SDFL prosecutions are, as I said previously, both spectacular and sad:

- FY 2005 – data not available
- FY 2006 – $138,000,000
- FY 2007 – $638,000,000
- FY 2008 – $793,448,162
- FY 2009 – $951,575,415

The Southern District's efforts continue to this day. In 2008, the Southern District of Florida model was used to establish a Health Care Fraud Strike force in Los Angeles, and in 2009, a third Strike Force in Houston. Strike Forces now exist in Detroit, Brooklyn, Baton Rouge and Tampa as well, and the efforts have been elevated within the Justice Department, with the May 2009 creation of the HEAT (Health Care Fraud Prevention and Enforcement Action Teams).

II.

Increased prosecutions, while commendable and important, are not the solution to Medicare fraud, waste and abuse. This may appear to be a surprising statement coming from a prosecutor. It is a belief based on my experience prosecuting health care fraud.

First, prosecutions are an insufficient deterrence. In FY 2010, federal court judges sentenced 146 defendants to terms of imprisonment averaging more than 40 months.[6] In the future, the average sentence will likely increase as, pursuant to a directive in the Patient Protection and Affordable Care Act, the U.S. Sentencing Commission implements a 2 to 4 level increase in Federal Sentencing Guidelines for crimes related to a government health program.[7] For a first time offender (likely a Level 22 under the Guidelines), these amendments would add 2 levels, resulting in a sentence of about 51 months.

These are serious sentences, yet they pale in comparison to the terms of imprisonment given for drug or other serious federal felonies. And, in my experience, they provide an insufficient deterrence. A quick thought experiment highlights some of the reasons why the deterrence is insufficient. Assume for example, that only 1 in 20 health care fraud criminals are identified and prosecuted. (Likely, a far lower percentage are prosecuted.) Would an individual, otherwise willing to commit crime, be willing to risk a five percent chance of a 51 month federal term of imprisonment in order to make an easy $2 million (the figure most likely associated with a Level 22)? Few fraudsters think in such numerical terms, yet scholarship establishes that there is a basis to believe that the risk to reward ratio in these circumstances provides for insufficient deterrence.

Second, prosecutions are resource intensive. The Justice Department's prosecutions pay for themselves many times over in dollars recovered and fraud prevented. Nonetheless, they are expensive and drain prosecutorial and federal investigative resources. Courts and jails cost money too, and these expenses too often are ignored when calculating the cost of enforcement. Although Congress has appropriately increased

[6] See http://www.hhs.gov/news/press/2011pres/01/20110124a.html.
[7] See http://www.ussc.gov/Legal/Amendments/Reader-Friendly/20110119_RFP_Amendments.pdf at 54 - 77.

funding for prosecutions (a funding increase that is clearly justified), prosecutions are not the most cost effective means of reducing fraud.

Third, prosecutions rarely recover the full taxpayer loss. Fraudsters tend to spend the money they illegally gain, or in some circumstances, to transfer the money overseas and beyond the reach of U.S. authorities. Even the wealthiest fraudsters often appear to have few assets by the time they are prosecuted.

Prevention is thus the preferred approach.

III.

The Patient Protection and Affordable Care Act implements both enhanced prosecutorial funding and penalties, discussed *supra*, and enhanced oversight and screening measures, including licensure checks, background checks and site visits.[8] These are important new tools, and I was gratified to read that the HHS Secretary, on January 31, 2011, announced an implementing final rule that would create a more rigorous screening process for providers and suppliers enrolling in Medicare and Medicaid.[9]

Effective prevention, however, requires more than mere front-end screening. Effective prevention requires continuous and proactive efforts to identify and stop fraud as it happens. Businesses do this effectively. Most Americans have received calls from credit card companies asking whether a particular charge was theirs. Insurance companies do this effectively. Most insured Americans have received letters asking for additional information regarding a particular claim. Private business can serve as a model for Medicare anti-fraud efforts.

Among the most important changes that Medicare should consider, in my opinion, is assigning unique ID numbers to Medicare beneficiaries. Presently, a beneficiary's Medicare number is his or her social security number. This makes fraud simple, as anyone with a beneficiary's social security number can submit fraudulent claims in a beneficiary's name. This

[8] Congressional Research Service, *Medicare Provisions in PPACA* at 15.
[9] http://www.hhs.gov/news/press/2011pres/01/20110124a.html

also makes stopping fraud difficult, as Medicare cannot cancel a number that is being wrongfully used by a third party to commit fraud.

Business long ago understood the importance of unique ID numbers on credit cards. Imagine, for example, if American Express used a social security number instead of a unique number. Imagine further that when a cardholder called to identify fraudulent billings, American Express responded by stating that they could not change the card number, and that the card holder should continue to monitor all bills and provide American Express notice of future fraud. American Express would likely be out of business, yet that is the system used by Medicare today. Biometric IDs, in lieu of paper Medicare cards, would be an additional step to ensure that the beneficiary is actually the person on whose behalf a claim is filed.

Effective predictive modeling is another tool that can assist with fraud prevention. I understand that Congress, in the Small Business Jobs Act of 2010, directed the Secretary to use predictive analytic technology to identify improper claims and to prevent the payment of these claims. I encourage the Secretary to use this authority aggressively.

The use of brand name inhalation drugs in South Florida shows the potential effectiveness of predictive modeling techniques. As U.S. Attorney, I prosecuted many cases involving fraudulent billing of inhalation drugs. Often, the claims submitted to Medicare were for fraudulent prescriptions that were not needed by beneficiaries, and in fact were not even filled. An April 2009 HHS-OIG Report revealed the scope of the problem. South Florida accounts for 17% of total Medicare reimbursements for inhalation drugs, even though South Florida accounts for only two percent of beneficiaries.[10] A very high incidence of claims for particularly expensive drugs explained this discrepancy. With respect to Budesonide (a steroid inhalation drug used to treat respiratory disorder), for example, providers in Miami-Dade County billed Medicare $93.9 million ($48.9 million paid). The next highest billing county in the nation was Cook County (Chicago) with $2.7 million billed and $1.8 million paid.[11]

This report made several observations. First, 74.5% of South Florida claims for Budesonide exceeded the 90 day maximum coverage quantity.

[10] *See* Office of Inspector General, *Aberrant Claim Patters for Inhalation Drugs in South Florida.*
[11] *See* Office of Inspector General, *Questionable Billing for Brand-Name Inhalation Drugs in South Florida.*

Other inhalation drugs similarly exceeded the coverage maximum. Second, 62% of beneficiaries that were supposedly receiving Budesonide treatment had not seen a prescribing physician in at least 3 years. Third, 10 South Florida physicians were each listed as ordering more than $3.3 million in inhalation claims. In others words, each of these 10 physicians was responsible for more claims than all the physicians in Chicago combined. Such statistics represent "red flags" that would cause any private insurer to stop payment and begin an immediate investigation. Medicare should use predictive modeling and advanced data analysis to identify and investigate such obviously problematic claims pre-payment. Experience shows that pre-payment prevention is preferable to post payment pay-and-chase.

V.

Mr. Chairman, Ranking Member DeGette and distinguished Members of the Committee. I am gratified by your interest in this issue. As a prosecutor, I am prepared to answer questions regarding criminal matters. I note, as well, that during my term as U.S. Attorney, we brought several civil matters as well, including several average weighted price qui tams, and am prepared to address civil matters. As an American citizen, however, I hope that your focus remains on prevention. Thank you for your time and your leadership.

Mr. STEARNS. I thank the gentleman.
Mr. Smith, you are recognized for 5 minutes.

STATEMENT OF CRAIG H. SMITH

Mr. SMITH. Thank you, Chairman Stearns, Ranking Member DeGette and distinguished members of the committee. Thank you for inviting me to testify today.

I do want to say at the outset that I am here in my personal capacity and that my views are not necessarily the views of my law firm, Hogan Lovells, or any of the firm's clients.

I was asked to appear today to share with you my views of ways we can detect and prevent Medicare and Medicaid fraud and abuse based principally on my time serving as General Counsel of Florida's Medicaid program which as you have heard operates one of the Nation's largest Medicaid programs in this country.

Now, we have certainly heard this morning about the serious problems that have plagued the Medicare and Medicaid programs in terms of fraud, waste and abuse. The real concern is that the expenditures under both programs as shown by the chart that is on the screen before us today are set to significantly increase over the next 10 years, and this means that there is an even greater number of bad actors who will look for ways to defraud these programs.

In the past 10 to 12 years, Florida officials realized that the rapidly rising costs of the Medicaid program were threatening the State's long-term financial health, and they began focusing on prepayment fraud and abuse prevention. That is going to be a recurrent theme you are going to hear with me as you heard from Mr. Acosta and others today.

Florida officials also began administering the Medicaid program more like a private health insurer would do. Medicare, in contrast, has for the most part continued along the "pay and chase" approach, as we have heard, and that made Medicare an especially easier target for fraudsters, especially in south Florida, as compared to Medicaid.

The recent sting operation involving 700 federal and State law enforcement officials across the country to apprehend 111 suspected health care fraud criminals was impressive but it shows that at a rate of about seven law enforcement officials to every one person arrested, the postpayment is inefficient and highly expensive.

In the written remarks I submitted to the subcommittee, I offered several recommendations for preventing fraud and abuse in these programs. For purposes of my testimony today, I would like to highlight three of those that have been very effective in Florida's Medicaid program. Number one, the first recommendation is that the programs need to better control the provider enrollment process and provider network process. You heard Ms. King testify this morning from the GAO that the Medicare program is an "any willing provider" program. This is a problem because bad actors should not be able to gain access to the program. One of the most egregious stories involves a Miami man who served 14 years in prison for murder and then recently purchased a medical supply business for $18,000 and proceeded to bill the Medicare program for over

$500,000 in false claims. Now, he was eventually arrested but that was only after he was charged with murdering another person and dismembering that person. This is the type of person we should not have in any of these programs and a better provider screening and enrollment process would catch that.

The other thing I want to highlight about the provider network process, going back to this "any willing provider" approach in Medicare is despite some misconceptions, there is no constitutional right for anyone to be a Medicare or Medicaid provider. There are entitlements for the beneficiaries but there is not a constitutional right to be a provider in these programs. Florida understands that in its Medicaid program and has added "without cause" termination provisions in its Medicaid provider agreements. These allow the program to very quickly get bad actors out of the program or people we don't need in the program whereas the Medicare program has really struggled expelling bad actors.

The second recommendation I have for the subcommittee is that the programs should consider shifting away from fee-for-service reimbursement methodologies that are ripe and very susceptible for fraud and abuse and move toward other payment systems including managed care. Risk-based managed care companies have a financial incentive to detect and prevent provider fraud and abuse in these programs. They could be a helpful partner to the government in stopping provider fraud and abuse and saving taxpayer dollars.

My third recommendation is that the programs, as Mr. Acosta said, should use predictive modeling and other analytical technologies. Prepayment predictive modeling has been used to analyze health care claims for many years but in the past its effectiveness has been hampered by the inability to limit false positives and produce focused, actionable results. Well, those technologies have significantly improved and so today, just as the credit card industry is able to send its cardholders an instant text message or alert if there is a suspected fraud transaction, the Medicare and Medicaid program ought to be able to do that up front, and as Agent Perez testified this morning, it would be great if they could do that in real time as the claims are coming in. In 2008, Medicare paid home health agencies in south Florida over $550 million just to treat patients with diabetes, and that is more than was paid to every other locale in the entire country combined. Predictive modeling can stop that.

So we have heard that the fraud, waste and abuse program is very real and I applaud the committee for having this hearing today. If we focus on prepayment for prevention, that is the way to best protect taxpayer dollars, and I welcome any questions you might have. Thank you.

[The prepared statement of Mr. Smith follows:]

Testimony to House Energy and Commerce Committee Subcommittee on Oversight and Investigations

"Waste, Fraud and Abuse: A Continuing Treat To Medicare and Medicaid"

Chairman Cliff Stearns (R-FL) Ranking Member Diana DeGette (D-CO)

By
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Partner
Hogan Lovells US LLP

Presented
Wednesday, March 2, 2011

Chairman Stearns, Ranking Member DeGette and Members of the Committee, thank you for inviting me to testify today. My oral and written remarks reflect solely my own views and not necessarily those of my law firm (Hogan Lovells US LLP), any of our firm's clients, or the Florida Agency for Health Care Administration, the public agency for which I previously served.

I was asked to share my views on effective ways to detect and prevent Medicare and Medicaid fraud, waste and abuse based principally on my prior experience serving as the General Counsel of Florida's Agency for Health Care Administration, which operates one of the largest Medicaid programs in the nation. As you undoubtedly have read or heard, South Florida frequently has

been referred to as "Ground Zero" for health care fraud, and therefore enforcement authorities in Florida have a lot of experience dealing with this problem. The situation became so dire that the 2009 Florida Legislature took the virtually unprecedented step of designating Miami-Dade County "a healthcare fraud crisis area for purposes of implementing increased scrutiny of home health agencies, home medical equipment providers, healthcare clinics, and other healthcare providers" to prevent fraud, waste and abuse.[1]

It is important to bear in mind that the focus of my remarks is on true fraud and abuse, as opposed to overpayments that occur as a result of honest mistakes. The overwhelming majority of healthcare providers serving Medicare and Medicaid beneficiaries are dedicated, honest, and high-quality caregivers who not only want to play by the rules, but also want enforcement authorities to apprehend and sanction those who do not. The best measures strike the proper balance between preventing waste, fraud and abuse while avoiding being so draconian and burdensome that honest providers and suppliers choose not to participate, thereby creating an access problem for program beneficiaries.

Unfortunately, there are enough criminals focusing their efforts on Medicare and Medicaid to create a significant fraud and abuse problem for this nation. The media have reported that the mafia and other organized crime rings have been drawn to Medicare fraud and as a result, federal investigators have been threatened, witnesses have been found "riddled with bullets, and a woman was discovered dead in a pharmacy under investigation, her throat slit with a piece of broken toilet seat."[2] Perhaps even more alarming is the fact that some criminals have been willing to risk the health and safety of vulnerable Medicare and Medicaid beneficiaries in order

to reap their ill-gotten financial gains.[3] Every taxpayer dollar wasted through fraud, abuse or other improper payments is a dollar that could have been used to provide a needed health care item or service to an eligible beneficiary. Accordingly, the Committee is right to focus on efforts to prevent Medicare and Medicaid waste, fraud and abuse.

On February 17, 2011, federal authorities announced that 111 doctors, nurses, company owners, "patient recruiters" and other individuals nationwide were arrested and charged with conspiring to loot more than $225 million from Medicare.[4] The Department of Justice announced that more than 700 federal and state enforcement authorities across the country participated in this operation, and arrests were made in Baton Rouge, Brooklyn, Chicago, Dallas, Detroit, Houston, Los Angeles, Miami, and Tampa.[5] While certainly impressive in its size and scope, this enforcement operation highlights two very significant points: (1) many corrupt individuals continue to view Medicare and Medicaid fraud as a lucrative career path, and (2) at a rate of nearly seven enforcement agents needed to apprehend one criminal, the post-payment (i.e., "pay and chase") approach to fraud and abuse detection and prevention is extremely expensive and highly inefficient.

What, then, can be done? In my view, the best techniques are those that prevent improper payments in the first place. With a greater emphasis on pre-payment fraud and abuse prevention, we can decrease significantly the loss of taxpayer dollars and make healthcare fraud a much less desirable career path. The best pre-payment prevention tactics seem to flow from a few guiding principles: limit the number of participating providers to those that are necessary to ensure access to quality care; trust but verify the claims submitted by participating providers; and expel

those providers, owners or other persons in control of provider organizations—and beneficiaries—who commit fraud or participate in fraud schemes. To some extent, the Medicare and Medicaid programs already do this. But the tactics employed are not always the best, and even the best tactics are not always utilized consistently. From experience, I believe the following five tactics are proven and effective ways of significantly reducing Medicare and Medicaid fraud and abuse that should be considered:

1. Maintain Better Control of the Provider Network. Despite the misconceptions of some, there is no constitutional right to be a Medicare or Medicaid provider. To the contrary, provider participation is based on an agreement between the provider and the governmen Accordingly, Congress (with respect to Medicare and Medicaid) and state legislatures with respect to Medicaid) have the authority to limit their participating provider networks—much like commercial insurers and managed care organizations do—based not only on the criminal or professional disciplinary records of individuals but also on other legitimate factors, including without limitation the need (or lack thereof) for additional providers in the relevant geographic market and whether the provider is accredited or otherwise has a proven record of providing high-quality care.

   Further, the Florida Medicaid program has chosen to include a "without cause" termination provision, as well as "for cause" termination provisions, in its Medicaid provider agreements. The "without cause" termination provision gives the Florida Medicaid program the ability to control its provider network and to act swiftly without the need to undergo lengthy administrative challenges or other litigation while being forced to continue paying the provider. In contrast, the Medicare program has not

historically exercised as much control over the scope of its provider network, and it has experienced difficulty in ousting certain providers it no longer wishes to have in its network. For example, when the Office of Inspector General (OIG) of the United States Department of Health and Human Services conducted unannounced site visits of 1,581 durable medical equipment (DME) suppliers in South Florida, the OIG found that 491 suppliers failed to maintain a physical facility or were not open and staffed during the unannounced site visits, which led the Centers for Medicare and Medicaid Services (CMS) to revoke all 491 suppliers' Medicare billing privileges.[6] Incredibly, Medicare hearing officers later reinstated the billing privileges for 91 percent (222 of 243) of those suppliers. In 2008, the OIG reported that of the 222 DME suppliers that had their Medicare billing privileges reinstated, 111 subsequently had their privileges revoked again; 37 had their billing privileges inactivated; and the U.S. Attorney's Office indicted 18 individuals connected to 15 of the 222 reinstated suppliers.[7]

The waste of taxpayer dollars in this story is incredibly frustrating. First, the Medicare program failed to prevent individuals perpetrating fraud from obtaining Medicare DME supplier privileges and bilking the Medicare program. Second, long after the fraud was perpetrated and the taxpayer dollars were wasted, the suppliers' billing privileges were revoked. However, the OIG reported that the Medicare supplier appeals process was so flawed that 91 percent of the revoked suppliers were reinstated.[8] The Justice Department ultimately obtained criminal convictions for a small percentage of the individual criminals, but the real problem is the significant amount of taxpayer dollars (improper Medicare payments, OIG investigation costs, Medicare appeals process costs, and

criminal prosecution costs) that was wasted along the way. If the Medicare program had exercised more control over its participating provider network, a significant portion of this problem could have been prevented before any taxpayer dollars were wasted.

2. Significantly Improve the Provider and Supplier Enrollment Screening Process. The Florida legislature in recent years has made it more difficult for bad actors to become enrolled as providers in the Medicaid program. But more can be done at the federal level to keep bad actors out of the Medicare program and, through cooperation with the states, the Medicaid program as well. The GAO issued a report in July 2008 after it performed covert testing to determine weaknesses in the DME supplier enrollment process. According to the GAO:

> Investigators easily set up two fictitious DMEPOS [Durable Medical Equipment, Prosthetics, Orthotics and Supplies] companies using undercover names and bank accounts. GAO's fictitious companies were approved for Medicare billing privileges despite having no clients and no inventory. CMS initially denied GAO's applications in part because of this lack of inventory, but undercover GAO investigators fabricated contracts with nonexistent wholesale suppliers to convince CMS and its contractor, the National Supplier Clearinghouse (NSC), that the companies had access to DMEPOS items. . . . As a result of such simple methods of deception, both fictitious DMEPOS companies obtained Medicare billing numbers. . . . However, if real fraudsters had been in charge of the fictitious companies, they would have been clear to bill Medicare from the Virginia office for potentially millions of dollars worth of nonexistent supplies.[9]

Another outrageous but unfortunately true example of the Medicare program failing to protect beneficiaries and taxpayer dollars involves the case of Guillermo Denis Gonzalez. According to reports, Mr. Gonzalez served 14 years in prison for murdering a man with a silencer-equipped handgun.[10] After being released from prison, Mr. Gonzalez in 2006 purchased a Medicare-certified medical supply business for $18,000, and within one year he had submitted $586,953 in false claims for supplies never provided to patients.[11] Medicare reimbursed Mr. Gonzalez only $31,442 before he was tracked down and arrested—but he also was charged again with murder: "this one for allegedly stabbing and dismembering an acquaintance during a monetary dispute."[12] It goes without saying that the Medicare program, at a minimum, should be taking a closer look at individuals who have a violent criminal past before allowing them to have a controlling interest in a Medicare participating provider or supplier business.

Some county and city officials have adopted ordinances making it tougher for fraudsters to obtain occupational licenses and other local approvals that are required as part of the enrollment applications with Medicare and Medicaid. That type of local level enforcement, together with continuous communication and coordination among federal, state and local officials certainly is a good start, but more can be done. Medicare and many state Medicaid programs could make more effective use of the electronic data systems that have collected and organized otherwise disparate information pertaining the criminal records, professional licensure sanctions and discipline, and other concerning conduct to prevent bad actors from having any involvement in an approved Medicare or Medicaid provider or supplier.

3. Continue Shifting Reimbursement Methodologies Away from Fee-for-Service. One of the reasons that the overwhelming number of fraud and abuse incidents in Florida occurs in the Medicare program as opposed to Florida's Medicaid program is that Florida greatly has shifted away from the previous fee-for-service reimbursement system to capitated managed care systems. The capitated Medicaid managed care organizations (MCO) that contract with the Florida Medicaid program have a significant financial incentive to prevent fraud and abuse, and for the most part they are successful. Even if a Medicaid provider under contract with the MCO were to commit fraud, the MCO suffers the financial hit, not Florida's Medicaid program. Of course, a shift to managed care presents its own unique set of challenges from a fraud and abuse perspective, but there are significantly fewer MCOs than providers and suppliers for the government to monitor; further, many of the MCOs are operated either by publicly traded companies or by companies with sufficient access to capital to be held financially accountable should any improper payments occur.

4. Increase the Role of Physicians in Detecting and Preventing Fraud. Much of the intentional Medicare and Medicaid fraud and abuse is perpetrated by providers or suppliers—for example, pharmacies, DME suppliers, home health agencies—that first must rely on a physician's prescription in order to obtain government reimbursement. Although the Medicare and Medicaid programs have enhanced the requirements for such ancillary providers and suppliers to demonstrate that the items or services they furnish to beneficiaries are done so in connection with a valid physician's prescription, it remains too easy for bad actors to forge documents or otherwise fraudulently misrepresent that a

physician ordered the item or service. The GAO previously has recommended that CMS require that physicians receive a statement of Medicare home health services beneficiaries received based on the corresponding physicians' certification, which in turn the physicians would review to detect any potential misuse of their authorizations. This type of simple and relatively inexpensive approach potentially could detect and prevent significant fraud and abuse not only in home health but in other provider and supplier areas as well; however, the GAO reported last month that CMS has not implemented this recommendation.[13]

5. Use Predictive Modeling and Other Enhanced Technologies. Pre-payment predictive modeling has been used to analyze health care claims for some time, but historically its effectiveness has been hampered by an inability to limit false positives and produce focused, actionable results. In recent years, however, technology in this area has improved significantly. Just as the credit card industry is able contemporaneously to identify potentially fraudulent transactions and instantly alert cardholders through email and text message alerts, the Medicare and Medicaid programs should be able to use these technologies—with an appropriately prompt level of clinical confirmation—to detect and prevent fraudulent claims for reimbursement on a prepayment basis.

In conclusion, recent arrests across the nation for alleged Medicare fraud crimes underscore that our nation continues to face a significant problem that threatens taxpayer dollars and in some cases, the safety of program beneficiaries. Although criminal and administrative enforcement actions are an important part of the overall fight against Medicare and Medicaid fraud and abuse, the best way to prevent the waste of taxpayer dollars and to assure appropriate is available and

accessible for vulnerable populations is to detect and prevent fraud and abuse on a prepayment basis.

* * *

Thank you Chairman Stearns and Ranking Member DeGette for holding this hearing and focusing on these very important issues. Upon request, I very much would look forward to working with members of the Subcommittee to develop proactive, innovative, and most importantly, effective ways to eliminate waste, fraud and abuse from Medicare and Medicaid.

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[1] See CS/CS/CS Senate Bill (1986) (2009).

[2] E. Martinez, "Health Care Goodfellas: Mafia Turns to Medicare Fraud," (Oct. 7, 2009), http://www.cbsnews.com/8301-504083_162-5368496-504083.html (last accessed on Feb. 25, 2011).

[3] See, e.g., "Miami Clinic Owner Pleads Guilty to Fraud," South Florida Business Journal, January 8, 2009 (reporting that as part of a plea agreement, the owner of two Miami-Dade medical clinics admitted that his "clinic employees intentionally manipulated patients' blood samples so they would appear to need treatment, when in fact, they did not.").

[4] See Dept. of Justice Press Release, "Thirty-Two South Florida Residents Charged as Part of Nationwide Takedown by Medicare Fraud Strike Force Operations," (Feb. 17, 2011), http://miami.fbi.gov/dojpressrel/pressrel11/mm021711.htm (last accessed on Feb. 26, 2011).

[5] See http://www.washingtonpost.com/wp-dyn/content/article/2011/02/17/AR2011021703492_pf.html (last accessed on Feb. 26, 2011).

[6] Department of Health and Human Services, Office of the Inspector General, South Florida Durable Medical Equipment Suppliers: Results of Appeals, at ii (October 2008).

[7] Id. at ii, iii.

[8] The OIG found that "[t]here are no criteria for hearing officers regarding the types of evidence required to reinstate a supplier's billing privileges. For suppliers that request a hearing, hearing officers generally accept all documentation submitted as legitimate, unless they have reason to believe otherwise." Id. at 10.

[9] United States Government Accountability Office, *Medicare: Covert Testing Exposes Weaknesses in the Durable Medical Equipment Supplier Screening Process,* (July 2008), available at http://www.gao.gov/new.items/d08955.pdf (last visited May 20, 2009).

[10] C. Hiassen, "Medicare corruption gusher worsens,"Miami Herald (Jul. 17, 2010)

[11] Id.

[12] Id.

[13] GAO High-Risk Series, An Update, GAO-11-278 at 157 (Feb. 16, 2011).

Mr. STEARNS. Thank you.

Ms. Rosenbaum, you are welcome for 5 minutes your opening statement.

STATEMENT OF SARA ROSENBAUM

Ms. ROSENBAUM. Thank you, Mr. Chairman, Ranking Member DeGette, committee members.

You have heard so much information this morning that what I would like to focus my comments on has to do with a question that arose during the question-and-answer period that I think merits a closer look, which is the extent to which fraud and abuse are issues in private insurance, not only in private insurance but actually fraudulent and abusive activities by private insurers.

One of the great things, in my view, about the Medicare and Medicaid programs is that they are public programs and so we are able to know a lot as evidenced by the testimony this morning about the extent to which fraud, waste and abuse may be happening in the programs. They are extensively studied. There are many, many reports. You have made many incredibly important investments in curbing fraud, waste and abuse in Medicare and Medicaid and those investments have begun to yield real benefits. We know very little actually about fraud, waste and abuse in private insurance. We do know that since 1995, according to at least some studies, 90 percent of health insurers have begun to institute more significant antifraud efforts. Clearly, they have concluded that they are experiencing some of the very same problems in their payment systems that Medicare and Medicaid are experiencing in their payment systems.

I would note that one factor about the Medicare and Medicaid programs that may make them slightly more susceptible to fraud and waste and something that I think would be very hard to remedy, even were the entire Medicare and Medicaid system changed, is the nature of the beneficiaries. A lot of studies show that fraud generally is more concentrated in communities and among populations who are extremely poor, extremely disadvantaged and much more vulnerable to fraud. Whether they were given public insurance or a voucher to buy private insurance, in communities with high concentrations of poor and vulnerable populations, this is an issue and the investment of federal resources and State resources in protecting them against fraud is enormous.

I think there is something else that is worth mentioning, and that is when we see fraudulent behavior by the insurance industry itself, and there are actually three kinds of fraud behaviors that I think are worth thinking about as you contemplate further efforts to try and reduce and prevent fraud. The first of course is Medicare Advantage marketing abuses. They are extensively documented. A simple Google search of Medicare Advantage marketing abuses shows thousands of reports. One of the most interesting is a study in rural Georgia. A group of public health students, near and dear to my heart, since I am a professor of public health, took on as a summer project in an effort to try and uncover marketing abuses in rural Georgia by Medicare Advantage salesmen going door to door. I would note that one of the best Web sites on the problem and what can be done about it is found in the Texas Department

of Insurance, so this is something the State insurance departments are aware of.

A second kind of abuse is an abuse in which a health insurer negotiates deep, deep, deep provider discounts, fails to disclose those discounts among its network providers to enrollees who then instead of paying what they think is a 20 percent coinsurance rate are paying coinsurance rates that are in some cases actually even more than the fee that was paid to the provider. And a third type of abuse, one that was disclosed by Attorney General Cuomo, is the abuse that we saw in the Ingenix cases in which out-of-network-provider payment standards are manipulated, reduced and enrollees who thought they had out-of-network coverage are in fact gouged and made to pay very high balance bills.

Now, these issues, I think, are important to focus on as we move into a time when tax subsidies are flowing into the purchase of private insurance products and health insurance exchanges and other locations, and so my strongest recommendation to the committee would be to consider further steps to empower investigation of insurer fraudulent and abusive behavior. Thank you.

[The prepared statement of Ms. Rosenbaum follows:]

Testimony before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigation

Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid

Sara Rosenbaum, J.D.
Hirsh Professor and Chair
Department of Health Policy
George Washington University
School of Public Health and Health Services

March 2, 2011

Mr. Chairman and Members of the Subcommittee;

Thank you for this opportunity to testify before you today. As this Committee undertakes the important work of assuring the integrity of the nation's largest public health insurance programs, I believe that four points are essential to bear in mind:

First: Health care fraud (which must be distinguished from payment errors) is endemic to health insurance and health care generally, and is not confined to public health insurance programs. Indeed, the crucial difference between public and private health insurance in this regard is the transparency (given their public nature) that Medicare and Medicaid administration and oversight activities bring to the problem of preventing, detecting, and curbing fraud.

Second: Health care fraud occurs at all levels of the health care system, including health care financing as well as the provision of health care. Corrupt and fraudulent practices can occur not only at the health care delivery level but also in the context of the sale of health plans to public and private sponsors.

Third: The problem of fraud is generally not one that involves beneficiary conduct. Even when beneficiaries are involved, their activities are unwitting. Indeed, the biggest issue facing low income, disabled, and elderly beneficiaries is their heightened vulnerability to acts of fraud.

Fourth: Vigilant fraud prevention and oversight of publicly sponsored health insurance is essential, regardless of whether the market is Medicare, Medicaid, or state health insurance exchanges. In this regard, the Affordable Care Act contains vital tools for combating fraud in all three markets.

* * *

Overview

Adequate safeguards against health care fraud are essential to the proper functioning of any health care system. Despite strong evidence that fraud is system-wide and affects the cost of health care in both public and private insurance, national reporting systems on health care fraud fail to capture private sector fraud. As a result, current evidence on the scope of health care fraud fails to present the full magnitude of the problem because it tends to focus on fraud solely involving public health insurance.

Existing information on health care fraud also tends to conflate evidence of fraud with evidence of payment errors. While payment errors in public health insurance programs pose a serious problem, the tools for remedying errors differ significantly from those used to address fraud.

As with any very large enterprise, the U.S. healthcare industry is susceptible to fraud and abuse in private and public programs alike. Evidence drawn from fraud studies suggests that fraud generally tends to disproportionately target vulnerable populations, such as the poor and the elderly. Furthermore, public programs operate under strict reporting requirements, thereby creating a situation in which the most commonly available information concerns public programs such as Medicaid and Medicare. Fraud can be committed by individual consumers and patients, but the most serious health care fraud is not the result of small schemes. It flows instead from large-scale misconduct by major industry actors, including insurers, health care providers, and corporate suppliers. The vast majority of fraud prosecutions emanate from the health care industry itself; indeed, a feature of fraud prosecutions involving patients can be the exposure of criminal enterprises designed by corrupt health care providers who in turn induce patients into participating in fraudulent schemes.

In 2007, the U.S. spent nearly $2.3 trillion on health care; that year public and private insurers processed more than 4 billion health insurance claims.[1] The National Health Care Anti-Fraud Association (NHCAA) has estimated that conservatively, 3% of all health care spending—or $68 billion—is lost to health care fraud. Other estimates by government and law enforcement agencies place fraud-related losses as high as 10% of annual health care expenditures.[2] At this rate, losses to fraud—over $220 billion in 2007 alone—would be enough to generously support coverage for all uninsured Americans.

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[1] National Health Care Anti-Fraud Association. *The Problem of Health Care Fraud.* Consumer Alert. Available at: http://www.nhcaa.org/eweb/DynamicPage.aspx?webcode=anti_fraud_resource_centr&wpscode=TheProblemOfHCFraud. Accessed on October 15, 2009.

[2] *Id. See also* Federal Bureau of Investigation, (2008). *Financial Crimes Report to the Public, Fiscal Year 2007.* Available at: http://www.fbi.gov/publications/financial/fcs_report2007/financial_crime_2007.htm

Fraud schemes are not specific to any geographic area and are found throughout the entire country.[3] Certain types of fraudulent activities (e.g., stealing patient ID numbers and falsely billing for care) tend to be more common. There is also evidence that consumers are more susceptible to fraud if they are older and/or poor, thus health care fraud, much like mortgage fraud, would tend to be more common in poorer communities because of the greater vulnerability of their residents.[4]

Certain aspects of health care increase the risk of fraud. Patients' dependence on their health care providers may mean that unscrupulous providers can engage in activities that patients may not understand or to which they may acquiesce without a full appreciation of the consequences, such as having patients sign forms affirming that they in fact received care when services were never furnished. The sheer volume of insurance transactions, coupled with their complexity, serves to increase system vulnerability to fraud.[5]

Experts in the field of fraud suggest that health care fraud perpetrators consider their conduct to be a low-risk crime, with both public and private insurers offering easy targets. Insurers' payment operations are geared toward rapidly processing massive amounts of claims, with a focus on coding, not fraud.[6] Moreover, the commercial insurance industry itself is linked with fraud. Fraudulent conduct has been discovered in Medicare Advantage marketing practices.[7] Furthermore, a widely-publicized investigation by then-New York Attorney General Andrew Cuomo, found that the industry has (not for the first time) used the complex nature of its own business to commit fraud, in this case by systematically underpaying health insurance claims, thereby exposing patients (and providers) to sizable unreimbursed costs that should have been covered under their plan terms.[8]

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[3] Clarke M, . "The Control of Insurance Fraud: A Comparative View," *The British Journal of Criminology*, 30(1) (Winter 1990), pp.1-33.

[4] Lee J., Soberon-Ferrer H. Consumer vulnerability to fraud: influencing factors. *Journal of Consumer Affairs*. 1997;31(1):70-89.

[5] Managed Healthcare Executive, (2004). *Healthcare fraud and abuse remains a costly challenge*. October 1. Available at: http://managedhealthcareexecutive.modernmedicine.com/mhe/Analysis+&+Indications/Healthcare-fraud-and-abuse-remains--a-costly-chall/ArticleStandard/Article/detail/127451.

[6] *Id.*

[7] A Google search of "Medicare Advantage marketing fraud" returned more than 87,000 items. See, e.g., Texas Department of Insurance Medicare Advantage Resource Page, containing extensive information on marketing standards as well as tips for consumers when dealing with the sale of both Medicare Advantage and Medicare Part D plans, http://www.tdi.state.tx.us/consumer/hicap/medicareadvanta.html (Accessed February 28, 2011) *Public Health Students Help Fight Marketing Fraud in Washington County* http://archwaypartnership.uga.edu/news/washington-health-news/uga-college-of-public-health-students-help-fight-medicare-fraud-in-washington-county/ (Accessed February 28, 2011) [Detailing Medicare Advantage marketing fraud in a rural Georgia town]; *State Suspends Medicare Advantage Salesman for Fraudulent Tactics* http://www.healthleadersmedia.com/print/HEP-248179/State-Suspends-Medicare-Advantage-Salesman-for-Fraudulent-Tactics (Accessed February 28, 2010)

[8] See ¶16 of the *Assurance of Discontinuance Under Executive Law §63(15)* entered into between UnitedHealth Group and New York Attorney General at http://www.oag.state.ny.us/bureaus/health_care/HIT2/pdfs/United%20Health.pdf.

Even as they improve quality and efficiency, electronic data exchange and other technological advances can create further fraud exposure. This is because electronic claims transactions both increase the volume of claims, and allow large enterprises to use technology to engage in fraud while avoiding computerized fraud detection systems.[9]

Numerous government agencies have found that no segment of the health care delivery system is immune from fraud, and[10] government investigations have uncovered fraud in all industry sectors.[11] Indeed, the failure to systematically and routinely measure the scope of fraud has been reported to be a characteristic of the insurance industry worldwide.[12]

Because Medicare and Medicaid are government-sponsored programs, efforts to reduce fraud tend to be more publicly visible, particularly since the federal government now issues regular reports across all healthcare sectors. But since 1995, 90% of all private insurers have launched anti-fraud campaigns.[13]

How Widespread is Health Care Fraud and What Forms Does it Take?

Estimates are that 80% of health care fraud is committed by medical providers, 10% by consumers, and the balance by others, such as insurers themselves and their employees.[14] According to the National Health Care Anti-Fraud Association, the majority of healthcare fraud is committed by dishonest providers.[15] The most common types of provider fraud are:

- billing for services that were never rendered; billing for more expensive services or procedures than were actually provided or performed ("upcoding");
- performing medically unnecessary services solely for the purpose of generating insurance payments;
- misrepresenting non-covered treatments as medically necessary;
- falsifying a patient's diagnosis to justify tests, surgeries or other procedures that aren't medically necessary;

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[9] *Id.*
[10] Health Care Fraud, (1995). Hearing before the Senate Select Comm. On Aging." 104th Cong.,1st sess. (March 21) (prepared statement of FBI Director Louis J. Freeh).
[11] GAO, (1992). *Health Insurance: Vulnerable Payers Lose Billions to Fraud and Abuse.* (GAO-T-HRD-92-29). May 7. Available at http://archive.gao.gov/t2pbat6/146578.pdf
[12] Clarke, *supra* note 3.
[13] Cohen EL, Cesta TG. Evolution of nursing case management in a changing health care system. In: Cohen EL, Cesta TG, eds. *Nursing case management: from essentials to advonced practice applications, 4th Ed.* St. Louis, MO: Mosby; 2004:399.
[14] Coalition Against Insurance Fraud. *Go Figure: fraud data.* Available at www.insurancefraud.org/stats.htm. Accessed on October 19, 2009.
[15] National Healthcare Anti-Fraud Association, *supra* note 1.

- billing a patient more than the co-pay amount for services that were prepaid;
- accepting kickbacks for patient referrals;
- waiving patient co-pays or deductibles;
- over-billing the insurance carrier or benefit plan;[16] and
- unbundling, that is, the practice of submitting bills in a fragmented fashion in order to maximize the reimbursement for various tests or procedures that are required to be billed together at a reduced cost.[17]

The Table below presents an illustrative overview of the types of fraudulent conduct that have been pursued in court or reported in the press in recent years. These examples have been drawn from a systematic search of reported actions using legal search engines, as well as a review of legal journal and news articles on health care fraud-related actions.

The types of fraud recovery actions described in the Table might be pursued privately by health insurers as civil fraud cases, while, as noted, state Attorneys General or the United States Department of Justice also have wide-ranging powers under state and federal law to pursue health care fraud under numerous legal theories.

Table. Examples of Health Care Fraud across the Health Care Industry: Private Health Insurance, Medicare, and Medicaid.

Private Health Insurance **Medicare** **Medicaid**

ACCUSED COMPANY	INDUSTRY	TYPE OF FRAUD	RECOVERY (Year)
UnitedHealth[18]	Managed Care	Underpaid consumers (10%-28%) by manipulating database it used to pay customers for out-of-network services	$350 million (2008)

[16] *Id.*
[17] Federal Bureau of Investigations. Financial Crimes Report to the Public Fiscal Year 2007. Available at: http://www.fbi.gov/publications/financial/fcs_report2007/financial_crime_2007.htm#health.
[18] *American Medical Association v. United Healthcare Corp.*, 588 F.Supp.2d 432 (S.D.N.Y. 2008)

ACCUSED COMPANY	INDUSTRY	TYPE OF FRAUD	RECOVERY (Year)
McKesson[19]	Pharmaceutical	Fraudulently inflated prices of approximately 450 drugs charged to insurers and consumers	$350 million[20] (2009)
HealthNet[21]	Managed Care	ERISA and RICO violations by underpaying consumers in several states	$215 million (2006)
Cleveland Clinic[22]	Integrated Health Care System	Medical identity theft; false claims	Unknown
Tenet[23]	Hospital	False claims, Kickbacks	$900 million (2003)
TAP Pharmaceuticals[24]	Pharmaceutical	False claims, Conspiracy, kickbacks	$ 559.5 million (2001)
St. Barnabas Hospitals[25]	Hospital	False claims	$265 million (2006)
HCA[26]	Hospital	False claims, kickbacks	$631 million (2003)
HealthSouth[27]	Rehabilitative Medicine Services	False claims	$325 million (2004)

[19] *New England Carpenters Health Benefits Fund, et ol. v. First DataBank, Inc. and McKesson Corp.*, 244 F.R.D. 79 (D. Mass. August 27, 2007)

[20] This settlement is a preliminary court approved settlement entered on March 31, 2009 and the hearing on final approval is scheduled for July 23, 2009. Available at: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aVpLVzpsq1NI.

[21] *Wachtel v. Health Net; McCoy v. Health Net; and Scharfman v. Health Net,* 239 F.R.D. 81 (D. N.J. December 6, 2006).

[22] Ronrad W. *A New Ailment: Medical ID Theft,* N.Y. Times, June 13, 2009.

[23] *United States v. Tenet Healthcare Corp.*, C. A. No. 03-206 (C.D. Cal. Jan. 9, 2003).

[24] *United States ex rel. Durand v. TAP Pharmaceuticals,* CA No. 00-12618-GAO (filed May 1996 in the E.D. Pa., later transferred to D. Mass, settled Sept. 28, 2001).

[25] *United States ex rel. Monahan v. St. Barnabas Health Care System, Inc.*, C.A. No. 02-5702 (D.N.J. June 15, 2006).

[26] *United States, ex. rel. Alderson, v. Columbia/HCA Corporation,* Case No. 99-3290 (RCL), part of Case No. 01-MS-50 (RCL) (D. D.C. 2003).

[27] *United States ex rel. James Devage v. HealthSouth Corporation, et al.*, Civ. Action No. SA-98-CA-0372FB (W.D. Tex.).; *United States ex rel. Manning v. HealthSouth Corporation*, (W.D. Tex.); and *United States ex rel. Brupbacher & Assaciates and Michael C. Freeman v. Natianal Institutional Pharmacy Services, Inc.* (D. N. Mex.) (cases settled Dec. 30 2004).

ACCUSED COMPANY	INDUSTRY	TYPE OF FRAUD	RECOVERY (Year)
Ciena Healthcare Management, Inc.[28]	Nursing Home	False claims from inadequate care in nutrition and hydration, the assessment and evaluation of needs, care planning and nursing interventions, medication management, fall prevention, and pressure ulcer care, including the prevention and treatment of wounds.	$1.25 million[29] (2007)
United Health Group and other insurers[30]	Insurance	Fraud, misrepresentation, deception through use of company-owned Ingenix system to systematically undervalue its payment obligations for physician services in order to shift the cost of out-of-network coverage from the insurer to members and plan sponsors	Approximately $100 million (2009)
Amerigroup[31]	Insurance/Managed Care	False claims involving the treatment of pregnant women and other patients	$225 million (2007)
Merck[32]	Pharmaceutical	False claims, Kickbacks	$650 million (2006)
Serono Group[33] AstraZenica Pharmaceuticals[34] Wyeth[35]	Pharmaceutical	False claims, Kickbacks.	$567 million $160 million Qui tam action pending

[28] *U.S. ex rel. Denise Hubbard v. Ciena Healthcare Management, et al.*, CV-03-60175 (E.D. Mich.).
[29] This case involves fraud against both the Medicare and Medicaid programs.
[30] *The Americon Medical Associotian v. United Healthcare Corparation, et al.*, 2009 U.S. Dist. LEXIS 45610 (S.D.N.Y May 7, 2009).
[31] *United States, ex rel. Tyson, et al. v. Amerigroup Illinois, Inc., et al.*, 2007 WL 781729 (N.D.Ill. March 13, 2007).
[32] *Stote of Nevada ex rel. Steinke v. Merck & Campany, Inc.*, 2006 WL 1506901(D. Nev. May 31, 2006).
[33] *United States ex rel. Driscoll v. Serona Laboratories,, Inc.*, C.A. No. 00-11680 (D. Mass. August 17, 2000).
[34] *Alabama v AstraZenica*, [reported in] BNA, 18 Health Law Reporter (June 3, 2009).
[35] *United States. ex. Rel. Kieff v Wyeth*, C.A. No. 03-12366DPW (D. Mass); USDOJ intervention May 18, 2009, [reported in] BNA Health Law Reporter 18:687 (June 3, 2009).

ACCUSED COMPANY	INDUSTRY	TYPE OF FRAUD	RECOVERY (Year)
			(2000 & 2009)
Bristol-Meyers Squibb,[36] KV Pharmaceuticals, Roxane Laboratories, Abbott Laboratories, Aventis Pharmaceutical, Teva Pharmaceuticals, Schering Plow/Warrick, Forest Laboratories, Baxter International, Dey Pharmaceuticals, Bayer Pharmaceuticals	Pharmaceutical	False Claims	$123.75 million (2009)
Omnicare, Inc.[37]	Pharmaceutical	False claims by replacing brand-name with generic drugs or switching dosage strengths.	$49.5 million (2006)
Johns Hopkins Bayview Medical Center[38]	Hospital	False Claims Act (qui tam)21 by submitting false claims about patients conditions that had not been actually diagnosed or treated to Medicare, Medicaid, and TRICARE	$2.75 million (2009)

Source: legal analysis of reported cases (Summer, 2009).

Provider Fraud: The Most Common Fraud

This case review suggests that the most common type of fraud involves systematically overcharging both private and public insurers for the cost of items and services for which payment is specified either by contract or in law. Thus, for example, many pharmaceutical companies have been pursued by Medicaid programs for failing to adhere to federal prescription drug rebate requirements, with resulting major overcharges to state agencies. (Because the Centers for Medicare and Medicaid Services have not yet reported on cases of either improper payment or fraud under the Medicare Part D program,[39] it is not possible to

[36] *Alabama v Abbott Laboratories*, No. CV-05-219 (Ala. Cir., Ct. May 22, 2009), [reported in] BNA Health Law Reporter 18: 685 BNA) (June 3, 2009).
[37] *United States et al., ex rel. Bernard Lisitza v. Omnicare, Inc.*, 01 C 7433, and *United States et al., ex rel. David Kammerer v. Omnicare, Inc.*, 04 C 2074 (N.D. Il.).
[38] *United States, ex rel. Mayer v. Jahns Hopkins Bayview Medical Center*, D. Md., No. 1:07-cv-02011-WDQ, (settlement announced 6/30/09).
[39] GAO, Improper Payments: Progress Made, *supra* note 18.

know the magnitude of such practices under Medicare). Similarly, hospitals have been charged with systematically upcoding Medicare claims to falsely elevate the cost of care. These cases underscore the fact that these schemes depend on intimate knowledge of the health care business, the ability to manipulate complex data, and on having an insider status that comes with being a health care provider. [40] The insurer fraud cases discussed below appear to be similarly dependent on complex knowledge and insider status.

There are unusual instances in which patients themselves appear to be part of the scheme, but by far the more common scenario involves the buying of patient information without patient knowledge. For example, on January 24, 2007, in *United States v. Ferrer, Southern District of Florida*, a federal jury convicted a defendant in a case involving the theft and transfer of Medicare patient information from the Cleveland Clinic in Weston, Florida. The defendant purchased the patient information from a co-defendant, a former Cleveland Clinic employee, who pled guilty on January 12, 2007 and testified against the defendant at trial. The theft resulted in the submission of more than $7 million in fraudulent Medicare claims, with approximately $2.5 million paid to providers and suppliers.[41]

Private Health Insurer Fraud: An Important Added Dimension

Some of the most striking examples of fraud are those that involve the private health insurance industry itself. In these cases, the deception can involve either overstating the insurer's costs in paying claims, or systematically and deceptively under-valuing the amounts owed by the insurer to a health care provider under the terms of its contract. The result is to shift increased responsibility for the cost of care to the plan member and group sponsor, thereby avoiding the insurer's obligations under the terms of its contract:

- In 2009, UnitedHealth, a leading insurance company, paid $350 million to settle lawsuits brought by the American Medical Association and other physician groups for shortchanging consumers and physicians on medical services outside its preferred network.[42] Under the United insurers' health plans, members pay a higher premium for the right to use out-of-network doctors. In exchange, the insurers promise to cover up to 80% of either the doctor's full bill or of the "reasonable and customary" rate, depending upon which is cheaper. The Attorney General's investigation found that by distorting the "reasonable and customary" rate, the United insurers were able to keep their reimbursements artificially low and force patients to absorb a higher share of the costs. This intentional manipulation of provider payments resulted in an estimated 10% to 28% increase in members' direct financial exposure for the cost of out-of-network care.[43]

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[40] Dixon P. The World Privacy Forum Report (2006). *Medical Identity Theft: The Information Crime that Can Kill You*, Spring, p.36. Available at http://www.worldprivacyforum.org/pdf/wpf_medicalidtheft2006.pdf

[41] http://www.usdoj.gov/opa/pr/2007/April/07_opa_278.html.

[42] *The American Medical Association v. United Healthcare Corporation, et al.*, 2009 U.S. Dist. LEXIS 45610 (S.D.N.Y. May 7, 2009).

[43] *Id.*

- Humana and its affiliated private insurer was found to have intentionally misrepresented the size of its hospitals' bills to employer-sponsored plan members, thereby causing members to pay amounts for their own care that vastly exceeded the 20% copays they legally owed. Humana secretly negotiated deep discounts with its own member hospitals. As a result, plan members were actually paying the majority of the hospital bills they incurred rather than the 20% copay they were promised.[44]

Anti-Fraud Enforcement and Recovery Efforts; Expansion of Fraud Prevention Tools Under the Affordable Care Act

Anti-fraud efforts have met with considerable success. The legislative expansion of anti-fraud laws and their active enforcement over the years have led to an increase in convictions and recoveries, especially in the case of public health insurance programs, as well as to an increase in funding for implementation and creation of anti-fraud programs and task forces.

Among the most important provisions of the Affordable Care Act aimed at strengthening fraud prevention and oversight are the following:

- The Act gives the HHS Secretary the authority to establish more rigorous enrollment and screening processes, such as implementing different screening procedures for providers or suppliers based on the risk of fraud, waste and abuse. The Act also gives the Secretary enhanced provider oversight measures, such as pre-payment review following enrollment. In addition, the ACA authorizes the Secretary to expand disclosure requirements, such as requiring suppliers or providers to disclose any affiliation with a provider or supplier that has uncollected debt or that has been subject to a payment suspension, exclusion, or revocation or denial of its billing privileges under a federal health care program. The Secretary is also empowered to impose enrollment moratoriums and to create requirements for compliance programs, such as expanding surety bond requirements.

- The Act provides that only Medicare-enrolled physicians or eligible professionals can write a home health or durable medical equipment prescription or referral for a range of covered services, and authorizes the HHS Secretary to extend this requirement to other Medicare-covered items and services.

- The Act requires that agents, clearinghouses, or other alternate payees that submit claims on behalf of Medicaid health care providers register with state Medicaid agencies and the Secretary.

- The Act creates new civil monetary penalties (CMPs) for certain types of infractions, including falsifying information on provider enrollment. It also expands the Inspector

[44] *Humana Inc. v. Forsyth*, 525 U.S. 299 (1999); 119 S. Ct. 710; 142 L. Ed. 2d 753.

General's authority to exclude from participation in Federal health care programs any individual or entity that makes a false statement or misrepresentation on an enrollment application. In addition, the Act expressly authorizes the Secretary to suspend payments to providers if the Secretary determines, in consultation with OIG, that there is a credible allegation of fraud.

- The Act expands the Inspector General's authority to obtain any information necessary from individuals or entities to validate claims for payment under Medicare and Medicaid, and for evaluation of program economy, efficiency, or effectiveness.

- The Act expands the Recovery Audit Contractor (RAC) program to require states to contract with one or more RACs to help indentify overpayments and underpayments for Medicaid services.

- The Act requires that overpayments be reported and returned within the latter of 60 days after identification of overpayment or the date that a corresponding cost report is due. If an overpayment is retained after the 60-day deadline it is considered an obligation for purposes of the False Claims Act.

- The Act establishes a specific link between the anti-kickback statute and the False Claims Act by providing that a claim submitted for "items or services resulting in a violation" of the anti-kickback statute also constitutes a false or fraudulent claim under the False Claim Act.

- The Act clarifies that civil liability may be imposed on parties other than the party that actually submitted the claim (e.g., others involved in the underlying arrangement).

- The Act revises the anti-kickback statute by lowering the intent standard needed to prove a violation. The revisions provide that a violation can now be found even if no criminal intent to specifically violate the Act is proved and even if there is no proof of actual knowledge that the statute prohibited such conduct.

- The Act amends the federal sentencing guidelines by increasing the level of offense (i.e., the severity of the offense for sentencing purposes) for defendants convicted of federal health care offenses involving a government program, including conviction under the anti-kickback statute.

- The Act establishes a self-referral disclosure protocol for providers and suppliers to disclose actual or potential violations of the physician self-referral law.

- The Act amends the False Claims Act to give government more control over whether a *qui tam* complaint can be dismissed based on a "public disclosure" bar. The Act also lowers the public disclosure bar by providing that only public disclosures resulting from

a federal government source will bar a *qui tam* relator's claim, and allows a *qui tam* relator's allegations to be based on indirect or secondhand information, as long as the allegation adds to information already in the public domain.

- Finally, the Act provides $350 million over 10 years to fight fraud and abuse.

Mr. STEARNS. Thank you.

Now I will start with questions. I just note, Ms. Rosenbaum, that you had indicated your strong support of the public sector but the public sector, Mr. Spiegel could not tell us at all how much fraud is in the Medicare system but I can assure you that in the private sector they would go out of business if they couldn't answer that question on a continual basis. They would go out of business.

Mr. Smith has outlined three ways he thinks he can prevent waste, fraud and abuse, and of course, the predictive modeling using computers was one that you mentioned, Mr. Acosta, too. Do you agree or would you add to the three that Mr. Smith mentioned I thought were pretty incisive? Are there any other ones you would suggest?

Mr. ACOSTA. I would agree with that and I also would like to support a prior comment made about the importance of data access. One of the ways that we were able to bring as many cases as we did in south Florida is, we employed a nurse practitioner that had access to not real-time data because we couldn't obtain that but fairly recent data to look for billing spikes, and we did that ourselves rather than have the HHS OIG agents defer to CMS. That kind of integrated data is very important and I would like to support Mr. Perez's request.

Mr. STEARNS. Mr. Acosta, Mr. Smith, do you think we should have Medicare issue something besides a Social Security number so that they could actually, when a person calls and said listen, there is fraud in my billing here, instead of saying well, just keep alerting us, do you think we should change that? Because that was not one that either one of you suggested and that has been mentioned.

Mr. ACOSTA. Well, let me—you know, let me apologize because I thought I had referenced that. I think it is absolutely critical. As U.S. Attorney, we would get calls on a weekly basis from individuals saying we have two legs yet Medicare is paying for a prosthetic leg. Medicare says they can do nothing about it.

Mr. STEARNS. In the 60 Minutes exposé, there is a woman there who said for 6 years she called for artificial limbs, artificial legs, 6 years and Medicare did nothing.

Mr. ACOSTA. Mr. Chairman, how long would American Express be in business if——

Mr. STEARNS. That is what I mean.

Mr. ACOSTA [continuing]. When you would call and say I lost my card, they say we can't help you.

Mr. STEARNS. Are either one of you concerned that here we are expanding the Medicaid program by 20 million people under Obamacare and federal spending on Medicare and Medicaid will rise from $900 billion in 2010 to almost $2 trillion in 2019? Are you concerned that, you know, unless we implement these things that obviously we are going to have more fraud?

Mr. ACOSTA. From my perspective, I think, you know, it is critical that Medicare and Medicaid spend money to modernize their system. That involves unique IDs, not the Social Security number. That involves predictive modeling. Again, credit cards, if your spending patterns deviate at all, they call you up. Why can Medicare not do the same thing?

Mr. STEARNS. Are you familiar with what the Medicare prevention fraud in the ACA does? Are either one of you, Mr. Smith or Mr. Acosta? Do you think they would help pay for the cost of this Medicare expansion and Medicaid expansion just based upon what you see in the bill, or do you know what is in the bill?

Mr. SMITH. I certainly am aware of some of the provisions in the bill. I think one of the big concerns is we heard testimony today from the OIG saying that the current problem, current Medicaid and Medicaid fraud problem with the current population of beneficiaries we have exceeds, in his estimate, $7 billion. So even if you took the CBO's suggestions that the additional funding in the federal health reform legislation could help save $6 billion or $7 billion, that is barely enough to get close to the estimates of what the OIG says is the problem today.

Mr. STEARNS. Excellent point.

Mr. Acosta, anything you would like to add?

Mr. ACOSTA. Yes. I would add to that that most of the—I assume you are referring to the ACA, most of the ACA focuses on screening measures, licensure checks, background checks, site visits, which are important. But, you know, it is not enough. You need to actually review claims as they come in using predictive modeling. You need to have prepayment screening of claims.

Mr. SMITH. And Chairman, I would echo that and say that that is why I really think it is important as part of the Small Business Jobs Act, that is where the predictive modeling legislation was added. It is not part of the original federal health reform legislation and so I think that predictive modeling and analytical technology——

Mr. STEARNS. It is hard to believe. So the predictive modeling using computers is not part of the prevention program in Obamacare right now. Is that the way you understand it?

Mr. SMITH. Well, I think that the federal health reform legislation does ask and does provide for additional technologies to be used but the predictive modeling piece and the key piece for prepayment——

Mr. STEARNS. Is not there. I am just going to close by asking you quickly, in your opinion, do you think organized-crime involvement in Medicare and Medicaid has been, you know, pretty prevalent in south Florida? Have you seen a lot of organized-crime figures engage in Medicare fraud?

Mr. ACOSTA. I certainly have. If I could just clarify a small point. The Small Business Jobs Act of 2010 did have authorization for predictive modeling. HHS is looking at this. But the authorization was put in a separate provision.

With respect to organized crime, I think it is a clear method by which organized crime makes money. It is highly profitable. We are talking not millions but billions of dollars, $2 billion in actual charged criminal indictments. That is not all of it that is on the street. That is simply what we proved in court in south Florida alone. One of the frustrations is when you take down an operation, when you do these national stings, you get the nominee owners, the individuals that are being paid a little bit of money so their name can be used but they are not really the brains behind the operation

and so you need to go up the chain just like you do in organized crime.

Mr. STEARNS. All right. My time is expired. The gentlelady from Colorado.

Ms. DEGETTE. Thank you so much, Mr. Chairman.

So Mr. Acosta, what you are saying is, in fact Congress did pass the predictive modeling, the prepayment information, it was just not in the same bill as Affordable Care Act, correct?

Mr. ACOSTA. Correct. If memory serves, I believe Senator—I don't know in the House but the Senate side Senator LeMieux added it——

Ms. DEGETTE. So it is in the law now, we can do that, right?

Mr. ACOSTA. HHS has the authorization if they choose to use it.

Ms. DEGETTE. The authorization. Now, both of you, I really—well, actually I want to thank all three of you for your testimony because I thought it all gave good, different perspectives on how we can target waste, fraud and abuse, and as we said with the last panel, we are all interested in rooting out waste, fraud and abuse in every part of the system. One of the new tools that we talked about that is in the Affordable Care Act and that CMS and HHS are using is this preventative approach so that we are moving away from the "pay and chase" model to the model that emphasizes keeping criminals out of the system to begin with, and I would assume, Mr. Acosta, you would agree with that approach, correct?

Mr. ACOSTA. I entirely agree that the "pay and chase" is a bad approach and that we need to move——

Ms. DEGETTE. Thank you.

Mr. Smith, would you agree with that?

Mr. SMITH. Absolutely agree that is not a good approach.

Ms. DEGETTE. You don't think that the preventative approach is a good approach, or you don't think that "pay and chase" is a good approach?

Mr. SMITH. "Pay and chase" is a terrible——

Ms. DEGETTE. Is a bad approach?

Mr. SMITH. Yes.

Ms. DEGETTE. And what about you, Ms. Rosenbaum?

Ms. ROSENBAUM. I agree that prevention is the best approach.

Ms. DEGETTE. OK. Now, Mr. Smith, you testified, this was really quite shocking to me. You said that there is "any willing provider" rule which would allow even people with murder convictions to become a provider. Here is my question. Is that under statute or is that just under practice?

Mr. SMITH. Well, Ms. King testified this morning referring to the "any willing provider" rule.

Ms. DEGETTE. Yes.

Mr. SMITH. Basically, CMS's approach historically has been to let providers in unless they clearly had an issue in the screening process that CMS caught, and they weren't very good historically at catching those problems.

Ms. DEGETTE. OK. So do you think that there are some criteria that we could pass that would be absolute barriers, like, for example, a felony conviction where you would say, you know, you are just—because I know they use their discretion so they could reject somebody for having a felony conviction. Are you saying that it

would be a good idea for us to pass a bright line of certain criteria that they just couldn't consider somebody if they met those criteria?

Mr. SMITH. Certainly, and there are certain criteria in statute that are bright lines but I would say that it goes beyond just felony convictions. It also goes to operating your provider network like an insurance company would, which is, if we have too many home health agencies in Miami-Dade, regardless of whether we think a particular provider is fraudulent, we shouldn't let more agencies in the program.

Ms. DEGETTE. Yes, I agree with that, but that is not a bright line, that is sort of a discretionary criterion, and that is what I am asking you. So if any of you actually think that there are additional bright-line criteria we should put in statute, we would appreciate it if you would supplement your answers and provide that to us because I agree too, those kind of outrageous things should not happening and sometimes I do think they slip through the cracks.

Now, Mr. Acosta, you testified that one thing that would be really helpful would be using these unique IDs, not using Social Security numbers, correct?

Mr. ACOSTA. Correct.

Ms. DEGETTE. Mr. Smith, do you agree with that, that that would be a good way to improve the system and to decrease fraud?

Mr. SMITH. Yes.

Ms. DEGETTE. And Ms. Rosenbaum, do you agree with that too?

Ms. ROSENBAUM. I do.

Ms. DEGETTE. I think that is a really great idea, and I appreciate you bringing that up. I guess that is all the questions I have. I yield back.

Mr. STEARNS. I thank the gentlelady.

Mr. Murphy from Pennsylvania is recognized for 5 minutes.

Mr. MURPHY. Thank you, and thank you to the panel. This is very enlightening.

Mr. Acosta, you were talking about—a couple of you, you and Mr. Smith were talking about issues involved with prevention versus chasing. Do we have any estimate of the costs involved with bringing a Medicare or Medicaid fraud case to justice, from bringing charges to jail time?

Mr. ACOSTA. The costs, well, I can tell you that in my office, I received a line item of about $1 million that I supplemented with about $2.5 million of my own discretionary spending and so I spent about $3.5 million per year to prosecute cases. Now, that does not include the costs of the agents from HHS, OIG and FBI.

Mr. MURPHY. Do you have any kind of ratio to make decisions with regard to whether or not to prosecute a case, if it is less than $1 million or so and it is going to cost you $3.5 million?

Mr. ACOSTA. We have cutoffs all the time. We don't like to discuss them publicly but obviously you have more cases than you can imaginably prosecute and so you go after the larger cases, and that is a problem and every now and then we prosecuted some smaller fraudsters because you don't want to send the message that if you stay below a certain number you get away with it.

Mr. MURPHY. What would the cost of prevention be?

Mr. ACOSTA. The costs of prevention at the end of the day I think are much lower and much more effective. Computer programs that screen, for example, inhalation drugs in south Florida. Budesonide that I mentioned is just one but there are a number of other inhalation drugs. In one year, Miami-Dade County received $93 million in billings. The next highest billing city was Cook County with $2.7 million. That is a red flag if I have ever heard one. That is the kind of issue that should be caught by a computer program, and if you can prevent those $93 million and reduce it to the size of Chicago of $2.7 million, that is $90 million that you are preventing right there.

Mr. MURPHY. Thank you.

And Mr. Smith, on the "any willing provider" issue, how do you recommend we define providers? Obviously we don't want to stop people who want to start a business who are legitimate about it but should it involve such things as the ranking member was talking about something alone the lines of a criminal background check requirement or would these be people who would be at a higher level of screening for their first year or two? Would they be specifically licensed on some other level to begin with, probationary? Do you have any recommendations for that?

Mr. SMITH. There already exists in law provider screening requirements that would look at convictions, different things in the person's past, and CMS did just recently come out with a final rule regarding provider screening enrollment and what they have done is try to tier the risk areas so a provider seeking or a person seeking to open up a new Medicare-certified durable medical equipment company, a home health agency or perhaps an infusion clinic would be tiered in a higher risk category and perhaps be screened closer than someone hoping to open up a new hospital, and I think that is a wise idea.

Mr. MURPHY. Do you think with regard to these issues, and you are familiar with Florida. I don't know if you heard my questions before regarding the questions of the Cuban government's role in this. Would we have picked up on this? Is there any thought that we might pick up when another country is involved perhaps in organized crime?

Mr. SMITH. I think from a Medicaid perspective, part of it goes to not only to making sure you screen for certain bad actions in their past but also making sure you collect enough data to get the people on the applications so that you know what the links are, and one of the things that is beneficial about the predictive modeling is not just the claims analysis but also it has the capability of doing what I call social network analytics so you can basically see which people who have had an experience with a fraudulent enterprise have links to other people that you might not be aware of, might not have their names in any applications but they are operating in clusters and they sort of swarm around like bees with patients and defraud the program. That type of technology has great opportunities for us to save money.

Mr. MURPHY. Mr. Acosta?

Mr. ACOSTA. Congressman Murphy, thank you. If I could, you asked earlier, you referenced the list of OIG's most wanted, and based on public information, my understanding is that a majority

of these individuals are in fact in Cuba. One of the issues that we had early on was that defendants were being granted bond by federal judges on the theory that because they were Cuban nationals, they could not return to the island of Cuba, and in fact, they were then jumping bond and we had a law enforcement problem. Since then federal judges have actually stopped using the fact that someone may not flee to Cuba as a reason to grant bond because of reduced risk of flight because in fact the risk of flight to Cuba is high because Cuba welcomes the hard currency that they receive from these individuals.

Mr. MURPHY. Thank you very much.

Thank you, Mr. Chairman.

Mr. STEARNS. The gentleman from Virginia is recognized, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman. I do think that is very interesting. So even if the Cuban government is not involved, they still welcome these folks in because they are bringing cash with them?

Mr. ACOSTA. They certainly welcome them in. There is some evidence that shows that there is governmental involvement as well but that is based on University of Miami reports.

Mr. GRIFFITH. Interesting.

Professor Rosenbaum, I am just trying to do some things on background, and I would just ask you some questions, if I might. I see that you have listed some government contracts on your Truth in Testimony form, and I am just wondering if you could tell me what those contracts involve.

Ms. ROSENBAUM. Sure. I am a law professor at George Washington University and I am the chair of the department of health policy in the medical center, and I am the principal investigator on a contract that provides analytical support to what is now I guess the center—as opposed to DCIIO, it's CCIIO—to review and summarize the comments for the requests for comments and the notices of proposed rulemaking related to health insurance exchanges.

Mr. GRIFFITH. OK. And so they don't have somebody in-house that is doing that?

Ms. ROSENBAUM. Oh, I am sure they must review as well but we do policy support work for the department and have under federal contracts for administrations since 1991.

Mr. GRIFFITH. Yes, ma'am. And is there anything else you are working on with HHS or CMS in regard to the Affordable Care Act and the regulations?

Ms. ROSENBAUM. I have no other contracts in which I am the investigator, no.

Mr. GRIFFITH. All right. I appreciate that. Thank you, ma'am.

Mr. Chairman, I yield back my time.

Mr. STEARNS. The gentleman yields back his time. I think we are all through. I am getting ready to close. I did have one follow-up for Mr. Smith. I think you talked about, or maybe it was Mr. Acosta, about using a data access process to cut fraud. I wasn't quite sure, because Inspector General and GAO can go in and look at these statistics to get—who were you talking about when you talked about data access?

Mr. ACOSTA. One of the issues that we had early on in south Florida for the health care fraud initiative that later became the strike force, we set up a separate location where we collocated the agents and the prosecutors to focus on this. At the time I had requested that everyone have access to the billing data so they could look for aberrant billing patterns. We were finally able to obtain access to some data and that was restricted in appropriate ways at the time.

Mr. STEARNS. So you want law enforcement agents——

Mr. ACOSTA. Absolutely.

Mr. STEARNS [continuing]. And the prosecutors to have access to this data prior to—while they are investigating a crime?

Mr. ACOSTA. As the data comes in, give law enforcement access to the CMS systems, protect privacy but give us access to the billing patterns so we can catch the fraudsters in the act.

Mr. STEARNS. Would you need to go to a judge to get access? Or you just want to be able to have access to it?

Mr. ACOSTA. Correct. Yes.

Mr. STEARNS. So you could call up the Health and Human Services and say we have this particular case, this particular modeling, we want you to give us access so we can look at the data?

Mr. ACOSTA. Not call up HHS but actually put your investigators, have the—we have a facility in south Florida. We would like a computer terminal there where we can go and see billings for X drugs spiked by 300 percent in the past month for these five providers. Well, maybe that is a reason we should investigate those five providers.

Ms. DEGETTE. Will the gentleman yield?

Mr. STEARNS. Sure. I would be glad to yield.

Ms. DEGETTE. Is that a legal barrier that you couldn't get the data or is that an agency policy that prevented you from getting the data?

Mr. ACOSTA. In all candor, I am uncertain whether it is legal or bureaucratic. I just know it is a barrier.

Ms. DEGETTE. As I said to the previous panel, I think that is some data that would be really helpful in these investigations, so if you can try to figure that out and supplement your answer, then we can know what we need to do to help expedite that.

Thank you, Mr. Chairman.

Mr. STEARNS. Thank you. Let me conclude by—oh, good. We have another member came back. The gentleman from Texas, Dr. Burgess, is recognized.

Mr. BURGESS. Thank you, Mr. Chairman. Actually, I have been watching off the floor. I have a couple of constituents that are here. They are both serving their country, so I am making some time for them while this hearing is going on.

Let me just ask a question, Ms. Rosenbaum—well, actually I want to ask it of Mr. Smith, but Ms. Rosenbaum made an observation that we should empower more investigation of fraudulent insurance behavior but Mr. Smith, some of your testimony to me indicated that you didn't feel that it was necessary to have the same focus. Would you care to expound upon that?

Mr. SMITH. I think what I said came at maybe a slightly different angle. I said one of my recommendations was that the Medicare

and Medicaid programs continue to move away from a fee-for-service-based system and more toward other payment systems such as managed care and also to operate the programs more like a private insurer would. I guess it might be interesting historically to hear what percentage private insurers have suffered in fraud and abuse but that goes to their bottom line, it doesn't go to taxpayer dollars. What the Medicare and Medicaid programs need to do is focus on protecting taxpayer dollars, and if you engage an outside managed care company and you pay them risk-adjusted rates, they have the financial incentive to stop provider fraud and abuse. If they don't, it goes to their bottom line. It doesn't hurt taxpayer dollars any further.

Mr. BURGESS. Yes, and that is interesting that you say that. When was this? June of 2009, you may be familiar with an article published in the New Yorker by Atul Gawande, and it was important to me because he was talking about Texas. I should point out that Texas today is 175 years old. It was 175 years ago this morning that Texas declared its independence and became an independent country. But that is another story.

Part of Dr. Gawande's investigation in south Texas led him—I don't know that he came right out and said it but he certainly implied that overutilization and overbilling of Medicare was rampant within the medical community in McAllen. So it bothered me. I know a lot of doctors, or I know some of the doctors who work there. We work together on border issues. So I took a trip down to McAllen to see for myself on the ground if I could what was going on, and just the point you make, Mr. Smith, was you don't see the headlines in the paper that Aetna Life and Casualty has been defrauded of 15 wheelchairs. It just doesn't happen. It is always Medicare, Medicaid and SCHIP. It is always the public side.

Now, Ms. Rosenbaum has some issues with private insurers, and I get that, but here we are talking about the actual delivery of care, and appropriately, it never seems to happen on the private sector, or if it does, perhaps they just don't talk about it the same way we do on the public side. But is that your observation as well?

Mr. SMITH. It has certainly been a prevalent problem in both programs. There was a report recently that in 2009 the Medicare program paid for over 420 million claims for mental health in Florida alone, which was four times higher than the amount paid in Texas and 635 times higher than the amount paid in Michigan, and to paraphrase Carl Hiaasen, who is a funny novelist out of Florida, he said no matter what you think of Floridians, there is no way that we are four times crazier than Texans, respectfully, Congressman.

Mr. BURGESS. Well, exception taken. Yes, I was going to suggest perhaps they need to move to Texas and that would solve our problem.

Well, it is just—you know, it raises an important issue. What is happening on the private side that prevents the same problems that are happening on the public side. Now, we talked a little bit about the payment error rate, and Ms. Rosenbaum, some of that is truly just a coding error. Someone makes a mistake when someone comes in and they write the code down and that goes into the payment error rate, correct?

Ms. ROSENBAUM. Absolutely.

Mr. BURGESS. But that error rate of 9.4 percent or whatever was quoted to us, that is not predominantly made up of honest mistakes made in tallying up the office visit. Is that correct?

Ms. ROSENBAUM. I am not sure I understand the question.

Mr. BURGESS. Well——

Ms. ROSENBAUM. You mean of the total amount?

Mr. BURGESS. Yes. How much is just simple coding errors that——

Ms. ROSENBAUM. I couldn't begin to answer the question.

Mr. BURGESS. It wouldn't these two guys that were on the panel earlier with their handcuffs and nightsticks? Just wouldn't be involved, right? The amount of the error rate that is just attributable to simple coding errors is likely pretty small out of that 9.4 percent?

Ms. ROSENBAUM. I truly don't know. I have only seen the numbers aggregated.

Mr. BURGESS. Well, let us even say this. Let us say it is that high for just simple coding errors. Doesn't that tell us something about how we should be approaching this problem, that if nothing else, perhaps some education of doctors and nurses and clinics about how to code properly would be part of what should be happening at the level of CMS?

Ms. ROSENBAUM. Yes. I think anything and everything that can be done to clarify how to bill, how to file appropriate claims——

Mr. BURGESS. I don't have any data on it but I would suspect that number is very low, because as you recall in the late 1990s, there were all of these compliance audits, and I know because I was in practice at the time, and they were very, very severe, and yes, you could be put in jail, so I am just telling you I think that number of actual coding errors of that 9.4 percent is in fact very small because most physicians and nurses and nurse practitioners do not want to undergo that type of scrutiny because we all had to go through those compliance audits, we all had to put forward what we were doing in our offices to prevent that from happening.

Mr. Chairman, I see I have gone over my time. Thank you for the indulgence.

Mr. STEARNS. All right. I thank the gentleman.

By unanimous consent, we would like to put the document binder into the record, and I will conclude by saying the purpose of Oversight and Investigations is to ferret out details. You have done an excellent job, the second panel here. We are going to recommend to the Health Subcommittee on Energy and Commerce a lot of the recommendations that have come out of this hearing and that is the purpose, and hopefully they will have a hearing and follow up with legislation. I know the Democrats think a lot of these suggestions you have made are part of Obamacare but I am not sure they all are, and obviously changing the Social Security number so a person can have a Medicare ID number that you seem to all agree upon is something that we should look at quickly.

So with that, the——

Mr. BURGESS. Mr. Chairman, just a point of personal privilege, can I recognize two of my constituents?

Mr. STEARNS. Sure.

Mr. BURGESS. Captain Dambravo and Captain Dambravo were visiting me today during the hearing, and I want to thank them for their service to their country. If I can further relate, my relationship with Captain Dambravo goes back some time. Without violating HIPAA, I delivered him 27 years ago. Thank you both for being here with us today.

Mr. STEARNS. Thank you for being here.

And with that, the subcommittee is adjourned.

[Whereupon, at 1:02 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of the Honorable Fred Upton
Chairman, House Committee on Energy and Commerce
"Waste, Fraud and Abuse:
A Continuing Threat to Medicare and Medicaid."
March 2, 2011

Thank you, Chairman Stearns, for holding this hearing on the battle against waste, fraud, and abuse in our Medicare and Medicaid systems. This perpetually recurring problem costs taxpayers tens of billions of dollars every year.

Along with eliminating burdensome government mandates and promoting job growth, I pledged in our Committee Oversight Plan to cut government spending through the elimination of waste, fraud, and abuse. This is a great place to start.

$60 billion a year is lost to Medicare fraud. We are not even sure about the amount lost to fraud in the Medicaid system—the HHS Deputy Inspector General for Evaluation and Inspections wrote that CMS does not adequately capture this data. We can't accurately estimate the extent of these problems in Medicaid, yet we are spending $674 billion over the next 10 years to expand the program. The Administration should end the rampant fraud in the system before vastly expanding it.

Now it must be noted that enforcement efforts have increased and those involved, including our witnesses, should be applauded. Last year, a record $4 billion was recovered from fraudulent providers and suppliers and, just this month, 111 defendants were arrested and charged with various schemes to defraud the government of more than $240 million. Yet, we still have a long way to go.

Democrats will inevitably say that since we voted to repeal PPACA, we must be against the new tools and authorities given to HHS and CMS. I would counter that

the elimination of the fraudulent practices discussed today will actually be a pillar of our replacement efforts as opposed to the tangential treatment it received in ObamaCare.

We must focus on detecting and preventing fraud before the check is out the door and the criminal has moved on. Fraudulent practices are increasingly sophisticated and we need to catch up. This January, HHS announced that it has new systems in place to enhance the screening processes for providers and suppliers and I look forward to hearing more about these efforts.

I hope the Administration will learn what is required to eliminate the fraud in the system and not just put a dent in it.

Thank you, Mr. Chairman. I yield back the balance of my time.

Opening Statement of the Honorable Cory Gardner

"Waste, Fraud, and Abuse: A Continuing Threat to Medicare and Medicaid"

March 2, 2011

Mr. Chairman, combating Medicaid and Medicare fraud is draining resources in states throughout the country. In the State of Colorado, the Department of Regulatory Agency has a specific sector devoted to combating waste, fraud and abuse within Medicaid and Medicare. In fact, just this past October, the Colorado Senior Medicare Patrol was awarded a $100,000 grant to educate seniors and other Medicaid and Medicare beneficiaries on how to prevent fraud. Colorado has over 600,000 Medicare enrollees and over 526,000 enrolled in Medicaid. Specifically, Colorado's Medicaid program pays out nearly $4 billion every year. Under the Affordable Care Act there will be an expansion of these entitlement programs. With this expansion there will certainly be more waste, fraud and abuse at the expense of taxpayers.

Throughout this hearing, my colleagues and I will reference the Government Accountability Office's study that classifies Medicare and Medicaid as "high risk" programs. Medicare has been classified as a "high risk" program since 1990. Yet, throughout the last 20 years, the departments throughout CMS devoted to ending this cycle of abuse in health care have failed to deliver results. President Obama has outlined that the Affordable Care Act will save money throughout our health care system by combating waste, fraud, and abuse in Medicare and Medicaid. However, with the

expansion of these entitlements, won't this problem only become worse? Evidence shows that CMS has been ineffective, and yet CMS will have to monitor even more abuses when the eligible Medicaid population expands to over 20 million people by 2014. If we are truly going to save money within our health care system, we need to examine ways to make CMS more effective in targeting fraud.

In 2009, Colorado was forced to institute a provider fee in order to keep Medicaid afloat and in order not to sacrifice coverage for those who need it. This provider fee was also implemented for a state-wide Medicaid expansion program. As a result, Colorado will see a rise in claims of Medicaid fraud. Is the federal government willing to assist states in combating Medicare and Medicaid fraud? My fear is that with rising entitlements enrollees, the bill for the abuses in the system will fall directly on state budgets. I look forward to the witnesses addressing these issues.

I thank the witnesses for being here, and I yield back the balance of my time.

Statement from Representative John D. Dingell
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
"Waste, Fraud, and Abuse: A Continuing Threat to Medicare and Medicaid."
March 2, 2011

Thank you, Mr. Chairman.

This Committee has a long, proud history of oversight and investigations into waste, fraud and abuse in all sectors of our government. Some of these investigations have turned up improper contracts or wasteful government purchases, others local con artists trying to rob the neediest populations of their assistance. Regardless, all have proven that we must continue to dedicate the personnel and financial resources necessary to crack down on waste, fraud and abuse, while also preventing and detecting these practices before they happen.

The Affordable Care Act included a number of anti-fraud provisions that are helping CMS today to increase their efforts to crack down on fraud and also provide the appropriate tools to prevent fraud before it occurs. Some of these provisions include:

- New enrollment requirements that will help CMS to identify and eliminate fraudulent providers prior to any payment from Medicare and Medicaid,
- Stronger penalties for fraudulent providers,
- Requirements for providers to establish plans on how they will prevent fraud,
- Increased funding for fighting Medicare and Medicaid fraud, and
- Enhanced data sharing that allows CMS, DOJ, states and other federal health care programs to share information.

The Obama Administration has acted swiftly to implement these provisions, issuing final rules on home health and hospice referrals in November 2010 and in provider and supplier screening requirements, enrollment moratoria and payment suspension in January 2011.

The use of these new tools will help CMS to continue to fight back against criminals who are raiding two of our most important health care programs. This is critical to protecting the services American seniors and families rely on, but also to reducing the deficit. Since 1997 the Health Care Fraud and Abuse Control Program has recovered and returned $18 billion to the treasury. According to HHS and DOJ, for every dollar spend on Medicare and Medicaid fraud enforcement spent since that time, $4.90 has been recovered and returned to taxpayers.

I was fortunate enough to join the Detroit Strike Force Team this past summer for a ride-along to witness first hand the good work the strike force teams are doing to identify and stop fraud in so-called health care fraud hotspots. Because of the strike force's efforts in Detroit, more than 40 people have been convicted, 90 others have been indicted and courts have ordered criminals to repay over $23 million to Medicare. As the first Member of Congress to ever join any unit of the Medicare Fraud Strike Force for a ride-along, this visit reinforced the need to protect the poor, the elderly and the sick from crooked criminals who have no shame in stealing Medicare from those in need.

I look forward to hearing from our witnesses today and hope to learn more about what Congress can do to crack down on waste, fraud and abuse before it occurs.

John Spiegel
Additional Written Questions for the Record
Energy & Commerce O&I Subcommittee
"Waste, Fraud and Abuse: A Continuing Threat to Medicare and Medicaid"

March 2, 2011

The Honorable Cliff Stearns

1. **Several of our law enforcement witnesses testified about the importance of having access to real-time claims data and provider profiles. Why don't they have access to this data now?**

Answer: CMS is committed to sharing all available data with our law enforcement partners. The Affordable Care Act increases data sharing between Federal entities to monitor and assess high risk program areas and better identify patterns of improper payments and potential sources of fraud. CMS is expanding its Integrated Data Repository (IDR) which is currently populated with five years of historical Part A, Part B, and Part D paid claims, to include near real time pre-payment stage claims data; this additional data will provide the opportunity to analyze previously undetected indicators of aberrant activity throughout the claims processing cycle. CMS intends to develop shared Medicare and Medicaid data models and is pursuing data sharing and matching agreements with the Department of Veterans Affairs, the Department of Defense, the Social Security Administration, and the Indian Health Service to identify potential fraud, waste, and abuse throughout Federal health care programs.

CMS has made important strides in making data available more quickly and efficiently to our law enforcement partners. We have been working to give access to data in the interim; OIG and DOJ currently have access to data through the Next Generation Desktop and through One PI business intelligence tools.

2. **Is the lack of access a problem that can be fixed at an administrative level or is there a statutory and/or regulatory barrier?**

Answer: We are working to increase our data sharing with law enforcement partners by implementing the new authorities granted in the Affordable Care Act. The Affordable Care Act increases data sharing between Federal entities to monitor and assess high risk program areas and better identify patterns of improper payments and potential sources of fraud and provides the HHS Office of Inspector General and the Attorney General access to claims and payment databases related to Medicare, Medicaid, and CHIP for the purpose of conducting law enforcement and oversight activities, consistent with applicable information, privacy, security, and disclosure laws.

3. **Which city/county in the United States has the most Medicare-certified home health agencies per Medicare beneficiary? What is that ratio? What is the ratio of the next closest city/county?**

Answer: Data indicates that access to home health services is adequate for Medicare beneficiaries. According to MedPAC's March 2011 Report, 99 percent of Medicare beneficiaries live in a zip code where a Medicare Home Health Agency (HHA) operates, and 98 percent live in a zip code with two or more agencies. Further, MedPAC reports that HHAs have record levels of participation in Medicare, with the number of HHAs rising faster than the growth in number of beneficiaries.

Based on 2009 data, Canovanas County, Puerto Rico has the highest ratio of enrolled Medicare-certified HHAs per Medicare beneficiary. Canovanas County has only one HHA and the county has 29 Medicare beneficiaries for a ratio of 3.45%. Greeley County, Kansas has the next highest ratio of Medicare-certified HHAs per Medicare beneficiary, with one HHA and 277 Medicare beneficiaries (a ratio of 0.36%). As further context, the nationwide ratio of Medicare-certified HHAs per Medicare beneficiary is 0.02%, and the county with the largest number of HHA providers, Miami-Dade County, Florida has a ratio of 0.17% with 608 HHAs serving 360,679 Medicare beneficiaries.

We would be happy to discuss this issue with you further to better understand your underlying concerns.

4. **Has CMS implemented GAO's recommendation that Medicare provide each ordering physician with a monthly summary of items and services for which his or her name and physician identifier has been used to justify billing Medicare? If no, why not?**

Answer: GAO recommended in April 2007 that CMS identify physicians with inefficient practice patterns. The Medicare High Risk report noted that CMS has begun to provide feedback to physicians but that feedback could be enhanced. MIPPA 2008 required CMS to establish a confidential feedback mechanism to physicians, and under Section 3003, the ACA has expanded this program. GAO estimated that these program enhancements could potentially save Medicare $336 billion.

5. **Has CMS considered using unique Medicare numbers rather than Social Security numbers as Medicare beneficiary identifiers? If CMS has considered this and rejected it, why?**

Answer: CMS has considered using unique Medicare numbers and has determined that there are considerable costs associated with changing the Medicare beneficiary identifier, not only for CMS but also for our public and private sector partners. The SSN identifier in the Health Insurance Claim Number (HICN) is the basis of eligibility for Medicare, and is integrated in more than 50 CMS systems, as well as communications with our partners in the Social Security Administration, state Medicaid departments, private Medicare health and drug plans, and over 2 million health care providers and suppliers. The risks of disruptions in beneficiaries' access to care are considerable.

I want to emphasize, however, that CMS shares your concerns about the importance of safeguarding and protecting Medicare beneficiaries from identity theft. We have taken many important steps regarding the display of SSNs or HICNs on Medicare cards. We removed the SSN from various notices and publications sent to beneficiaries, and from beneficiary reimbursement checks. We prohibited Part C and D Plans from using the SSN or HICN as a beneficiary identifier. We have also taken action to educate beneficiaries about steps they should take to prevent identity theft and fraud, including posting information on the CMS website, and adding information to the "Medicare & You" Handbook.

6. **What is the total amount of Medicare overpayments initially identified by the contingency fee based Medicare Recovery Audit Contractors to date? How much of that amount has been recovered by CMS? How much has been successfully challenged by the providers that were the targets of those audits?**

Answer: Recovery Auditors have proven successful at identifying and correcting Medicare Fee-For-Service (FFS) improper payments. In the demonstration project, Recovery Auditors corrected $1.03 billion in improper payments, including approximately $990 million in overpayments collected. Since the inception of the permanent Medicare FFS Recovery Audit program, as of March 1, 2011, the contractors have corrected a total of $261.5 million in improper payments, including $43.6 million in underpayments corrected and $217.9 million in overpayments collected.

CMS actively monitors the national Recovery Audit program and makes necessary adjustments to maintain a balance between provider burden (both financial and administrative) and increasing recoveries. CMS is committed to working with the Recovery Auditors, the provider community, and others to continuously improve the program and refine ongoing operations.

Regarding the appeals process, CMS has received successful feedback. During the Recovery Audit demonstration 8.2% of overpayment determinations were both challenged and overturned on appeal. Preliminary experience from the national program indicates the percentage of claims appealed may be less.

The Honorable Joe Barton

1. **How often does CMS conduct internal audits to determine whether people working for CMS or other enforcement agencies are participating in scams?**

Answer: CMS' Office of Acquisition and Grants Management (OAGM) adheres to all internal control requirements in the Federal Acquisition Regulation (FAR) in managing CMS funds and administering CMS grants and contracts. Contractors are required to follow strict reporting rules for any alleged improprieties. CMS acquisition personnel are subject to procurement integrity rules and undergo extensive training to ensure our employees maintain the public trust. CMS Contracting Officers are also required to annually file financial disclosure forms that are reviewed for potential conflicts of interest.

The CMS Ethics Office, as required by Executive Order, develops an Annual Training Plan for CMS employees at the beginning of each calendar year. These plans are designed to address internal ethics issues, such as impropriety or conflicts of interest. Training conducted under the Plan is periodically targeted to specific responsibilities, such as contracting and procurement or the administration of Federal funds, benefits, and grants. In addition, managers and other CMS leadership positions are required to undergo internal control trainings on a regular basis. All CMS employees are required to take annual ethics training, which is constantly and consistently performed through the calendar year on a scheduled basis throughout CMS' Baltimore headquarters and the Washington D.C. and Regional Offices.

Additionally, in the event that an employee was suspected of misconduct, he/she would be referred to the HHS Office of the Inspector General (OIG). Managers are required to inform the Chief Operating Officer when it is known to them that a matter has been referred to the OIG. We do not have any reason to believe that CMS or other enforcement agency employees pose an increased risk of fraud to the federal health care programs that would require increased screening and monitoring over and above our current internal training.

2. **What rate of fraudulent activity do these internal audits reveal?**

Answer: There is nothing to suggest that CMS or other enforcement agency employees pose an increased risk of fraud to the federal health care programs that would require an increased screening and monitoring over and above our current internal training.

We believe that our existing and newly implemented program integrity controls, including risk-based screening of providers and suppliers, identifies fraudulent schemes, regardless of the nature of the relationship of the scammer to CMS. Should an employee be found to have participated or aided in a fraudulent scheme, the individual would be prosecuted to the full extent of the law.

<u>The Honorable Lee Terry</u>

1. **How much did CMS spend in 2008, 2009, and 2010 on fraud prevention?**

Answer: The Medicare Integrity Program has been the primary funding source for CMS' efforts to prevent and detect fraud, waste, and abuse. CMS does not assign costs specifically to fraud prevention or detection. In the fiscal years for which information has been requested, "Prepay Medical Review" and "Provider Outreach and Education" could be considered to be the primary means of preventing fraud. However, the intent of both programs is to ensure that payments are made properly. This is not the same as preventing fraud.

In addition to the activities listed above, in FY 2010 CMS embarked on an $8 million fraud prevention campaign. These funds educated beneficiaries through fraud summits, public service announcements, and other activities to help beneficiaries better understand their Medicare Summary Notices, the services being paid, and potential fraud schemes. CMS also began to develop initial activities for implementing innovative analytic techniques. This included the

launch of geospatial technology that maps "hot spots" for beneficiary complaints of fraud; implementation of a "rapid response" process for the quick development of new leads based on proactive analysis and enhancing a central database of compromised beneficiary and provider identification numbers and using the database to screen providers, trigger administrative actions, and support law enforcement actions.

2. **How much did CMS spend in 2008, 2009, and 2010 on fraud detection after claims were already paid?**

Answer: On the detection side of the equation, programs such as "Audit" also have a primary purpose of ensuring that proper payments are made, not necessarily to detect fraud. "Benefit Integrity" on the other hand, focuses on fraud detection. However, even here, there are sentinel effects of the conducted activities that result in fraud prevention.

Fraud prevention and detection falls within a continuum of activities and it is difficult to provide an accurate allocation of costs between them. This chart below gives a break out of Medicare Integrity Program activities and cost.

Medicare Integrity Program

(Dollars in Millions)

	2008	2009	2010
Audit	169.6	124.9	89.1
Medicare Secondary Payer	117.5	105.8	105.3
Medical Review	121.7	62.1	48.4
Provider Outreach and Education	37.1	22.4	20.9
Benefit Integrity	103.8	121.8	135.8
Provider Enrollment	23.5	19.7	17
CFO/comprehensive Error Rate Testing	12.0	15.9	25.3
Managed Care Integrity Program	5.5	5.2	
Plan Bid Review and Audit	12.7	32.3	
SAS 70 Internal Control Reviews	0.0	2.0	1.5
MACs/DMACs	56.6	171.6	206.7
DRA Specialty Hospital Study	0.1	0.0	0.0
Drug Benefit	27.2	7.1	
IT Projects	30.2	36.8	47.4
Medi-Medi	36.0	48.0	60.0
Mandatory Totals	753.5	775.6	757.4
Fraud Response Initiative		53.9	51.2
Part C & D Oversight		36.6	101.4
Other PI Activities		8.2	14.5
IT Projects		47.6	19.7
Discretionary Totals		146.3	186.8

Grand Totals	753.5	921.9	944.2

3. **What percentage of CMS' total budget do these figures represent?**

Answer: For 2010, the total CMS Medicare expenditures totaled $525.6 billion; the Medicare Integrity spending totaled $944 million, or approximately 0.2% of the total CMS budget.

4. **How much does the private sector spend to prevent and detect fraud?**

Answer: CMS does not have access to information on private industry spending on fraud prevention and detection efforts.

The Honorable Phil Gingrey

1. **How much waste, fraud, and abuse is in the private sector versus Medicare and Medicaid?**

Answer: CMS is not an authority on waste, fraud, or abuse specific to the private sector and does not have access to this information. However, we know that private sector health care programs are vulnerable to some of the same fraud schemes as Medicare and Medicaid. The Department of Health and Human Services Office of the Inspector General has worked joint cases with private sector health plans in which perpetrators were defrauding both our public programs and private sector plans. Because public and private sectors face common challenges in fighting fraud and keeping fraudulent providers at bay, through our fraud summits and other provider outreach activities, we are working together and building partnerships with the private sector to develop common solutions to this problem.

The Honorable Steve Scalise

1. **What do you estimate is the cost of defensive medicine to the Medicare and Medicaid system?**

Answer: While many health care practitioners would freely admit that defensive medicine occurs in public and private health care systems, there is no recognized way to define "defensive medicine" practices and to quantify these costs to the American health care system. Nevertheless, we should scale back the excessive defensive medicine that reinforces our current system, and shift to a system where we are providing better care – rather than simply more treatment.

The President has expressed his support for reforms to our medical liability system to ensure that it improves the quality of care and patient safety, fairly and expeditiously compensates patients who are harmed by medical negligence, reduces liability premiums and the costs associated with defensive medicine, and weeds out frivolous lawsuits.

To that end, before the passage of the Affordable Care Act, the Administration established a $25 million initiative ($23 million in grants; $2 million for an evaluation) to support efforts by states and health systems to implement and evaluate patient safety and medical liability reforms. This is the most ambitious effort to date by HHS and the largest government investment connecting the medical liability system to quality and safety rather than just negligence and punishment.

Building on that effort, the President's FY 2012 Budget includes $250 million in grants to states to reform their medical liability laws. The Department of Justice, in consultation with the HHS, will administer this program. The goal of these reforms is to fairly compensate patients who are harmed, reduce providers' insurance premiums, weed out frivolous lawsuits, improve health care quality and patient safety, and reduce "defensive medicine" costs. States could propose reforms to their medical malpractice system through various approaches, such as:

- Health courts
- Safe harbors
- Early disclosure and offer
- Other legal reforms (these reforms could include some that were proposed by the President's National Commission on Fiscal Responsibility and Reform such as modifying the "collateral source" rule or replacing joint-and-several liability with a fair share rule).

In addition, the Affordable Care Act authorized demonstration grants to state to develop, implement, and evaluate alternatives to current medical tort litigation.

The Honorable Sue Wilkins Myrick

1. **Do states have to report fraud estimates to CMS?**

Answer: While States are not required to report fraud estimates to the Centers for Medicare & Medicaid Services (CMS), States are required to participate and report on activities to prevent or address fraud in the Medicaid program. Such activities include State Program Integrity Reviews, State Program Integrity Assessments, Audit Medicaid Integrity Contractors, and State Medicaid Fraud Control Units. See below for more detail on each of these activities.

State Program Integrity Reviews. Triennial State program integrity reviews play a critical role in how CMS provides effective support and assistance to States in their efforts to combat provider fraud and abuse. The reviews are comprehensive, including examinations of provider enrollment, provider disclosures, program integrity, managed care and the State's relationships with the Medicaid Fraud Control Unit (MFCU). See the CMS website at http://www.cms.gov/FraudAbuseforProfs/05_StateProgramIntegrityReviews.asp#TopOfPage for more details.

State Program Integrity Assessment (SPIA). SPIA is an annual activity to collect State Medicaid program integrity data, develop profiles for each State based on these data, determine areas to provide States with technical support and assistance, and develop measures to assess States' performance in an ongoing manner. SPIA represents the first national baseline collection of data on State Medicaid integrity activities for the purposes of program evaluation and technical

assistance support. In FY 2009, CMS completed the first national collection of SPIA data. With this information, States and CMS can identify areas of opportunity to build on already effective practices and to identify areas for improvement. Individual State reports, a complete dataset, and a high-level executive summary of the results are available on the CMS website at http://www.cms.gov/FraudAbuseforProfs/11_SPIA.asp.

Audit Medicaid Integrity Contractors (Audit MICs). Audit MICs are entities with which CMS has contracted to perform audits of Medicaid providers. The overall goal of the provider audits is to identify overpayments and to ultimately decrease the payment of inappropriate Medicaid claims. Audit MICs prepare draft audit report and CMS, the State, and the audit provider review and comment on the draft report. Once finalized, the report and any identified overpayments are sent to the State. The State then pursues the collection of any overpayment in accordance with State law. A CMS Fact Sheet on Audit MICs can be found on the CMS website at http://www.cms.gov/ProviderAudits/Downloads/mipfactsheet.pdf.

State Medicaid Fraud Control Units (MFCUs). Under the oversight of the Department of Health and Human Services' Office of the Inspector General (HHS-OIG), the mission of the MFCUs is to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. MFCUs provide an annual report to OIG outlining their success in detecting, investigating, and prosecuting Medicaid fraud and patient abuse and neglect cases. In FY 2009, MFCUs reported recoveries of $1.3 billion in court-ordered restitution, fines, civil settlements, and penalties. They also obtained 1,331 convictions. MFCUs reported a total of 642 instances in which civil settlements and/or judgments were achieved. For more information on MFCUs, visit the HHS-OIG website at http://oig.hhs.gov/fraud/mfcu/.

2. **What other resources or authorities do you need from Congress to prevent and detect waste, fraud, and abuse in Medicare and Medicaid?**

Answer: The Administration's FY 2012 budget continues to make fighting health care fraud and reducing improper payments a top priority. These efforts will safeguard public funds and send a clear message that fraud and waste in our Federal health care programs will not be tolerated.

The Budget Request includes $270 million increase in discretionary program integrity resources as part of a multi-year investment to enable HHS and its partners to take ground-breaking steps to detect, prevent, and prosecute heath care fraud. The Budget also proposes a series of new legislative authorities that will strengthen existing program integrity oversight in Medicare and Medicaid. If enacted, these authorities will show real, measureable results, and are estimated to save $32.3 billion over ten years. Fully funding the Administration's FY 2012 budget request will provide the appropriate level of resources for CMS and its law enforcement partners.

The Honorable Cory Gardner

1. **What percentage of the 4.4 million claims CMS gets per day do you review more closely than the automatic claims edits?**

Answer: The Medicare Fee-for-Service (FFS) program processes over 1 billon claims annually, which are submitted by over 1 million providers. The claims are paid by a network of claims processing contractors who make payments to the providers in accordance with Medicare rules and regulations; perform pre-payment review of selected claims; and educate providers about how to submit accurately coded claims that meet Medicare medical necessity guidelines.

While all claims submitted to Medicare are screened by many system edits prior to payment, claims are generally paid without requesting the supporting medical records. Less than 0.002 percent of claims are reviewed against the supporting medical records prior to payment. Due to the volume of claims received, CMS relies on system edits and the post-payment review of claims to identify erroneous payments.

2. **How many levels of review are there and what is included in each step of review?**

Answer: Medicare contractors conduct several types of medical review and target their reviews on services and items that pose the greatest financial risk to the Medicare program. Claims that require a documentation review are only subjected to that one level of review. The following types of review are conducted:

- **Automated reviews** are completed at the system level, using available electronic information without the intervention of personnel.
- **Routine reviews** are completed by specially trained nonclinical staff who review the nonclinical portions of claims to ensure documentation compliance. For example, they may review documentation to confirm that an order was written before a service was provided.
- **Probe reviews** are complex reviews conducted to verify that the program vulnerabilities identified through a contractor's data analysis exist and require additional education and possible further review.
- **Complex reviews** are completed by licensed medical professionals who use clinical review judgment to review claims against supporting medical records.

Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Waste, Fraud, and Abuse: A Continuing Threat to Medicare and Medicaid
March 2, 2011

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THE WALL STREET JOURNAL.
WSJ.com

February 2, 2010, 8:47 AM ET

Reminder: Medicare, Medicaid Are Gobbling Up the Budget

President Obama's budget is still in the news this morning, and there's plenty of interesting health stuff in there. But it's worth pausing to note that the big drivers are mandatory spending on Medicare and Medicaid — huge, rapidly growing costs that are outside the purview of Obama's (or any president's) annual recommendations for discretionary spending.

Take a look at the table on pages 5-7 of this PDF, which explains Obama's proposed funding of the Department of Health and Human Services.

Total discretionary outlays (funding for CDC, NIH, that sort of thing) are $82.8 billion. Sure, that's a lot of money. But mandatory outlays for Medicare under existing law are $489.3 billion; the figure for Medicaid is $264.5 billion.

Under current law, spending on Medicare and Medicaid is set to rise by $58 billion between 2010 and 2011. Throw in the extra $25.3 billion in Medicaid funding proposed by the president, and just the year-over-year growth for Medicare and Medicaid is comparable to all of the HHS discretionary spending combined.

Medicare Fraud Costs Taxpayers More Than $60 Billion Each Year

In Easy to Execute Scams, Criminals Rip-Off Taxpayers, Make Millions and Run

BY CYNTHIA MCFADDEN AND ALMIN KARAMEHMEDOVIC

MARCH 17, 2010

A four month "Nightline" investigation into Medicare fraud makes one thing perfectly clear: this is a crime that pays and pays and pays. The federal government admits that a staggering $60 billion is stolen from tax payers through Medicare scams every year. Some experts believe the number is more than twice that.

Fraudulent pharmacies, clinics and medical supply companies seem to pop up like mushrooms in South Florida, the area widely considered to be ground zero in the fight against a crime that requires little training and involves few risks.

Former car mechanics and drug dealers, bus boys and clerks can be involved in individual scams, taking tens of millions of dollars every year from the government program designed to provide health care to the nation's elderly. As one government official told "Nightline," having a Medicare license is having a license to steal.

The victims of the schemes? American taxpayers.

Federal agents Brian Piper and Omar Peres of the Office of Inspector General are part of a special strike force in South Florida on the trail of some of the most elusive and richest criminals in the U.S.

We rode along with them over two days recently, as they ran down tips and knocked on doors in pursuit of people defrauding Medicare.

Our first stop with Piper and Peres is a place that is registered as a pharmacy that Medicare has paid $1 million to in two months. When they arrive, there is nobody there. The shelves are nearly bare. The chances are that it never sold so much as an aspirin.

It looks to be what the agents say is a typical scam: a fraudster buys a pharmacy along with its Medicare license and entire patient database. This one was sold five months ago for just $45,000.

"They've left the patient records for all of the Medicare beneficiaries that they were billing. So if these records had been thrown in the trash, they could be found by anyone," said Piper.

Piper and Peres have often seen the scam before.

"This is actually someone's name, Medicare number, address, phone number, and this person may not even know that they were being billed yet," Piper noted.

The scheme is relatively low-risk and requires little investment. Investigators allege that one person at a computer terminal could have submitted the million dollars worth of claims this pharmacy sent to Medicare in two months, before shuttering the place and disappearing.

"You don't have to hire anyone," said Piper. "If you buy an existing company like has happened here, one person can come in at night -- midnight -- submit all the claims and you never even have to open the business."

It's that easy because Medicare is based on trust. When the program was introduced in the 1960s it was assumed that no one would try to defraud a system designed to take care of the health needs of the elderly. The government was required to reimburse vendors in less than 30 days. To this day, in 99.9 percent of the cases, Medicare "auto-

adjudicates" claims within 30 days. In other words, the computer decides if the right codes are in the right boxes. If they are, jackpot, the checks are sent.

"That means that if you check the right boxes and fill out the right forms, you're going to get paid," said Kirk Ogrosky, who until recently was the federal prosecutor in charge of all criminal Medicare fraud at the Department of Justice.

Ogrosky said criminals' forms are often filled out more completely than actual health care providers'.

"Real hospitals and doctors who are struggling every day to keep up with the paperwork sometimes miss things ...whereas if you are a criminal trying to steal, all the forms look perfect every time because the whole goal of the enterprise is to check the right boxes," he said.

Medicare Makes Life Easy for Criminals

Medicare makes life very easy for criminals. Unlike credit card companies that stop payment the second a suspicious charge is made, "Nightline" learned Medicare is slow to respond even when people call to tell them about fraud.

Paula Teller spent three years trying to convince Medicare that fraudulent charges were being made using her Medicare number.

"Every week there was a charge of maybe $1,000 or $2,000," Teller said, "Thousands of dollars for treatments that I didn't even know what they were actually -- some kind of diabetes medication. ... I called Medicare and they kind of questioned if I was sure I hadn't had it done."

Teller estimates that $50,000 in phony claims was made under her Medicare card.

Judge Marshall Ader, who sat on the Florida state bench for decades, said he even had trouble getting Medicare to pay attention. When he saw that Medicare was being billed for two prosthetic legs using his Medicare number -- for the record he has both of his legs -- he hit the roof.

"I saw that there was a report for some prosthesis that I, of course, didn't use and had never used," said Ader, who has both of his legs and no need for prosthesis. "The bill was something like $30,000."

"I called Medicare, the investigative fraud unit ...Nobody seemed to care," he said. Ader told us it took over a year to sort out the situation.

"I saw that there was a report for some prosthesis that I, of course, didn't use and had never used," said Ader, who has both of his legs and no need for prosthesis. "The bill was something like $30,000."

"I called Medicare, the investigative fraud unit ...Nobody seemed to care," he said. Ader told us it took over a year to sort out the situation.

Criminals Get Rich Quick

Meanwhile, criminals continue to get rich quick, often buying expensive toys from helicopters to sports cars and race horses, from these easy-to-execute scams.

Another variation of the scam took place at a phony AIDS clinic, where a patient being paid off by fraudsters made a fake Medicare claim at the facility. "Nightline" was provided with undercover video inside the clinic documenting the scam in action.

Medicare Fraud Costs Taxpayers More Than $60 Billion Each Year: In Easy to Execute Scams, Criminals Rip-Off Taxpayers, Make Millions and Run By Cynthia McFadden & Almin Karamehmedovic

The video shows the informant following the fraudsters into a back room, where he gets a cash kickback for use of his Medicare number.

According to Piper, Medicare was billed three times a week at this clinic and paid out $10,000 per claim -- more than $30,000 a week for a service that was never provided.

"That's just per patient. One patient," he said. "So when you get a group of 10, 20, 30 patients you can see what a lucrative crime this was."

The clinic was closed, but not before Medicare paid the fraudsters $2 million. The criminals were sent to prison in sentences ranging for three to seven years.

Prosecuting Medicare Fraudsters

Plenty of criminals are arrested by the FBI and the Office of Inspector General. Just recently in Detroit, where another strike team is located, agents conducted an early morning raid on a clinic that had collected $15 million in an alleged Medicare scam.

U.S. Attorney Jeffrey Sloman spearheads prosecutions in South Florida. He meets with us in a secret location and shows us the row after row of pending cases representing what he calls "over a billion dollars of fraud... probably...two billion." Sloman said: "there is definitely more out there."

Despite the fact that the South Florida strike force prosecuted approximately 170 cases last year, all their hard work hardly makes a dent.

"That's the stunning thing about it...from my standpoint, relatively simple fixes can be instituted and aren't then something's terribly wrong," Sloman said.

Obama Administration on Stopping Medicare Fraud

Earlier this week President Obama said stopping such fraud would help fund his ambitious health care plan.

"Nightline" asked Obama's Secretary of Health and Human Services, Kathleen Sebelius, how much money the administration is counting on saving over the next ten years.

"Well, right now, I think the estimates are somewhere in the $25 billion range," she said.

While that may sound like a lot, at the rate things are going, it isn't very ambitious; $1 trillion is likely to be stolen from Medicare in the same period.

Sen. Charles Grassley, R-Iowa, who has been holding hearings for decades on Medicare fraud, said he's worried the president's health care bill fails to address the problem at the heart of the matter: pay and chase. Medicare pays the criminals and then chases after them.

"What's in there is good," says Grassley, referring to the Medicare fraud provisions in the Administration's bill, "but it isn't as fundamental of a fix as we need. The fix is to shut down the check-wiring for suspected fraud until you find out whether there's real fraud of not."

When asked why the fix isn't part of the president's health care bill, Grassley said: "I hope it's an oversight, but except for saying it's an oversight, I can't give you a reason why it's not in there."

http://abcnews.go.com/Nightline/medicare-fraud-costs-taxpayers-60-billion-year/story?id=10126555&page=3

Medicare Fraud Costs Taxpayers More Than $60 Billion Each Year: In Easy to Execute Scams, Criminals Rip-Off Taxpayers, Make Millions and Run By Cynthia McFadden & Almin Karamehmedovic

So we asked Secretary Sebelius. She said it was not an oversight.

"I think we have a difficult balance here," she said in an interview with "Nightline." "They can't just slow down payments willy-nilly because that's an unfair burden on the majority of providers who are legitimate."

In fact, Sebelius' staff later told us that despite what Sen. Grassley said, they already have the power to stop payments --- though it's an option they rarely use, even when there is clear evidence of fraud.

"Medicare very rarely suspends payment. Many of the criminals that are stealing from Medicare file the same claims over and over again for different patients," Ogrosky said. "If you have one hundred patients getting a dosage of a drug intended for chemo, they would be getting the same amount of the drug regardless of their body weight, regardless of the state of their diseases, regardless of their condition...if you were to ask any doctor, they would tell you that's impossible."

That should be good evidence of fraud, he said, yet over and over again, Medicare pays. Meanwhile, the vicious cycle continues: law enforcement continues to do its best to chase down the bad guys and the system continues to pump out the checks to the cheats.

Testimony of:
Daniel R. Levinson
Inspector General
U.S. Department of Health & Human Services

Good afternoon Chairman Obey, Ranking Member Tiahrt, and other distinguished Members of the Subcommittee. I am Daniel Levinson, Inspector General for the U.S. Department of Health & Human Services (HHS). I thank you for the opportunity to appear before you today to discuss the Office of Inspector General's (OIG) efforts to combat health care fraud, waste, and abuse in Medicare and Medicaid. I also thank you for your continued commitment to furthering our shared goal of safeguarding the fiscal integrity of these programs against those who would divert resources that are vital to so many Americans.

Medicare and Medicaid fraud, waste, and abuse cost the taxpayers billions of dollars each year and put the programs' beneficiaries' health and welfare at risk. The growing numbers of people served by these programs and the increased strain on Federal and State budgets caused by the economic recession further exacerbate the impact of these losses. It is critical that we strengthen oversight of these essential programs and reduce their vulnerability to fraud, waste, and abuse.

My testimony today will describe the nature and scope of the health care fraud, waste, and abuse that we have identified; strategies and recommendations to fight these problems; and OIG's role in fraud prevention, detection, and enforcement, including our highly productive collaboration with our colleagues in HHS and the Department of Justice (DOJ). It will also describe how we have deployed our resources and the results we have achieved, as well as our plans for the new appropriations requested in the President's Budget for fiscal year (FY) 2011.

OIG's Mission to Protect the Medicare and Medicaid Programs and Beneficiaries

OIG fights health care fraud, waste, and abuse through a nationwide program of investigations, audits, evaluations, and enforcement and compliance activities. Our FY 2010 appropriation included approximately $232 million in funding dedicated to protecting the integrity of Medicare and Medicaid.[1] In recognition of the value and impact of OIG's oversight and enforcement activities, the President's Budget for FY 2011 requests approximately $272 million in Medicare and Medicaid integrity funding for OIG, a net increase of $40 million. With this increased funding, OIG will expand its activities in support of the joint HHS-DOJ Health Care Fraud Prevention and Enforcement Action Team (known as HEAT and described in more detail below), including expanding the OIG-DOJ Medicare Fraud Strike Forces to 13 new locations.

OIG's funding is used to hire and support investigators, auditors, evaluators, attorneys, and management and support staff to carry out our mission and functions. OIG is comprised of more than 1,500 professionals who perform comprehensive oversight and enforcement activities for HHS programs, including:

[1] OIG's total appropriation for FY 2010 was approximately $282 million, which also included $50 million to oversee the more than 300 other HHS programs.

- Office of Investigations: conducts criminal, civil, and administrative investigations of health care fraud, which result in convictions, monetary recoveries, and exclusions of providers and suppliers from Federal health care programs;
- Office of Audit Services: conducts and oversees audits of Medicare and Medicaid payments and operations, identifies improper payments and program vulnerabilities, and recommends audit disallowances and program improvements;
- Office of Evaluation and Inspections: conducts evaluations of the Medicare and Medicaid programs to identify program integrity vulnerabilities and make recommendations to prevent fraud, waste, and abuse and to promote economy, efficiency, and effectiveness; and
- Office of Counsel to the Inspector General: represents OIG in all civil and administrative fraud cases and, in connection with these cases, negotiates and monitors corporate integrity agreements; provides guidance to the health care industry to promote compliance; and provides legal support to OIG operations.

OIG's program integrity activities are a sound investment.

In FY 2009, OIG investigations resulted in $4 billion in settlements and court-ordered fines, penalties, and restitution, and in 671 criminal actions. OIG audits resulted in almost $500 million in receivables through recommended disallowances. We also produced equally important but less quantifiable gains in deterrence and prevention of fraud, waste, and abuse. OIG has recommended numerous actions to address program integrity vulnerabilities. For example, we found that Medicare's average spending per beneficiary for inhalation drugs was five times higher in South Florida, an area rife with Medicare fraud, than in the rest of the country, and that a disproportionately high rate of these claims in South Florida exceeded the maximum dosage guidelines. OIG's recommendations included adding new claims edits to prevent fraudulent or excessive payments, including edits to detect dosages exceeding coverage guidelines. Many other recommendations to prevent and deter fraud, waste, and abuse are described in our annual *Compendium of Unimplemented OIG Recommendations*, the latest edition of which will be published later this month.

OIG Work Highlighting the Nature and Scope of Health Care Fraud, Waste, and Abuse

Fraud is a serious problem requiring a serious response.

Although there is no precise measure of health care fraud, we know that it is a serious problem that demands an aggressive response. We must not lose sight of the fact that the vast majority of health care providers are honest and well-intentioned; nonetheless, a small minority of providers intent on abusing the system can cost billions of dollars. We believe that the $4 billion in settlements and court-ordered returns in FY 2009 resulting from OIG fraud investigations is just the tip of the iceberg. More disturbing, even if the rate of fraud remains constant, as health care expenditures continue to rise, the financial impact of health care fraud will continue to increase.

OIG investigations uncover a range of fraudulent activity. Health care fraud schemes commonly include billing for services that were not provided or were not medically necessary, billing for a higher level of service than what was provided ("upcoding"), misreporting costs or other data to increase payments, paying kickbacks, and/or stealing providers' or beneficiaries' identities. The

perpetrators of these schemes range from street criminals, who believe it is safer and more profitable to steal from Medicare than trafficking in illegal drugs, to Fortune 500 companies that pay kickbacks to physicians in return for referrals.

Many OIG investigations target fraud committed by criminals who masquerade as Medicare providers and suppliers but who do not provide legitimate services or products. The rampant fraud among durable medical equipment (DME) suppliers in South Florida is a prime example. In these cases, our investigations have found that criminals set up sham DME storefronts to appear to be legitimate providers, fraudulently bill Medicare for millions of dollars, and then close up shop and reopen in a new location under a new name and repeat the fraud. The criminals often pay kickbacks to physicians, nurses and even patients to recruit them as participants in the fraud scheme.

The Medicare program is increasingly infiltrated by violent criminals, and our investigations are also finding an increase in sophisticated and organized criminal networks. Some of these fraud schemes are viral, i.e., schemes are replicated rapidly within geographic and ethnic communities. Health care fraud also migrates – as law enforcement cracks down on a particular scheme, the criminals may shift the scheme (e.g., suppliers fraudulently billing for DME have shifted to fraudulent billing for home health services) or relocate to a new geographic area. To combat this fraud, the Government's response must also be swift, agile, and organized.

Health care fraud is not limited to this blatant fraud among sham providers. Major corporations such as pharmaceutical and medical device manufacturers and institutions such as hospitals and nursing facilities have also committed fraud, sometimes on a grand scale. OIG has a strong record of investigating these corporate and institutional frauds, which often involve complex billing frauds, kickbacks, accounting schemes, illegal marketing, and physician self-referral arrangements. In addition, we are seeing an increase in quality of care cases involving allegations of substandard care.

Waste and abuse cost taxpayers billions of dollars and must be addressed.

Waste of funds and abuse of the health care programs also cost taxpayers billions of dollars. In FY 2009, CMS estimated that overall, 7.8 percent of the Medicare fee-for-service claims it paid ($24.1 billion) did not meet program requirements. Although these improper payments do not necessarily involve fraud, the claims should not have been paid. For our part, OIG reviews specific services, based on our assessments of risk, to identify improper payments. For example, an OIG audit uncovered $275.3 million in improper Medicaid payments (Federal share) from 2004 to 2006 for personal care services in New York City alone. An OIG evaluation of payments for facet joint injections (a pain management treatment) found that 63 percent of these services allowed by Medicare in 2006 did not meet program requirements, resulting in $96 million in improper payments.

OIG's work has also repeatedly demonstrated that Medicare and Medicaid pay too much for certain services and products and that aligning payments with costs could produce substantial savings. For example, OIG reported that Medicare reimbursed suppliers for pumps used to treat pressure ulcers and wounds based on a purchase price of more than $17,000, but that suppliers

paid, on average, approximately $3,600 for new models of these pumps. Likewise, in 2006, Medicare allowed approximately $7,200 in rental payments over 36 months for an oxygen concentrator that cost approximately $600 to purchase. Beneficiary coinsurance alone for renting an oxygen concentrator for 36 months exceeded $1,400 (more than double the purchase price).

OIG's Strategy and Recommendations for Combating Fraud, Waste, and Abuse

Combating health care fraud requires a comprehensive strategy of prevention, detection, and enforcement. OIG has been engaged in the fight against health care fraud, waste, and abuse for more than 30 years. Based on this experience and our extensive body of work, we have developed five principles of an effective health care integrity strategy. OIG uses these principles in our strategic work planning to assist in focusing our audit, evaluation, investigative, enforcement, and compliance efforts most effectively.

1. Enrollment: Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment in the health care programs.

The first step in preventing health care fraud and abuse is to stop those who would defraud or abuse the programs from gaining entry to them. The concept is simple but the execution can be challenging. The Medicare program was designed to make it easy to enroll as a provider to encourage participation and ensure beneficiary access to services. However, this also makes it too easy for sham providers and suppliers to obtain Medicare billing numbers and bill for millions of dollars in fraudulent claims.

In 2006 and 2007, OIG conducted unannounced site visits to almost 2,500 Medicare DME suppliers in South Florida and Los Angeles and found that almost 600 of these suppliers (about 24 percent) did not maintain a physical facility or were not open and staffed during business hours, as required. OIG has recommended heightened enrollment screening and oversight for high-risk items and services. CMS has taken some important steps toward this end, particularly for DME providers in South Florida. Additional scrutiny for high risk areas through unannounced site visits, background checks, enhanced claims screening for new enrollees, and enhanced authorities (such as explicit authority to impose temporary enrollment moratoriums) could further discourage this type of fraud. OIG will continue to monitor the effectiveness of provider enrollment safeguards.

2. Payment: Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.

Establishing reasonable and responsive payment methodologies prevents the type of waste, described above, that results when payment methodologies are misaligned with costs and market prices. OIG has identified these misalignments for various health care services and products, and we have recommended fixes. For example, capping rental of oxygen concentrators at 13 months instead of 36 months would save Medicare billions of dollars.

Applying this principle can also deter fraud. For example, an OIG evaluation found that in 2007, Medicare allowed, on average, about $4,000 for standard power wheelchairs that cost suppliers, on average, about $1,000 to acquire. Profit margins like these attract fraud. OIG has investigated numerous cases of fraudulent billing for power wheelchairs, and in some of these cases, the suppliers actually provide wheelchairs to beneficiaries who do not need them because the reimbursement – even after purchasing the wheelchair – is high enough to make this scam lucrative. CMS has the authority to make certain adjustments to payments for DME and other items or services, but for some changes (such as reducing the rental period for oxygen concentrators), legislative changes are needed.

3. Compliance: Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.

The vast majority of health care providers and suppliers are honest and well-intentioned. They are valuable partners in ensuring the integrity of Federal health care programs. OIG seeks to collaborate with health care industry stakeholders to foster voluntary compliance efforts. Toward this end, OIG has produced extensive resources (available on our Web site at http://oig.hhs.gov) to assist industry stakeholders in understanding the fraud and abuse laws and designing and implementing effective compliance programs. These resources include sector-specific Compliance Program Guidance documents that describe the elements of effective compliance programs and identify risk areas, advisory opinions, and fraud alerts and bulletins. We have a self-disclosure program that encourages providers to self-report fraud uncovered within their company and to work with OIG to resolve the problem fairly and efficiently. Effective compliance programs help make honest providers our partners in the fight against health care fraud. OIG recommends that providers and suppliers should be required to adopt compliance programs as a condition of participating in the Medicare and Medicaid programs.

4. Oversight: Vigilantly monitor the programs for evidence of fraud, waste, and abuse.

Rapid detection of fraud, waste, and abuse is essential to ensuring the integrity of health care dollars. This includes using data and technology to detect potential problems as claims are submitted and before they are paid. It also includes conducting advanced data analysis to identify, track, and monitor patterns of fraud to target enforcement efforts. With appropriate protections, identifying effective ways to share information across Federal and State agencies and with private insurers can leverage resources and improve our collective effectiveness in fighting fraud, waste, and abuse. Through HEAT, progress has been made in improving law enforcement's access to Medicare data, sharing information and intelligence, and conducting data analysis to prioritize and target our fraud-fighting efforts.

5. Response: Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.

Although it is ideal to prevent payments for fraudulent or improper claims, there will never be perfect prevention. An effective anti-fraud strategy must incorporate a strong enforcement component. Criminals balance the risk of detection and punishment against the benefits of the crime and have concluded that Medicare and Medicaid fraud are a good bet. It is imperative that

we change the calculation by increasing the risk of prompt detection and the certainty of punishment.

As part of this strategy, OIG is working closely with its partners in DOJ and in the States to accelerate and maximize the effectiveness of our law enforcement response to fraud. Medicare Fraud Strike Forces represent one very successful enforcement model. In addition, OIG investigates and DOJ prosecutes civil cases that return billions of dollars to the Medicare and Medicaid programs. OIG is also using our administrative authorities to hold responsible individuals accountable for fraud, including physicians who accept kickbacks and responsible corporate officials whose companies have committed fraud.

CMS and States must also respond swiftly to recoup misspent funds, take appropriate administrative actions (e.g., revoking billing privileges, suspending payments), and remedy program vulnerabilities. Through the HEAT initiative, described in more detail below, the Government is significantly accelerating and strengthening its response to fraud, waste, and abuse.

Resources and Tools for Health Care Oversight and Enforcement Activities

Adequate funding of the Health Care Fraud and Abuse Control (HCFAC) Program is vital to the fight against fraud, waste, and abuse.

The Health Care Fraud and Abuse Control (HCFAC) Program is a comprehensive program under the joint direction of the Attorney General and the Secretary of HHS, acting through our OIG, designed to coordinate Federal, state and local law enforcement activities with respect to health care fraud and abuse. The HCFAC Program draws funds from the Medicare Trust Fund to finance anti-fraud activities. Certain of these sums are to be used only for activities of OIG, with respect to the Medicare and Medicaid programs. The HCFAC Program is OIG's primary funding stream, and accounts for 73 percent of our FY 2010 appropriation.

From its inception in 1997 through 2008, HCFAC Program activities returned more than $13.1 billion to the Federal Government. The HCFAC return-on-investment is $6 for every $1 invested in OIG, DOJ, and HHS activities through the HCFAC Account.[2] This return-on-investment calculation includes only actual recoveries, such as dollars returned to the Federal Government and redeposited in the Medicare Trust Fund, the Treasury or returned to other Federal "victim" agencies. Savings realized from implementation of OIG's recommendations to promote economy, efficiency, and effectiveness of Medicare and Medicaid operations create additional returns from OIG operations, but these are not captured in HCFAC return-on-investment calculations.

Thanks to this Subcommittee's support for investing in HCFAC activities, OIG's total HCFAC appropriation for FY 2010 is $207 million, which includes $177 million in mandatory funds and almost $30 million in discretionary funding. OIG is directing these resources to conduct

[2] The $6 to $1 return on investment is a 3-year rolling average from 2006-2008, which is used to help account for the natural fluctuation in returns from investigative, enforcement, and audit activities.

Medicare and Medicaid investigations, audits, evaluations, enforcement, and compliance activities to support our health care program integrity strategy described above. Examples of our HCFAC-funded activities include:

- Establishment of Strike Force teams in seven cities;
- Support of Civil False Claims Act investigations and enforcement;
- Support of administrative enforcement activities;
- Evaluations of Medicare contractor operations, services provided to nursing home residents, Medicare and Medicaid reimbursement for prescription drugs, and other issues;
- Audits of payments to hospitals, home health agencies, Medicare Advantage plans, and Medicare Part D plans, among other providers;
- Monitoring of providers under corporate integrity agreements; and
- Issuance of advisory opinions and other guidance to the health care industry.

In addition to the $30 million in discretionary HCFAC funds in FY 2010 (which will continue into FY 2011), the President's FY 2011 Budget proposes an additional $65 million increase in HCFAC discretionary funding. This represents a net increase of $40 million in total funding for OIG's health care integrity activities.

The proposed $65 million increase in HCFAC discretionary funding includes $25 million to continue funding OIG's oversight and enforcement activities that were previously funded through the Deficit Reduction Act of 2005 (DRA). The DRA provided $25 million each year in FYs 2006-2010 to fund OIG's Medicaid integrity activities. In recognition of the continued need for OIG oversight and enforcement beyond FY 2010, the Administration included $25 million in its request for FY 2011 for OIG to sustain health care oversight activities. The proposed budget would enable us to continue fraud-fighting efforts that would otherwise necessarily dwindle as the DRA funding ceased. Further, providing these funds under HCFAC provides the advantages of consolidating funding streams with similar purposes and expanding the authorized use of these funds to include Medicare oversight as well as Medicaid oversight. Medicare and Medicaid program integrity activities are often related. For example, many of our investigations involve an individual or entity committing fraud against both programs.

The proposed $65 million HCFAC increase also includes $40 million in new funding for OIG's activities in support of the HEAT initiative, including establishing Strike Force teams in 13 new locations. We estimate that almost $25 million of this funding would be needed to support the Strike Force expansions and the remaining $15 million would support OIG's other HEAT activities, including audits, evaluations, civil and administrative enforcement, and compliance activities.

Through HEAT, OIG is enhancing the impact of our prevention, detection, and enforcement efforts.

OIG is a key member of HEAT; indeed, HEAT's fraud and abuse prevention, detection, and enforcement activities are our primary focus and core mission. The collaboration brought about by HCFAC and enhanced by HEAT has improved coordination and communication, which has in turn led to greater impact and effectiveness of our collective fraud-fighting efforts.

Prevention. Prevention of health care fraud, waste, and abuse was written into the legislation that created OIG – it is integral to our mission and activities. OIG makes recommendations to the Centers for Medicare & Medicaid Services (CMS) to remedy program vulnerabilities that we uncover through our evaluations and audits. OIG also provides CMS with intelligence gleaned from our investigations and data analysis to help CMS target its prevention efforts effectively. In addition, OIG's guidance and outreach to the health care industry help the well-intended health care providers avoid fraudulent or abusive conduct and promote compliance with program requirements. Further, our enforcement activities prevent fraud by stopping ongoing schemes and deterring future fraud.

HEAT has strengthened these prevention efforts. It has provided a forum for advancing OIG's recommendations to remedy program vulnerabilities in Medicare and Medicaid. For example, senior staff from OIG and CMS are working together to plan actions that CMS can take in the short term to address some of OIG's outstanding recommendations. In addition, HEAT has increased interagency communication about fraud trends, new initiatives, and ideas through the creation of committees and work groups comprised of experts from across HHS and DOJ who meet regularly to collaborate and develop new strategies for preventing fraud, waste, and abuse. Also, in conjunction with HEAT, OIG is considering further outreach opportunities to engage health care providers in fraud prevention.

Detection. In support of HEAT, OIG has developed and leads a data analysis team, which includes DOJ and CMS, to identify fraud patterns and trends and strategically target all of our resources. This data analysis team identified geographic concentrations of fraud to help determine in what cities to establish new Strike Force teams and analyzes fraud indicators to provide specific investigative leads to Strike Force teams.

Collaborating with our partners through HEAT has also resulted in improved data access for law enforcement. Access to "real-time" claims data – that is, as soon as the claim is submitted to Medicare – is critical to identifying fraud as it is being committed. With "real time" knowledge, we would be better able to stop the fraud more quickly and to bring the perpetrator to justice and recoup the stolen funds before the criminal or the money disappears. Timely data is also essential to our agile response as criminals shift their schemes and locations to avoid detection. Although we do not yet have access to comprehensive real-time claims data, we have made important strides in obtaining data more quickly and efficiently. On a pilot basis, CMS recently provided several OIG investigators and analysts access to a Medicare data system that includes much of the real-time claims data that law enforcement needs. OIG, DOJ, and CMS have also worked together to develop a data request template so that CMS contractors can process our data requests faster and with more efficiency.

Enforcement. OIG and DOJ jointly lead the Medicare Fraud Strike Force teams, which have expanded through HEAT from two to seven locations. The successes of these Strike Forces are described in detail below. In addition, HEAT has also led OIG and DOJ to jointly reassess our resource allocation for our civil fraud cases, which have yielded billions of dollars in returns, to ensure that we are prioritizing these resources most effectively.

Medicare Fraud Strike Forces have proven to be successful in fighting health care fraud.

The Strike Forces are an essential component of HEAT and have achieved impressive enforcement results. Collectively, Strike Forces have resulted in approximately 270 convictions, indictments of more than 500 defendants, and more than $240 million in court-ordered restitutions, fines, and penalties. Strike Forces also deter fraud. For example, during the first year of Strike Force operations in Miami, which focused on DME fraud, submissions of DME claims decreased by 63 percent, representing a decrease of $1.75 billion, compared to the previous year. The Strike Force model is especially effective for investigating and prosecuting health care fraud cases involving sham Medicare providers and suppliers masquerading as legitimate health care providers and suppliers.

Strike Forces are designed to identify, investigate, and prosecute fraud quickly. Strike Force teams are comprised of dedicated DOJ prosecutors and Special Agents from OIG, the Federal Bureau of Investigations, and, in some cases, State and local law enforcement agencies. These "on the ground" enforcement teams are supported by the data analysis team (described above) and by CMS program experts and contractors. This coordination and collaboration has accelerated the Government's response to criminal fraud, decreasing by roughly half the average time from an investigation's start to the case's prosecution.

Under HEAT, Strike Forces have expanded from two locations (Miami and Los Angeles) to seven. In May 2009, new Strike Forces were announced in Houston and Detroit. In December 2009, Strike Forces teams became operational in Brooklyn, Tampa, and Baton Rouge.

The President's FY 2011 Budget proposal would expand Strike Forces to 13 new locations, bringing the total number of Strike Force locations to 20. The selection of Strike Force locations is based on data analysis of Medicare claims to determine fraud hot spots.

OIG estimates that it will require almost $25 million to establish and operate Strike Forces in 13 new locations. This funding would support an estimated 130 full-time employees dedicated to Strike Force operations and support. These 130 employees would primarily be comprised of investigative staff, including criminal investigators, supervisory investigators, computer forensic specialists, and investigative operations trainers. Additional staff supporting the new Strike Forces would include auditors, evaluators, data analysts, attorneys, and administrative and information technology (IT) staff.

With this funding, OIG is committed to working with our DOJ partners to establish Strike Forces in 13 new locations. We anticipate that it will take us through 2012 to fully launch Strike Force teams in all 13 cities, consistent with the two-year time frame for which the money would be available under the President's proposal. However, immediately upon receiving the funding, we will begin hiring and training staff and conducting the other preparatory work, such as leasing additional space and purchasing IT and other equipment, necessary to launch and support the new Strike Force teams.

Conclusion

Health care fraud, waste, and abuse are serious problems that cost taxpayers billions of dollars every year and require focused attention and commitment to solutions. Protecting Medicare and Medicaid beneficiaries and taxpayer dollars is integral to OIG's mission. Through the dedicated efforts of my staff and our collaboration with HHS and DOJ, we have achieved substantial results in the form of recoveries of stolen and misspent funds; enforcement actions taken against fraud perpetrators; improved methods of detecting fraud and abuse; and solutions to address program vulnerabilities and prevent fraud, waste, and abuse from occurring. Working together, we are maximizing our collective effectiveness and success in this endeavor. Health care fraud, waste, and abuse are long-standing problems that require sustained commitment to combat them. On behalf of OIG, I make that commitment to you. Thank you for your attention to and support for this mission. I welcome your questions.

News Release

FOR IMMEDIATE RELEASE
Thursday, February 17, 2011

Contact: HHS Press Office
(202) 690-6343

Medicare Fraud Strike Force Charges 111 Individuals for more than $225 Million in False Billing and Expands Operations to Two Additional Cities

Doctors, Nurses, Health Care Company Owners and Executives Among the Defendants Charged; Law Enforcement Agents Execute 16 Search Warrants

WASHINGTON – The Medicare Fraud Strike Force today charged 111 defendants in nine cities, including doctors, nurses, health care company owners and executives, and others, for their alleged participation in Medicare fraud schemes involving more than $225 million in false billing, announced Attorney General Eric Holder, Health and Human Services (HHS) Secretary Kathleen Sebelius, FBI Executive Assistant Director Shawn Henry, Assistant Attorney General Lanny A. Breuer of the Criminal Division and HHS Inspector General Daniel Levinson. Also today, the Department of Justice (DOJ) and HHS announced the expansion of Medicare Fraud Strike Force operations to two additional cities – Dallas and Chicago. Today's operation is the largest-ever federal health care fraud takedown.

The joint DOJ-HHS Medicare Fraud Strike Force is a multi-agency team of federal, state, and local investigators designed to combat Medicare fraud through the use of Medicare data analysis techniques and an increased focus on community policing. More than 700 law enforcement agents from the FBI, HHS-Office of Inspector General (HHS-OIG), multiple Medicaid Fraud Control Units, and other state and local law enforcement agencies participated in today's operation. In addition to making arrests, agents also executed 16 search warrants across the country in connection with ongoing strike force investigations.

"With this takedown, we have identified and shut down large-scale fraud schemes operating throughout the country. We have safeguarded precious taxpayer dollars. And we have helped to protect our nation's most essential health care programs, Medicare and Medicaid," said Attorney General Holder. "As today's arrest prove, we are waging an aggressive fight against health care fraud."

"Over the last two years our joint efforts have more than quadrupled the number of anti-fraud Strike Force teams operating in fraud hot spots around the country from two to nine -- with the latest additions Chicago and Dallas -- bringing hundreds of charges against criminals who had billed Medicare for hundreds of millions of dollars. Last year alone, our partnership recovered a record $4 billion on behalf of taxpayers. From 2008-2010, every dollar the Federal Government spent under its Health Care Fraud and Abuse Control programs averaged a return on investment of $6.80," said HHS Secretary Sebelius.

The defendants charged today are accused of various health care fraud-related crimes, including conspiracy to defraud the Medicare program, criminal false claims, violations of the anti-kickback statutes, money laundering and aggravated identity theft. The charges are based on a variety of alleged fraud schemes involving various medical treatments and services such as home health care, physical and occupational therapy, nerve conduction tests and durable medical equipment.

According to court documents, the defendants charged today participated in schemes to submit claims to Medicare for treatments that were medically unnecessary and oftentimes, never provided. In many cases, indictments and complaints allege that patient recruiters, Medicare beneficiaries and other co-conspirators were paid cash kickbacks in return for supplying beneficiary information to providers, so that the providers could submit fraudulent billing to Medicare for services that were medically unnecessary or never provided. Collectively, the doctors, nurses, health care company owners, executives and others charged in the indictments and complaints are accused of conspiring to submit a total of more than $225 million in fraudulent billing.

"Every American bears the burden of health care fraud, and the FBI, in conjunction with our inter-agency partners, will continue to dismantle criminal networks that bilk the system," said Shawn Henry, Executive Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Our agents and analysts use task forces and undercover operations to identify individuals who treat the health care system as a vehicle to line their pockets."

"Today, Strike Force operations have charged doctors, nurses, health care executives, and others – from Los Angeles to New York and cities in between – with engaging in Medicare fraud schemes that cheat taxpayers and patients alike," said Assistant Attorney General Breuer. "With this nationwide takedown and the expansion of the Strike Force to two additional cities, our message is clear: we are determined to put Medicare fraudsters out of business."

"Today, more than 300 special agents from OIG, in partnership with federal and state agencies across the country, are making more than a hundred arrests on charges of health care fraud," said Daniel R. Levinson, HHS Inspector General. "These unprecedented operations send a clear message – we will not tolerate criminals lining their pockets at the expense of Medicare patients and taxpayers."

In Miami, 32 defendants, including 2 doctors and 8 nurses, were charged for their participation in various fraud schemes involving a total of $55 million in false billings for home health care, durable medical equipment and prescription drugs. Twenty-one defendants, including three doctors, three physical therapists and one occupational therapist, were charged in Detroit for schemes to defraud Medicare of more than $23 million. The Detroit cases involve false claims for home health care, nerve conduction tests, psychotherapy, physical therapy and podiatry.

In Brooklyn, N.Y., 10 individuals, including three doctors and one physical therapist, were charged with fraud schemes involving $90 million in false billings for physical therapy, proctology services and nerve conduction tests. Ten defendants were charged in Tampa for participating in schemes involving more than $5 million related to false claims for physical therapy, durable medical equipment and pharmaceuticals.

Nine individuals were charged in Houston for schemes involving $8 million in fraudulent Medicare claims for physical therapy, durable medical equipment, home health care and chiropractor services. In Dallas, seven defendants were indicted for conspiring to submit $2.8 million in false billing to Medicare related to durable medical equipment and home health care.

Five defendants were charged in Los Angeles for their roles in schemes to defraud Medicare of more than $28 million. The cases in Los Angeles involve false claims for durable medical equipment and home health care. In Baton Rouge, La., six individuals were charged for a durable medical equipment fraud scheme involving more than $9 million in false claims.

In Chicago, charges were filed against 11 individuals associated with businesses that have billed Medicare more than $6 million for home health, diagnostic testing and prescription drugs.

The Medicare Fraud Strike Force operations are part of the Health Care Fraud Prevention & Enforcement Action Team (HEAT), a joint initiative announced in May 2009 between the Department of Justice and HHS to focus their efforts to prevent and deter fraud and enforce current anti-fraud laws around the country.

Since their inception in March 2007, Strike Force operations in nine districts have charged more than 990 individuals who collectively have falsely billed the Medicare program for more than $2.3 billion. In addition, the HHS Centers for Medicare and Medicaid Services, working in conjunction with the HHS-OIG, are taking steps to increase accountability and decrease the presence of fraudulent providers.

The cases announced today are being prosecuted and investigated by Strike Force teams comprised of attorneys from the Fraud Section in the Justice Department's Criminal Division and from the U.S. Attorney's Offices for the Southern District of Florida, the Eastern District of Michigan, the Eastern

District of New York, the Middle District of Florida, the Southern District of Texas, the Central District of California, the Middle District of Louisiana; the Northern District of Illinois, and the Northern District of Texas; and agents from the FBI, HHS-OIG, and state Medicaid Fraud Control Units.

An indictment is merely a charge and defendants are presumed innocent until proven guilty.

To learn more about the Health Care Fraud Prevention and Enforcement Action Team (HEAT), go to: www.stopmedicarefraud.gov.

GAO
Accountability-Integrity-Reliability

Highlights

Highlights of GAO-09-628T, a testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

Why GAO Did This Study

GAO's work over the past several years has demonstrated that improper payments are a long-standing, widespread, and significant problem in the federal government. The Improper Payments Information Act of 2002 (IPIA) has increased visibility over improper payments by requiring executive branch agency heads, using guidance from the Office of Management and Budget, to identify programs and activities susceptible to significant improper payments, estimate amounts improperly paid, and report on the amounts of improper payments and their actions to reduce them.

This testimony addresses (1) progress made in agencies' implementation of IPIA for fiscal year 2008, and (2) several major challenges that continue to hinder full reporting of IPIA information. GAO was also asked to provide an overview of Medicare and Medicaid programs' implementation of IPIA. This testimony is based primarily on GAO products, Office of Inspector General (OIG) audit reports, and agencies' fiscal year 2008 reported improper payment information, including information reported by the Department of Health and Human Service's (HHS) Centers for Medicare and Medicaid Services (CMS). GAO also analyzed fiscal year 2008 governmentwide improper payment information to identify trends and reviewed Medicare and Medicaid programs' reported actions to identify, estimate, and reduce improper payments.

To view the full product, including the scope and methodology, click on GAO-09-628T. For more information, contact Kay L. Daly at (202) 512-9095 or dalykl@gao.gov.

April 22, 2009

IMPROPER PAYMENTS

Progress Made but Challenges Remain in Estimating and Reducing Improper Payments

What GAO Found

Agencies reported improper payment estimates of $72 billion for fiscal year 2008, which represented about 4 percent of the $1.8 trillion of reported outlays for the related programs. This represents a significant increase from the fiscal year 2007 estimate attributable to (1) a $12 billion increase in the Medicaid program's estimate and (2) 10 newly reported programs with improper payment estimates totaling about $10 billion.

- **Progress made in estimating and reducing improper payments.** The governmentwide improper payment estimates rose about $23 billion from fiscal year 2007 to 2008. This represents a positive step to improve transparency over the full magnitude of the federal government's improper payments. Further, of the 35 agency programs reporting improper payment estimated error rates for each of the 5 fiscal years since implementation of IPIA—2004 through 2008—24 programs (or about 69 percent) reported reduced error rates when comparing fiscal year 2008 error rates to fiscal year 2004 error rates. Also, the number of programs with error rate reductions totaled 35 when comparing fiscal year 2008 error rates to fiscal year 2007 rates.
- **Challenges remain in meeting the goals of IPIA governmentwide.** The total improper payment estimate does not yet reflect the full scope of improper payments across executive branch agencies; noncompliance issues with IPIA continue; and agencies continue to face challenges in the design or implementation of internal controls critical to identifying and preventing improper payments. The fiscal year 2008 total improper payment estimate of $72 billion reported for fiscal year 2008 did not include any estimate for ten programs—including the Medicare Prescription Drug Benefit program—with fiscal year 2008 outlays totaling about $61 billion that were identified as susceptible to significant improper payments. Over half of the agencies' OIGs identified management or performance challenges that could increase the risk of improper payments, including challenges related to effective internal controls.
- **Medicare and Medicaid programs' implementation of IPIA and its challenges.** Medicare and Medicaid comprise 50 percent of reported governmentwide improper payments in fiscal year 2008. HHS reported improper payment amounts of $10.4 billion in Medicare Fee-for-Service and $6.8 billion in Medicare Advantage. HHS also reported in its agency financial report that it issued its first full-year Medicaid improper payment rate estimate of 10.5 percent, or $18.6 billion for the federal share of expenditures for fiscal year 2008. This Medicaid improper payment estimate represents the largest amount that any federal agency reported for a program in fiscal year 2008. While CMS has taken steps to enhance its program integrity efforts, further work remains to put in place the internal controls necessary to effectively identify and detect improper payments. For example, GAO's work on Medicare's home health care administration and enrollment of durable medical equipment suppliers found weaknesses that exposed the program to significant improper payments. The magnitude of Medicaid improper payments indicates that CMS and the states face significant challenges in addressing the program's vulnerabilities in estimating national improper payment rates for diverse state-administered programs.

5862 Federal Register / Vol. 76, No. 22 / Wednesday, February 2, 2011 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, 447, 455, 457, and 498

Office of Inspector General

42 CFR Part 1007

[CMS–6028–FC]

RIN 0938–AQ20

Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office of Inspector General (OIG), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period will implement provisions of the ACA that establish: Procedures under which screening is conducted for providers of medical or other services and suppliers in the Medicare program, providers in the Medicaid program, and providers in the Children's Health Insurance Program (CHIP); an application fee imposed on institutional providers and suppliers; temporary moratoria that may be imposed if necessary to prevent or combat fraud, waste, and abuse under the Medicare and Medicaid programs, and CHIP; guidance for States regarding termination of providers from Medicaid and CHIP if terminated by Medicare or another Medicaid State plan or CHIP; guidance regarding the termination of providers and suppliers from Medicare if terminated by a Medicaid State agency; and requirements for suspension of payments pending credible allegations of fraud in the Medicare and Medicaid programs. This final rule with comment period also discusses our earlier solicitation of comments regarding provisions of the ACA that require providers of medical or other items or services or suppliers within a particular industry sector or category to establish compliance programs.

We have identified specific provisions surrounding our implementation of fingerprinting for certain providers and suppliers for which we may make changes if warranted by the public comments received. We expect to publish our response to those comments, including any possible changes to the rule made as a result of them, as soon as possible following the end of the comment period. Furthermore, we clarify that we are finalizing the adoption of fingerprinting pursuant to the terms and conditions set forth herein.

DATES: *Effective date:* These regulations are effective on March 25, 2011.

Comment date: We will consider public comments only on the Fingerprinting Requirements, contained in §§ 424.518 and 455.434 and discussed in section II.A.5. of the preamble of this document, if we receive them at one of the addresses provided below, no later than 5 p.m. on April 4, 2011.

ADDRESSES: In commenting, please refer to file code CMS–6028–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for "submitting a comment."

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–6028–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–6028–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Frank Whelan (410) 786–1302 for Medicare enrollment issues. Claudia Simonson (312) 353–2115 for Medicaid and CHIP enrollment issues. Lori Bellan (410) 786–2048 for Medicaid payment suspension issues and Medicaid termination issues. Joseph Strazzire (410) 786–2775 for Medicare payment suspension issues. Laura Minassian-Kiefel (410) 786–4641 for compliance program issues.

SUPPLEMENTARY INFORMATION: Due to the many organizations and terms to which we refer by acronym in this final rule with comment period, we are listing these acronyms and their corresponding terms in alphabetical order below. In addition, we are providing a table of contents which follows the list of acronyms to assist readers in referencing sections contained in this preamble.

Acronyms

ABC American Board for Certification in Orthotics and Prosthetics
A/B MAC Part A or Part B Medicare Administrative Contractor
ACA "Affordable Care Act"
APD Advance planning document
ASC Ambulatory surgical center
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BIPA Medicare Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (Pub. L. 106–544)
CAH Critical access hospital
CAP Competitive acquisition program
CBA Competitive bidding area
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CJIS Criminal Justice Information Services
CLIA Clinical laboratory improvement amendments
CMHC Community mental health centers
CMS Centers for Medicare & Medicaid Services
CON Certificate of Need
CoP Condition of participation
CORF Comprehensive outpatient rehabilitation facility
CPI–U Consumer price index for all urban consumers
DAB Department Appeal Board

DEA Drug Enforcement Agency
DHUD Department of Housing and Urban Development
DME Durable medical equipment
DMEPOS Durable medical equipment prosthetics, orthotics, and supplies
DOB Dates of birth
DOJ Department of Justice
EIN Employer Identification Number
EMTALA Emergency Medical Treatment and Active Labor Act
VIN Vehicle Identifier Number
ESRD End-stage renal disease
EPLS General Service Administration's Excluded Parties List System
FBI Federal Bureau of Investigation
FFP Federal Financial Participation
FFS Medicare fee-for-service program
FQHC Federally qualified health center
GAO Government Accountability Office
HHAs Home health agencies
HHS [Department of] Health and Human Services
HIO Health insuring organization
IAFIS Integrated Automated Fingerprint Identification System
ICF/MR Intermediate care facilities for persons with mental retardation
IDTF Independent diagnostic testing facility
IHCIA Indian Health Care Improvement Act
IHS Indian Health Service
IHSS In-home supportive services
IPF Inpatient psychiatric facility
IRF Inpatient rehabilitation facility
ISDEAA Indian Self-Determination and Education Assistance Act
LEIE List of Excluded Individuals/Entities
MCEs Managed care entities
MFCU Medicaid fraud control unit
MAO Medicare Advantage organizations
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
NASDAQ National Association of Securities Dealers Automated Quotation System
NF Nursing facility
NPI National Provider Identifier
NPPES National Plan and Provider Enumeration System
NSC National Supplier Clearinghouse
NTIS National Technical Information Service
NPDB National Practitioner Data Bank
NYSE New York Stock Exchange
OIG Office of Inspector General
OMB Office of Management and Budget
OPO Organ procurement organization
PAHP Prepaid ambulatory health plan
PECOS Provider Enrollment, Chain, and Ownership System
PIHP Prepaid inpatient health plan
PSC Program Safeguard Contractors
PTAN Provider transaction account number
RFA Regulatory Flexibility Act
RHC Rural health clinic
RNHCI Religious nonmedical health care institution
SEC Securities and Exchange Commission
SMP Senior Medicare Patrol
SNFs Skilled nursing facilities
SPIA State Program Integrity Assessment
SSA Social Security Administration
SSA DMF Social Security Administration Death Master File
SSN Social Security Number
TTAG Tribal Technical Advisory Group
WAN [FBI CJIS Division's] Wide Area Network
ZPIC Zone Program Integrity Contractors

Table of Contents

I. Background

The Medicare program (title XVIII of the Social Security Act (the Act)) is the primary payer of health care for 47 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or an organization qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations (*see*, for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act; and 42 CFR Chapter IV, subchapter G, which concerns standards and certification requirements).

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to ensure compliance with applicable statutes, as well as to promote the furnishing of high quality care. As Medicare program expenditures have grown, we have increased our efforts to ensure that only qualified individuals and organizations are allowed to enroll or maintain their Medicare billing privileges.

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program for eligible low-income individuals providing coverage to more than 51 million people. States have considerable flexibility in how they administer their Medicaid programs within a broad Federal framework and programs vary from State to State.

The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that provides health care coverage to more than 7.7 million otherwise uninsured children.

Historically, States, in operating Medicaid and CHIP, have permitted the enrollment of providers who meet the State requirements for program enrollment.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act or ACA) makes a number of changes to the Medicare and Medicaid programs and CHIP that enhance the provider and supplier enrollment process to improve the integrity of the programs to reduce fraud, waste, and abuse in the programs.

The following is an overview of some of the statutory authority relevant to enrollment in Medicare, Medicaid, and CHIP:

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program. Section 1102 of the Act also provides general authority for the Secretary to prescribe regulations for the efficient administration of the Medicaid program and CHIP.
- Section 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees including directors and officers of corporations and non-profit organizations and charities. The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.
- Section 936(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended the Act to require the Secretary to establish a process for the enrollment of providers of services and suppliers. We are authorized to collect information on the Medicare enrollment application (that is, the CMS–855, (Office of Management and Budget (OMB) approval number 0938–0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by title XVIII of the Act.
- Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the Medicaid State Plans with every person or institution providing services under the State plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for providing services under the State plan.
- Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions apply to States under title XXI, including 1902(a)(4)(C) of the Act, relating to conflict of interest standards.
- Section 1903(i)(2) of the Act relating to limitations on payment.
- Section 1124 of the Act relating to disclosure of ownership and related information.
- Sections 6401, 6402, 6501, and 10603 of the ACA and 1304 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended the Act by establishing: (1) Procedures under which screening is conducted for providers of medical or other services and suppliers in the Medicare program, providers in the Medicaid program, and providers in the CHIP; (2) an application fee to be imposed on providers and suppliers; (3) temporary moratoria that the Secretary may impose if necessary to prevent or combat fraud, waste, and abuse under the Medicare and Medicaid programs and CHIP; (4) requirements that State Medicaid agencies must terminate any provider that is terminated by Medicare or another State plan; (5) requirements for suspensions of payments pending credible allegations of fraud in both the Medicare and Medicaid programs.

II. Proposed Provisions and Responses to Public Comments

We received approximately 300 timely pieces of correspondence containing multiple comments on the Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers proposed rule published September 23, 2010 (75 FR 58204). We note that we received some comments that were outside the scope of the proposed rule. These comments are not addressed in this final rule with comment period. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule with comment period under the appropriate headings.

A. Provider Screening Under Medicare, Medicaid, and CHIP

1. Statutory Changes

Section 6401(a) of the ACA, as amended by section 10603 of the ACA, amends section 1866(j) of the Act to add a new paragraph, paragraph "(2) Provider Screening." Section 1866(j)(2)(A) of the Act requires the Secretary, in consultation with the Department of Health of Human Services' Office of the Inspector General (HHS OIG), to establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under Medicare, Medicaid, and CHIP. Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening to be conducted according to the risk of fraud, waste, and abuse with respect to the category of provider of medical or other items or services or supplier. The provision states that the screening shall include a licensure check, which may include such checks across State lines; and the screening may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse, include a criminal background check; fingerprinting; unscheduled or unannounced site visits, including pre-enrollment site visits; database checks, including such checks across State lines; and such other screening as the Secretary determines appropriate. Section 1866(j)(2)(C) of the Act requires the Secretary to impose a fee on each institutional provider of medical or other items or services or supplier that would be used by the Secretary for program integrity efforts including to cover the cost of screening and to carry out the provisions of sections 1866(j) and 1128J of the Act. We discussed the fee in section II.B. of the proposed rule.

Section 6401(b) of the ACA amends section 1902 of the Act to add new paragraph (a)(77) and (ii), which requires States to comply with the process for screening providers and suppliers as established by the Secretary under 1866(j)(2) of the Act.[1] Note that section 6401(b) of the ACA erroneously added a duplicate section 1902(ii) to the Act. Therefore, in the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309), the Congress enacted a technical correction to redesignate the section 1902(ii) of the Act added by section 6401(b) of ACA as section 1902(kk) of the Act. In this regulation, we therefore reference section 1902(kk) of the Act when referring to the provisions added by section 6401(b) of the ACA.

We noted in the proposed rule that the statute uses the terms "providers of medical or other items or services," "institutional providers," and "suppliers." The Medicare program enrolls a variety of providers and suppliers, some of which are referred to as "providers of services," "institutional providers," "certified providers," "certified suppliers," and "suppliers." In Medicare, the term "providers of services" under section 1861(u) of the Act means health care entities that furnish services primarily payable under Part A of Medicare, such as hospitals, home health agencies (including home health agencies providing services under Part B), hospices, and skilled nursing facilities. The term "suppliers" defined in section 1861(d) of the Act refers to health care entities that furnish services primarily payable under Part B of Medicare, such as independent diagnostic testing facilities (IDTFs), durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) suppliers, and eligible professionals, which refers to health care suppliers who are individuals, that is, physicians and the other professionals listed in section 1848(k)(3)(B) of the Act. For Medicaid and CHIP, we use the terms "providers" or "Medicaid providers" or "CHIP providers" when referring to all Medicaid or CHIP health care providers, including individual practitioners, institutional providers, and providers of medical equipment or goods related to care. The term "supplier" has no meaning in the Medicaid program or CHIP.

The new screening procedures implemented pursuant to new section 1866(j)(2) of the Act are applicable to newly enrolling providers and suppliers, including eligible professionals, beginning on March 25, 2011. These new procedures are applicable to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals beginning on March 23, 2012. These new screening procedures implemented pursuant to new section 1866(j)(2) of the Act are applicable beginning on March 25, 2011 for those providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information. Within Medicare, the March 25, 2011 implementation date will impact those current providers and suppliers whose 5-year revalidation cycle (or 3-year revalidation cycle for DMEPOS suppliers) results in revalidation occurring on or after March 25, 2011 and before March 23, 2012.

The requirements for revalidation are discussed in § 424.515. It is important to note that revalidation—for purposes of both provider enrollment in general and this final rule with comment period—does not include routine changes of information as described in § 424.516(d) and (e), such as address changes or changes in phone number.

2. Summary of Existing Screening Measures

Before we outline the new measures we are finalizing under the ACA, it may be helpful to provide a summary of some of the screening measures already being utilized in Medicare, Medicaid, and CHIP. Pursuant to other authority, but with the notable exception of background checks and fingerprinting, Medicare, generally through private contractors, already employs a number of the screening practices described in section 1866(j)(2)(B) of the Act to determine if a provider or supplier is in compliance with Federal and State requirements to enroll or to maintain enrollment in the Medicare program.

We also believe it important to note that nothing in this rule is intended to abridge our established screening authority under existing statutes and regulations or to diminish the screening that providers and suppliers currently undergo. To the contrary; the provisions specified in this final rule with comment period are intended to enhance our existing authority. This rule's provisions, in other words, set "floors"—not ceilings—on enrollment requirements for each screening level.

a. Licensure Requirements—Medicare and Medicaid

Over the past several years, we have taken a number of steps to strengthen our ability to deny or revoke Medicare billing privileges when providers or suppliers do not have or do not maintain the applicable State licensure requirements for their provider or supplier type or profession. We established reporting responsibilities for all providers, suppliers, and eligible professionals in earlier regulations at § 424.516(b) through (e). To ensure that only qualified providers and suppliers remain in the Medicare fee-for-service (FFS) program, we require that Medicare

[1] We believe that the reference to section 1886(j)(2) of the Act in section 6401(b)(1) of the ACA is a scrivener's error. We believe the Congress intended to refer to section 1866(j)(2) of the Act, which, as amended by section 6401(a) of the ACA, requires the Secretary to establish a process for screening providers and suppliers. Because the drafting error is apparent, and a literal reading of the reference to section 1886(j)(2) of the Act would produce absurd results, we interpret the cross-reference to section 1886(j)(2) in the new section 1902(kk) of the Act as if the reference were to section 1866(j)(2).

contractors review State licensing board data on a monthly basis to determine if providers and suppliers remain in compliance with State licensure requirements. Medicare billing privileges would be revoked for those providers and suppliers who do not report a final adverse action (for example, license revocation or suspension, felony conviction) within the applicable reporting period, as required in § 424.516(b) through (e). Medicare suppliers of DMEPOS and IDTFs are already subject to similar provisions in § 424.57(c) and § 410.33(g), respectively. DMEPOS suppliers are also subject to additional requirements including accreditation and surety bonding, pursuant to § 424.57(c)(22) through (26) and § 424.57(d).

Medicare Advantage organizations (MAOs) are required to verify licensure of providers and suppliers, including physicians and other health care professionals, in accordance with § 422.204.

For Medicaid and CHIP, most States do some checking of in-State provider licenses, but the extent of scrutiny varies. For example, in some States, the existence of the license may be verified, but little attention might be given to any restrictions on the license.

b. Site Visits—Medicare

Pursuant to § 424.517, Medicare conducts the following site visits and takes the following actions, generally through private contractors under CMS direction:

- The National Supplier Clearinghouse (NSC) Medicare Administrative Contractor (the Medicare contractor that processes enrollment applications for suppliers of DMEPOS) conducts pre-enrollment site visits to DMEPOS suppliers that are not associated with a chain supplier of DMEPOS (a chain supplier of DMEPOS is a supplier with 25 or more distinct practice locations.)
- The NSC also conducts unannounced post-enrollment site visits to DMEPOS suppliers for which CMS or the NSC believes there is a likelihood of fraudulent or abusive activities to ensure those DMEPOS suppliers remain in compliance with the supplier standards found at § 424.57(c). CMS at times exercises its right to—
- Have the NSC conduct ad hoc pre- and post-enrollment site visits to any DMEPOS supplier;
- Have Medicare contractors conduct pre-enrollment site visits to all IDTFs; and
- Conduct ad hoc pre-and post enrollment site visits to any prospective Medicare provider and supplier or any enrolled Medicare provider or supplier.

In addition, under 42 CFR parts 488 and 489, a State survey agency or an approved national accreditation organization with deeming authority conducts pre-enrollment surveys for certified providers and suppliers to determine whether they meet the applicable Federal conditions and requirements for their provider or supplier type before they can participate in the Medicare program.

We note that the site visits discussed here and elsewhere within this preamble and the final regulations are separate and apart from the site visits that are conducted pursuant to the Clinical Laboratory Improvement Amendments (CLIA). We will work with our State survey agency partners in coordinating these site visits so as to avoid duplication and burden on providers.

c. Database Checks—Medicare

Under existing regulation, Medicare contractors employ database checks of eligible professionals, owners, authorized officials, delegated officials, managing employees, medical directors, and supervising physicians (at IDTFs and laboratories) as part of the Medicare provider and supplier enrollment process. These include database checks with the Social Security Administration (SSA) (to verify an individual's SSN), the National Plan and Provider Enumeration System (NPPES) to verify the National Provider Identifier (NPI) of an eligible professional, and State licensing board checks to determine if an eligible professional is appropriately licensed to furnish medical services within a given State. These checks also include checking a provider or supplier against the HHS OIG's List of Excluded Individuals/Entities (LEIE) and the General Service Administration's Excluded Parties List System (EPLS). All of the database checks have been used to assess the eligibility and qualifications of providers and suppliers to enroll in the Medicare program, to confirm the identity of an eligible professional to ensure that he or she may be considered for enrollment in the Medicare program.

Also, on a monthly basis, CMS' Medicare contractors systematically compare enrolled providers, suppliers, and eligible professionals against the information in the Medicare Exclusions Database. The Medicare Exclusions Database identifies providers, suppliers, and eligible professionals who have been excluded from the Medicare and Medicaid programs by the HHS OIG. When a match is found, the HHS OIG exclusion information is systematically noted in the Medicare enrollment record of the provider, supplier, or eligible professional. In the Medicare program, we deny or revoke the billing privileges of providers, suppliers, and eligible professionals who have been excluded by the HHS OIG. If the HHS OIG lifts the exclusion, the provider, supplier or eligible professional must reapply for enrollment in the Medicare program. In addition, Medicare contractors also review State licensure Web sites on a monthly basis to ensure that eligible professionals continue to meet State licensing requirements.

In addition, since January 2009, we have compared date of death information obtained from the Social Security Administration Death Master File (SSA DMF) with the information maintained in the National Plan and Provider Enumeration System (NPPES), the system that assigns an NPI to individuals and organizations. Based on this comparison and the subsequent verification, we have deactivated the NPIs of more than 11,500 individuals who were previously assigned a type 1 (individual) NPI. We automatically transfer this information from NPPES to the Provider Enrollment, Chain, and Ownership System (PECOS), CMS' national Medicare enrollment repository to deactivate a deceased individual's Medicare billing privileges. In addition, Medicare contractors are required to review and act upon monthly files that contain a list of non-practitioner individuals enrolled in the Medicare program who have been reported to the SSA as deceased. These individuals include: Owners, authorized officials, and delegated officials.

MAOs, as required by § 422.204, generally use database checks to verify licensure and licensure sanctions and limitations with State licensing boards and the Federation of State Medical Boards, DEA certificates with the National Technical Information Service (NTIS), history of adverse professional review actions and malpractice from the National Practitioner Data Bank (NPDB), accreditation status of institutional providers and suppliers with national accrediting boards, such as The Joint Commission (TJC), and search for HHS OIG exclusions using the HHS OIG Web site *http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp*.

d. Criminal Background Checks—Medicare

Section 6401(a) of the ACA amended Section 1866(j) of the Act authorized the Secretary to perform criminal background checks. As described in § 424.530(a) and § 424.535(a), CMS or its

designated Medicare contractor may deny or revoke the Medicare billing privileges of the owner of a provider or supplier, a physician or non-physician practitioner, and terminate any corresponding provider or supplier agreement for a number of reasons, including an exclusion from the Medicare, Medicaid, and any other Federal health care program, a felony within the preceding 10 years that is considered detrimental to the Medicare program, and/or submission of false or misleading information on the Medicare enrollment application. While we require our Medicare contractors to verify data submitted on, and as part of, the Medicare provider/supplier enrollment application, our contractors are not able to verify information that may have been purposefully omitted or changed in a manner to obfuscate any previous criminal activity. A 2005 report issued by the National Task Force on the Criminal Backgrounding of America, sponsored by the Bureau of Justice Statistics and the U.S. Department of Justice, defined a Criminal History Record Check as a check that returns records from official criminal repositories (meaning State repositories and the Federal Bureau of Investigations (FBI) Interstate Identification Index that links Federal and State criminal record systems), and the FBI uses the same terminology. For purposes of responding to comments in this document we use the term criminal history record check to mean criminal background checks when referring to such fingerprint-based checks. Criminal History Record Checks have not been historically used in the FFS Medicare enrollment screening process.

e. Medicare MAO Requirements

As mentioned earlier in this section, MAOs already employ a number of screening procedures in accordance with regulations and CMS manual instructions. Specifically, under § 422.204(b)(3) in the case of providers meeting the definition of "provider of services" in section 1861(u) of the Act, basic benefits may only be provided through providers if they have a provider agreement with us permitting them to furnish services under original Medicare. With respect to other entities like suppliers, § 422.204(b)(3) requires that they "meet the applicable requirements of title XVIII and Part A of title XI of the Act." Given these requirements we considered to what extent MAOs would be required to apply the identical screening requirements we proposed for the original Medicare program or whether substantively similar alternative approaches adopted by MAOs would be acceptable. Accordingly, we solicited public comments on whether or to what extent MAOs should be required to implement the same enhanced screening requirements for providers, suppliers and physicians that we proposed for the original Medicare program.

f. Fingerprinting—Medicare

Previous to this final rule with comment period fingerprinting and fingerprint-based criminal history record information from the FBI was not used in the Medicare enrollment screening process.

g. Screening—Medicaid and CHIP

States vary in the degree to which they employ screening methods such as unscheduled and unannounced site visits and database checks, including such checks across State lines, criminal background checks, and fingerprinting. However, at least a few States utilize each of those methods.

States also varied in what they require their managed care entities (MCEs) [2] to do in terms of screening network-level providers that are not also enrolled in the Medicaid program as FFS providers. We considered to what extent States must require their MCEs to apply the identical screening requirements we proposed for the States or whether substantively similar alternative approaches adopted by MCEs are acceptable. Accordingly, we solicited public comments on whether or to what extent MCEs should be required to implement the same enhanced screening requirements for Medicaid and CHIP providers that we proposed for State Medicaid and CHIP programs.

We again stress that the provider enrollment verification tools that we are currently using—including, but not limited to, those described previously—will not in any way be diminished as a result of this final rule with comment period. In other words, the validation techniques in this rule do not supplant those that are presently in use.

[2] For purposes of this preamble and the final regulations, "managed care entity" and "MCE" will have the meaning Medicaid managed care organization (MCO), primary care case manager (PCCM), prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (PAHP), and health insuring organization (HIO). This definition differs from the meaning in section 1932(a)(1)(B) of the Social Security Act, which limits MCEs to Medicaid MCOs and PCCMs. We are using a more inclusive definition for the regulation so that all those entities in States' managed care programs will provide disclosure information.

3. General Screening of Providers—Medicare

a. Proposed Screening Requirements

Section 1866(j)(2)(B) of the Act requires the Secretary to determine the level of screening applicable to providers and suppliers according to the risk of fraud, waste, and abuse the Secretary determines is posed by particular provider and supplier categories.

In considering how to establish consistent screening standards, we proposed to designate provider and supplier categories that are subject to certain screening procedures based on CMS' assessment of fraud, waste and abuse risk of the provider or supplier category, taking into consideration a variety of factors. These factors include our own experience with claims data used to identify fraudulent billing practices as well as the expertise developed by our contractors charged with investigating and identifying instances of Medicare fraud across a broad spectrum of providers. In addition, CMS has relied on insights gained from numerous studies conducted by the HHS–OIG, GAO, and other sources. We have designated categories of providers or suppliers (for example, "newly enrolling DME suppliers" or "currently enrolled home health agencies") that are subject to screening procedures based on our assessment of the level of screening based on the risk presented by the category of provider. There are three levels of screening and associated risk: "limited," "moderate" and "high," and each provider/supplier category is assigned to one of these three screening levels. The categories described below and associated risk levels assigned are designed to identify those categories of providers and suppliers that pose a risk of fraud, waste, and abuse.

The screening procedures applicable to each screening level are set by us and are included in this final rule with comment period. Under this approach, the relevant Medicare contractor (for example, fiscal intermediary, regional home health intermediary, carriers, Part A or Part B Medicare Administrative Contractor (A/B MAC), or the NSC Administrative Contractor) would utilize the screening tools mandated by us for the screening level assigned to a particular provider or supplier category.

We solicited comments on the proposed assignment of specific provider and supplier types to the proposed risk screening levels, including what criteria should be considered in making such assignments, whether such assignments should be

released publicly, whether they should be subject to agency review and updated according to an established schedule (that is, annually, bi-annually), and the extent to which they should be updated according to evolving risks. We also solicited comments on any additional database checks that we should consider as a type of screening.

Based on the level of screening assigned, we proposed that the Medicare contractors would establish and conduct the following categorical screenings.

TABLE 1—PROPOSED SCREENING LEVELS AND PROCEDURES FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X
Conduct license verifications, (may include licensure checks across States)	X	X	X
Database Checks (to verify Social Security Number (SSN), the National Provider Identifier (NPI), the National Practitioner Data Bank (NPDB) licensure, an OIG exclusion; taxpayer identification number; tax delinquency; death of individual practitioner, owner, authorized official, delegated official, or supervising physician)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X

As described previously, we already require Medicare contractors to ensure that every provider or supplier meets any applicable Federal regulations or State requirements, including applicable licensure requirements [3] for the provider or supplier type prior to making an enrollment determination. In addition, we also require that Medicare contractors conduct monthly reviews of State licensing board actions to determine if an individual practitioner, such as a physician or non-physician practitioner continues to meet State licensing requirements. In the case of organizational entities, we also require our Medicare contractors to conduct monthly or periodic checks to determine if an organizational entity continues to meet the Federal and State requirements for its provider or supplier type. Such verifications help ensure that a prospective provider or supplier is eligible to participate in the Medicare program or that an existing provider or supplier is eligible to maintain its Medicare billing privileges.

Previous to this final rule with comment period, in the Medicare program, DMEPOS suppliers were required to re-enroll every 3 years, and other providers were required to revalidate their enrollment every 5 years. The terms revalidation and re-enrollment were often used interchangeably, but are actually specific to these provider types. To eliminate any confusion about which term applies to which provider or supplier, we proposed language at § 424.57(e) to change all references from re-enroll or re-enrollment to revalidate or revalidation. In addition, the ACA requires that no provider or supplier shall be allowed to enroll in Medicare or revalidate its enrollment in Medicare after March 23, 2013 without being screened pursuant to the authorities covered by this final rule with comment period. To assist us in assuring that the statutory effective date is met, we proposed at § 424.515 to permit us to require that a provider or supplier revalidate its enrollment at any time. After the revalidation, the current cycle for revalidation (3 years for DMEPOS, and 5 years for all other providers) would apply.

(1) Limited

Based on our own analysis of historical trends and our own experience with provider screening and enrollment we proposed that, as a category, the following providers and suppliers pose a limited risk to the Medicare program: Physician or non-physician practitioners and medical groups or clinics; providers or suppliers that are publicly traded on the NYSE or NASDAQ; ambulatory surgical centers (ASCs); end-stage renal disease (ERSD) facilities; Federally qualified health centers (FQHCs); histocompatibility laboratories; hospitals, including critical access hospitals (CAHs); Indian Health Service (IHS) facilities; mammography screening centers; organ procurement organizations (OPOs); mass immunization roster billers, portable x-ray suppliers; religious nonmedical health care institutions (RNHCIs); rural health clinics (RHCs); radiation therapy centers; skilled nursing facilities (SNFs), and public or government-owned ambulance services suppliers.

In § 424.518(a), we proposed that the following screening tools will apply to providers and suppliers in categories designated as limited risk: (1) Verification that a provider or supplier meets any applicable Federal regulations, or State requirements for the provider or supplier type prior to making an enrollment determination; (2) verification that a provider or supplier meets applicable licensure requirements; and (3) database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.

To assist readers in understanding the type of providers and suppliers that we proposed to include in the limited risk screening level, we are providing the following table.

TABLE 2—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "LIMITED" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Physician or non-physician practitioners and medical groups or clinics.
Providers or suppliers that are publicly traded on the NYSE or NASDAQ.

[3] We note that under section 408 of the reauthorized Indian Health Care Improvement Act, "[a]ny requirement for participation as a provider of health care services under a Federal health care program that an entity be licensed or recognized under the State or local law where the entity is located to furnish health care services shall be deemed to have been met in the case of an entity operated by the [Indian Health] Service, an Indian tribe, tribal organization, or urban Indian organization if the entity meets all the applicable standards for such licensure or recognition, regardless of whether the entity obtains a license or other documentation under such State or local law." 25 U.S.C. 1647e.

TABLE 2—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "LIMITED" CATEGORICAL RISK FOR SCREENING PURPOSES—Continued

Provider/supplier category
Ambulatory surgical centers, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, organ procurement organizations, mass immunization roster billers, portable x-ray supplier, religious non-medical health care institutions, rural health clinics, radiation therapy centers, skilled nursing facilities, and public or government-owned or -affiliated ambulance service suppliers.

(2) Moderate

Based on our experience, we proposed that community mental health centers (CMHCs); comprehensive outpatient rehabilitation facilities (CORFs); hospice organizations; independent diagnostic testing facilities (IDTFs); independent clinical laboratories; and non-public, non-government owned or affiliated ambulance services suppliers pose a moderate risk to the Medicare program. However, we provided that any such provider or supplier that is publicly traded on the NYSE or NASDAQ would be considered limited risk. Furthermore, we proposed that currently enrolled (revalidating) home health agencies would be considered "moderate" risk, except any such provider that is publicly traded on the NYSE or NASDAQ would be considered limited risk. Finally, we proposed that currently enrolled (re-validating) suppliers of DMEPOS pose a moderate risk, except that any such supplier that is publicly traded on the NYSE or NASDAQ would be considered "limited" risk. We provide our rationale for these categories in this section below.

For those provider and supplier categories in the "moderate" screening level, we proposed that Medicare contractors would conduct unannounced pre- and/or post-enrollment site visits in addition to those screening tools applicable to the limited level of screening. Based on the success of pre-and/or post enrollment site visits conducted by the NSC during the enrollment process for suppliers of DMEPOS and a similar process established by carriers and A/B MACs during the enrollment of IDTFs, we believe that unscheduled and unannounced pre-and post-enrollment site visits help ensure that suppliers are operational and meet applicable supplier standards or performance standards. In addition, we believe that unscheduled and unannounced pre-and post-enrollment site visits are an essential tool in determining whether a provider or supplier is in compliance with its reporting responsibilities, including the requirement in § 424.516 to notify the Medicare contractor of any change of practice location.

Moreover, § 424.530(a)(5) and § 424.535(a)(5) give us the authority to deny or revoke Medicare billing privileges for providers and suppliers if the provider or supplier is not operational or the provider does not maintain the established provider or supplier performance standards. And while we do not believe that unscheduled or unannounced site visits are necessary for all providers and suppliers, we do believe that a number of businesses, like the ones mentioned below, pose an increased risk to the Medicare program, due at least in part to the lack of individual professional licensure.

In addition, as discussed below, we have found that certain types of providers and suppliers that easily enter a line or business without clinical or business experience—for example, by leasing minimal office space and equipment—present a higher risk of possible fraud to our programs. As such, we believe that because these types of providers pose an increased risk of fraud they should be subject to substantial scrutiny before being permitted to enroll and bill Medicare, Medicaid, or CHIP. This type of pre-enrollment scrutiny will help us move away from the "pay and chase" approach.

Most of the provider and supplier categories in the moderate screening level are generally highly dependent on Medicare, Medicaid, or CHIP to pay their salaries and other operating expenses and are subject to less additional government or professional oversight than the providers and suppliers in the limited risk screening level. Accordingly, we believe it is appropriate and necessary to conduct unscheduled and unannounced pre-enrollment site visits to ensure that these prospective providers and suppliers meet our enrollment requirements prior to enrolling in the Medicare program. Moreover, we believe that post-enrollment site visits are also important to ensure that the enrolled provider or supplier remains a viable health care provider or supplier in the Medicare program.

Accordingly, we proposed in § 424.518(b) that in addition to the categorical screening tools used with respect to limited risk providers and suppliers, Medicare contractors would conduct unannounced and unscheduled site visits prior to enrolling the providers and suppliers assigned to the moderate risk screening level, as set forth earlier in this Section.

In the proposed rule, we set forth our rationale for the assessment of risk ascribed to the providers and suppliers assigned to the "moderate" level of screening. First, we noted that HHS OIG and GAO have issued studies indicating that several of the provider and supplier types cited previously pose an elevated risk of fraud, waste and abuse to the Medicare and Medicare programs and CHIP. In an October 2007 report titled, "Growth in Advanced Imaging Paid under the Medicare Physician Fee Schedule" (OEI–01–06–00260), the HHS OIG recommended that CMS consider conducting site visits to monitor IDTFs' compliance with Medicare requirements." In addition, in an April 2007 report titled, "Medicare Hospices: Certification and Centers for Medicare & Medicaid Services Oversight" (OEI–06–05–00260), the HHS OIG recommended that CMS seek legislation to establish additional enforcement remedies for poor hospice performance. In response to this recommendation, CMS stated that it was considering whether to pursue new enforcement remedies for poor hospice performance. While the Medicare enrollment process is not designed to verify the conditions of participation, we do believe that more frequent onsite visits may help identify those hospice organizations that are no longer operational at the practice location identified on the Medicare enrollment application.

In a January 2006 report titled, "Medicare Payments for Ambulance Transports" (OEI–05–02–000590), the HHS OIG found that "25 percent of ambulance transports did not meet Medicare's program requirements, resulting in an estimated $402 million in improper payments."

In an August 2004 report titled, "Comprehensive Outpatient Rehabilitation Facilities: High Medicare Payments in Florida Raise Program Integrity Concerns" (GAO–04–709), the GAO concluded that, "[s]izeable disparities between Medicare therapy payments per patient to Florida CORFs and other facility-based outpatient therapy providers in 2002—with no clear indication of differences in patient needs—raise questions about the appropriateness of CORF billing practices. After finding high rates of medically unnecessary therapy services to CORFs, CMS's claims administration

contractor for Florida took steps to ensure appropriate claim payments for a small, targeted group of CORF patients. Despite its limited success, billing irregularities continued among some CORFs and many CORFs continued to receive relatively high payments the following year. This suggests that the contractor's efforts were too limited in scope to be effective with all CORF providers."

In addition to GAO and HHS OIG studies and reports, a number of Zone Program Integrity Contractors (ZPIC) and Program Safeguard Contractors (PSC) used by CMS in helping to fight fraud in Medicare, have taken a number of administrative actions including payment suspensions and increased medical review, for the provider and supplier types shown previously. For example, the Zone 7 ZPIC contractor in South Florida has conducted onsite reviews at 62 CORFs since January 2010 and recommended revocation for 51 CORFs, or 82 percent of the CORFS in the area. The same contractor has conducted an onsite reviews at 38 CMHCs located in Dade, Broward, and Palm Beach County since January 2010, and recommended that 30 CMHCs be revoked for noncompliance (79 percent of the CMHCs in the area). In each instance where the ZPIC requested a revocation, the CMHC was also placed on prepay review. We have also conducted an analysis of IDTF licensure requirements and have found several circumstances that indicate irregularity and potential risk of fraud. Although independent clinical laboratories are subject to survey against CLIA requirements, there are nonetheless a number of potentials for fraud, not the least of which is the sheer volume of service and associated billing generated by these entities.

We believe that there is ample evidence to support the use of post-enrollment site visits as a reliable and effective tool to ensure that a current supplier of DMEPOS remains operational and continues to meet the supplier standards found in § 424.57(c). In a March 2007 report titled, "Medical Equipment Suppliers Compliance with Medicare Enrollment Requirements" (OEI–04–05–00380), the HHS OIG concluded that, "By helping to ensure the legitimacy of DMEPOS suppliers, out-of-cycle site visits may help to prevent fraud, waste, and abuse in the Medicare program. CMS may want to consider the findings of our study as they determine how and to what extent out-of-cycle site visits of DMEPOS suppliers will occur." Today, the NSC MAC utilizes post-enrollment site visits as the primary screening to determine ongoing compliance with the enrollment criteria set forth in § 424.57(c). Therefore, we have included currently enrolled DMEPOS suppliers in the "moderate" category.

We also noted that, in addition to the new screening measures proposed in the proposed rule under the existing regulation at § 424.517, a Medicare contractor may conduct an unannounced or unscheduled site visit at any time for any provider or supplier type prior to enrolling a prospective provider or supplier or for any existing provider or supplier enrolled in the Medicare program. While the primary purpose of an unannounced and unscheduled site visit is to ensure that a provider or supplier is operational at the practice location found on the Medicare enrollment application, a Medicare contractor may also verify established supplier standards or performance standards other than conditions of participation (CoP) subject to survey and certification by the State Survey agency, where applicable, to ensure that the supplier remains in compliance with program requirements.

To assist readers in understanding the type of providers and suppliers that we proposed to be in the "moderate" risk screening level, we are providing the following table.

TABLE 3—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "MODERATE" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; and non-public, non-government owned or affiliated ambulance services suppliers. (Except that any such provider or supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)
Currently enrolled (revalidating) home health agencies. (Except that any such provider that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)
Currently enrolled (re-validating) suppliers of DMEPOS. (Except that any such supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)

(3) High

For those provider and supplier categories assigned the "high" level of screening, we proposed that, in addition to the screening tools applicable to the limited and moderate level of screening, Medicare contractors would use the following screening tools in the enrollment process: (1) Criminal background check; and (2) submission of fingerprints using the FD–258 standard fingerprint card. (The FD–258 fingerprint card is recognized nationally and can be found at local, county or State law enforcement agencies where, for a fee, agencies will supply the card and take the fingerprints.) We proposed that these tools would be applied to owners, authorized or delegated officials or managing employees of any provider or supplier assigned to the "high" level of screening. We believe that criminal background checks will assist us in determining if such individuals submitted a complete and truthful Medicare enrollment application and whether an individual is eligible to enroll in the Medicare program or maintain Medicare billing privileges. We believe that this position is supported by testimony of the GAO before the subcommittees for Health and Oversight and Ways and Means within the House of Representatives on June 15, 2010, stating in part that "[c]hecking the background of providers at the time they apply to become Medicare providers is a crucial step to reduce the risk of enrolling providers intent on defrauding or abusing the program. In particular, we have recommended stricter scrutiny of enrollment processes for two types of providers whose services and items CMS has identified as especially vulnerable to improper payments—home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)."

In § 424.518(c)(1), we proposed that, unless they are publicly traded on the NYSE or NASDAQ, newly enrolling HHAs and suppliers of DMEPOS would be assigned to the high risk screening level. Based on our experience and on work conducted by the HHS OIG and the GAO, and because we do not have the monitoring experience with newly enrolling DMEPOS suppliers or HHAs that we have with those currently enrolled, we assigned these providers and suppliers to the "high" risk screening level. We are especially concerned about newly enrolling HHAs and suppliers of DMEPOS because of the high number of HHAs and suppliers of DMEPOS already enrolled in the Medicare program and program vulnerabilities that these entities pose to the Medicare program. Below is a list of HHS OIG and GAO reports identifying home health agencies and suppliers of DMEPOS as posing an elevated risk to the Medicare program.

- In a December 2009 report titled, "Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic

Areas in 2008" (OEI–04–08–00570), the HHS OIG recommended that CMS continue with efforts to strengthen enrollment standards for home health providers to prevent illegitimate HHAs from obtaining billing privileges.

• In a February 2009 report titled, "Medicare: Improvements Needed to Address Improper Payments in Home Health" (GAO–09–185), the GAO concluded that the Medicare enrollment process does not routinely include verification of the criminal history of applicants, and without this information individuals and businesses that misrepresent their criminal histories or have a history of relevant convictions, such as for fraud, could be allowed to enter the Medicare program. In addition, the GAO recommended that CMS assess the feasibility of verifying the criminal history of all key officials named on the Medicare enrollment application.

• In a February 2008 report titled, "Los Angeles County Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits" (OEI–09–07–00550) and in a March 2007 report titled, "South Florida Suppliers' Compliance with Medicare Standards: Results from Unannounced Visits (OEI–03–07–00150), the HHS OIG recommended that CMS strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards. The HHS OIG provided several options to implement this recommendation including: (1) Conducting more unannounced site visits to suppliers; (2) performing more rigorous background checks on applicants; (3) assessing the fraud risk of suppliers; and (4) targeting, monitoring, and enforcement of high risk suppliers.

• In a September 2005 report titled, "Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers" (GAO–05–656), the GAO concluded that,

> CMS is responsible for assuring that Medicare beneficiaries have access to the equipment, supplies, and services they need, and at the same time, for protecting the program from abusive billing and fraud. The supplier standards and NSC's gate keeping activities were intended to provide assurance that potential suppliers are qualified and would comply with Medicare rules. However, there is overwhelming evidence—in the form of criminal convictions, revocations, and recoveries—that the enrollment processes and the standards are not strong enough to thoroughly protect the program from fraudulent entities. We believe that CMS must focus on strengthening the standards and overseeing the supplier enrollment process. It needs to better focus on ways to scrutinize suppliers to ensure that they are responsible businesses, analogous to Federal standards for evaluating potential contractors.

We recognize that there may also be circumstances where a particular provider or supplier or group of providers and suppliers may pose a higher risk of fraud, waste, and abuse than the screening level assignment for their category assessed. Therefore, in § 424.518(c)(3), we proposed specific criteria that we would use to adjust the classification of a provider or supplier into a higher risk screening level than would generally apply to the entire category of provider or supplier, in order to address specific program vulnerabilities. We solicited comments on specific additional circumstances that might justify shifting a provider or supplier into a higher screening level than would generally apply to its category. We also solicited comments on the criteria that we could use to shift the screening level back down.

In § 424.518(c)(3)(i), we proposed to adjust a provider or supplier from the limited or "moderate" risk screening level to the "high" risk screening level when we have evidence from or concerning a physician or non-physician practitioner that another individual is using his or her identity within the Medicare program. In § 424.518(c)(3)(ii) and (iii), which in this final rule with comment period has been redesignated § 424.518(c)(3)(i) and (ii), we proposed to adjust a provider or supplier from the "limited" or "moderate" level of screening to the "high" screening level when: The provider or supplier has been placed on a previous payment suspension within the previous ten years; or the provider or supplier has been excluded by the HHS OIG or had its Medicare billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges for a new practice location or by enrolling as a new provider or supplier. In addition, we believe that providers that have been terminated or otherwise precluded from billing Medicaid should be adjusted from the "limited" or "moderate" screening level to the "high" screening level. We believe that such providers or suppliers pose an elevated level of risk to the Medicare program.

In § 424.518(c)(3)(iv), redesignated in this final rule with comment period as § 424.518(c)(3)(iii), we proposed to adjust providers or suppliers from the "limited" or "moderate" level of screening to the "high" level of screening for 6 months after we lift a temporary moratorium (*see* section II.C. of this final rule with comment period) applicable to such providers or suppliers. This would include providers and suppliers revalidating their enrollment if the moratorium is applicable to the provider or supplier type. We solicited comments on criteria that would justify reassignment of providers or suppliers from the "limited" or "moderate" screening level to the "high" screening level. We also solicited comments on criteria appropriate to the reassignment from "high" to "moderate" screening levels or "limited" screening levels. We also solicited comment on the applicability of geographical circumstances as a possible criterion for adjusting providers or suppliers from one screening level to another. We also solicited comment on whether non-practitioner owned facilities and suppliers should be subject to a higher level of screening than their practitioner-owned counterparts or, whether there is an appropriate corresponding trigger for non-practitioner owned facilities and suppliers. We solicited comment on whether providers and suppliers should be subject to higher levels of screening when the provider specialty does not match clinic type on an enrollment application. We solicited comment on what objective conditions might support a broad set of circumstances or factors that would allow us to determine that provider screening levels by risk should be based on "other conditions or factors that CMS determines are necessary to combat fraud, waste, and abuse."

We solicited public comment on the appropriateness of using criminal background checks in the provider enrollment screening process, including the instances when such background checks might be appropriate, the process of notifying a provider, supplier or individual that a criminal background check is to be performed, and the frequency of such checks.

We solicited comment on the use of fingerprinting as a screening measure in our programs. We recognized that requesting, collecting, analyzing, and checking fingerprints from providers and suppliers are complex and sensitive undertakings that place certain burdens on affected individuals. There are privacy concerns and operational concerns about how to assure individual privacy, how to check fingerprints against appropriate law enforcement fingerprint databases, and how to store the results of the query of the data bases and also how to handle the subsequent analysis of the results. As a result, we solicited comments on how CMS or its contractor should maintain and store fingerprints, what security processes

and measures are needed to protect the privacy of individuals, and any other issues related to the use of fingerprints in the enrollment screening process. We were interested in comments on possible circumstances in which fingerprinting would be potentially useful in provider screening or other fraud prevention efforts. Our proposed screening approach contemplated requesting fingerprints from providers and suppliers designated as presenting a "high" risk of fraud. We solicited comment on this requirement, the circumstances under which it is appropriate, limitations on its use and any alternatives to the proposed approach regarding fingerprints. Our proposed approach allowed denial of billing privileges to newly enrolled providers and suppliers and revocation of billing privileges for revalidating providers and suppliers if owners or officials of providers or suppliers refused to submit fingerprints when requested to do so. We solicited comments on this proposal including its appropriateness and utility as a fraud prevention tool. In addition, we also solicited comment on the applicability and appropriateness of using, in addition to or in lieu of fingerprinting, other enhanced identification techniques and secure forms of identification including but not limited to other biological or biometric techniques, passports, United States Military identification, or Real ID drivers licenses. As technology and secure identification techniques change, the tools we use may change to reflect improvements or shifts in technology or in risk identification. We solicited comment on the appropriate uses of these techniques.

We noted that any physician or non-physician practitioner or organizational provider or supplier that is denied enrollment into the Medicare program or whose Medicare billing privileges are revoked is afforded due process rights under § 405.874.

To assist readers in understanding the type of providers and suppliers that we proposed to include in the "high" risk screening level, we are providing the following table.

TABLE 4—PROPOSED MEDICARE PROVIDERS AND SUPPLIERS DESIGNATED AS A "HIGH" CATEGORICAL RISK FOR SCREENING PURPOSES

Provider/supplier category
Prospective (newly enrolling) home health agencies and suppliers of DMEPOS. (Except that any such provider or supplier that is publicly traded on the NYSE or NASDAQ is considered "limited" risk.)

The new screening procedures implemented pursuant to new section 1866(j)(2) of the Act will be applicable to newly enrolling categories providers and suppliers beginning on March 25, 2011. These new screening procedures will also be applicable beginning on March 25, 2011 for those providers and suppliers currently enrolled in Medicare, Medicaid, and CHIP who revalidate their enrollment information. For Medicare, this will impact those providers and suppliers whose revalidation cycle results in revalidation occurring between March 25, 2011 and March 23, 2012. Finally, these new procedures will be applicable to currently enrolled Medicare, Medicaid, and CHIP providers and suppliers beginning on March 23, 2012, in accordance with section 1866(j)(2)(ii) of the Act. As such, some providers and suppliers may be required to revalidate their enrollment outside of their regular revalidation cycle. However, the additional screening procedures for categories and individuals in the high level of screening, namely, as discussed below, fingerprint-based criminal history record checks, will be implemented 60 days following the publication of subregulatory guidance.

b. Analysis of and Responses to Public Comment on Medicare Screening Categories

Below is a summary of the comments we received regarding the screening categories and the validation activities contained within each category.

Comment: Several commenters expressed concern that we differentiated between publicly traded and non-publicly traded entities. Many commenters stated that CMS did not specify how publicly traded companies were any less of a fraud risk than companies that are not publicly traded. Several commenters suggested this distinction was arbitrary and without merit. One commenter stated that being publicly traded does not offer immunity from risk, and that having one set of standards for all providers will make it easier for governments, providers and consumers to identify and address fraud and abuse. One trade association argued that it preferred an approach that would elevate its members into a higher risk screening level than to distinguish among its members based upon whether a particular entity was publicly traded. Another commenter suggested that CMS withdraw its proposal; and requested that if CMS decides to implement it, it should provide the data analysis it used in creating this policy choice and explain why large privately held companies are a greater risk than publicly traded companies.

Response: We agree with the arguments the commenters made regarding distinguishing among screening levels based on a provider or supplier's publicly traded status, and thus we have eliminated the distinction between publicly traded and non-publicly traded companies for purposes of the screening levels. While it has been our general experience that publicly traded companies have not posed the elevated risk of fraud, waste or abuse as non-publicly traded companies, we do not believe the risk differential between publicly traded and non-publicly traded entities is such as to warrant the automatic assignment of the former into a lesser screening level.

Comment: Similar to the distinction between publicly traded versus non-publicly traded, several comments suggested that the distinction between government-owned or affiliated versus non-government owned or affiliated ambulance service suppliers was not based on any evidence. One commenter stated that CMS furnished little or no supporting data for the position that publicly owned companies pose less of a risk. Another commenter contended that this distinction presented challenges that would make it difficult for states to operationalize. Another commenter believes that the distinction is arbitrary, and noted that private ambulance companies are, like public companies, held to the same strict standards, such as the need for them and their personnel to be State-licensed. The commenter added that there is no evidence to support the assertion that private ambulance services pose a greater risk of fraud, waste or abuse than public companies, and that the OIG report referred to in the proposed rule entitled "Medicare Payments for Ambulance Transports" (OEI–05–02–000590) did not single out private ambulance services as posing such a risk. Another commenter was concerned that assigning private ambulance companies to a higher screening level could put them at a competitive disadvantage vis-à-vis their public counterparts.

Response: We disagree that this distinction would be difficult to operationalize. The enrollment process generally captures information on the supplier's ownership; this enables contractors and States to distinguish between government-owned and non-government owned entities. However, we do agree with the arguments made regarding the use of public ownership as a criterion for making a distinction in the level of screening as determined by the risk of fraud, waste or abuse posed to the programs, and we have eliminated the distinction between government-owned and non-government owned ambulance companies for purposes of the screening level assignments. The available evidence does not suggest that the risk differential between government-owned and non-government owned ambulance companies is such as to warrant the automatic placement of the former into a lower screening level. Moreover, we note that the ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by a categorical assessment of the risk of fraud, waste or abuse to the programs—rather than assessing individual's risk—is consistent with the requirements of the statute. While we believe that a more nuanced and precise approach for classifying specific categories of providers and suppliers into screening levels, for example using a scoring algorithm to create categories, could also be consistent with the statute under certain circumstances and were we able to provide an adequate rationale for the classification, we do not yet have experience with such an approach, and are therefore finalizing an approach based on classifications by entire provider and supplier types. We may consider additional classifications in future rulemaking.

Comment: A commenter supported CMS's designation of provider fraud and abuse risk into three levels for Medicare, Medicaid, and CHIP providers, and stated that CMS appropriately assigned hospitals (including critical access hospitals) to the limited level.

Response: We appreciate this commenter's support.

Comment: A commenter expressed support for CMS's proposal to move a provider type from one screening level to another only if it has been found by CMS to pose more or less of a fraud and abuse risk. However, the commenter suggested, that CMS: (1) Review a provider class over pre-prescribed time periods (for example, 24 months), and (2) allow sufficient time for the provider community to offer comment prior to changing a provider's screening level.

Response: Our proposal to reassign providers or suppliers or provider or supplier types to another level of screening was based on changes in circumstances that contribute to the risk of fraud. We believe that to restrict ourselves to reassigning providers and suppliers only at specific, pre-defined time intervals would not provide us with the flexibility we need to quickly address emerging program integrity risks. If a situation arose where there was an immediate risk of fraud that required the imposition of enhanced screening procedures, we must be able to deal with it rapidly, rather than wait until a particular prescribed time interval arrives. We will periodically reexamine screening level classifications for provider and supplier categories. Should a change in a particular provider or supplier type's assignment be warranted and should it necessitate a change in existing regulatory language, we will publish notice of the change in the **Federal Register**.

Comment: A commenter expressed support for CMS' inclusion of physicians, non-physician practitioners, and medical groups or clinics in the limited screening level. The commenter stated that these suppliers submit the CMS–855I to enroll in Medicare and are subject to all of the penalties listed in Section 14 of CMS–855I regarding falsifying information.

Response: We appreciate the commenter's support.

Comment: A commenter requested that CMS consider moving CMHCs and CORFs from the "moderate" screening level to the "limited" screening level. With respect to CORFs, the commenter stated that CMS' studies regarding program integrity concerns have been limited to the State of Florida, and contended that it is arbitrary to extrapolate that experience to the rest of the country.

Response: We disagree with the commenter's assessment of the risk of fraud associated with CMHCs and CORFs. These risks extend beyond any single region of the country. As a result we have decided to keep these provider types assigned to the moderate level of screening. We believe that the assignment of CMHCs and CORFs into the moderate screening level was appropriate based on the information we presented in the proposed rule.

Comment: A commenter expressed support for background checks and fingerprinting, but requested that they be limited to only providers and suppliers assigned to the high risk level because of the potential administrative burden.

Response: The final rule with comment period is clear that fingerprint-based criminal background checks are only applicable to providers and suppliers assigned to the high screening level.

Comment: A commenter stated that CMS, in listing various provider types and the levels of risk into which they were assigned, did not provide the documentation on which it based its conclusions, therefore violating the Administrative Procedure Act. The commenter recommended that CMS furnish the following information by provider/supplier type to justify its conclusions and to inform the public as to why certain providers are a limited risk to the Medicare program: (1) Number of Medicare revocations; (2) number of Medicare deactivations; (3) Medicare payment suspensions; (4) Medicare civil monetary penalties; (5) OIG mandatory exclusions; (6) OIG permissive exclusions; (7) indictments; and (8) felony convictions.

Response: We based our risk assessments on a variety of factors, including some of those listed by the commenter, as well as others. However, because our conclusions were not based on any one factor nor any specific combination of factors, but rather on CMS's aggregate experience with each provider and supplier type, providing the data requested by the commenter would not serve to clarify the determinations of risk.

Comment: Several commenters stated that CMS did not describe how it will screen providers and suppliers with a designated "other" category, or which types of providers and suppliers fall within this category and how many there are. One commenter stated that providers and suppliers in the "Other" category should be assigned to the high risk level.

Response: The "other" category is largely reserved for future situations in which a statute is enacted that authorizes a particular provider or supplier type to bill the Medicare program; it is designed as a placeholder of sorts pending the revision of the CMS–855 application to accommodate the new provider or supplier type. Since we cannot predict which new provider or supplier types may be able to bill Medicare in the future, we are unable to assign them to a particular screening level in this final rule with comment period.

Comment: Several commenters stated that CMS did not explain which risk level outpatient physical therapy/occupational therapy (PT/OT), speech pathology, and rehabilitation agencies would fall into.

Response: We received a number of comments on this issue. We will assign occupational therapists, speech language pathology, and rehabilitation agencies to the "limited" level of risk because we do not have evidence of program integrity risk that suggest that these entities should be assigned to the moderate or high levels of screening. However, we will assign physical therapists (including physical therapy groups) to the moderate screening level. We believe this classification is supported, in part, by a recent OIG report entitled "Questionable Billing for Medicare Outpatient Therapy Services" (December 2010) (*http://oig.hhs.gov/oei/reports/oei-04-09-00540.pdf*), which found, among other things, that Miami-Dade County had three times, and nineteen other counties had at least twice, the national level on five of six questionable billing characteristics. Law enforcement has also identified fraudulent billing schemes involving physical therapy.

Comment: One commenter stated that CMS did not describe how it would screen new providers or suppliers types permitted to enroll in Medicare. Since CMS excluded these providers and suppliers from its discussion, the commenter recommended that these entities be considered a high risk.

Response: Since we cannot predict which new provider or supplier types may be able to bill Medicare in the future, we are unable to assign them to a particular screening level in this final rule with comment period. When such entities emerge, we will make an appropriate determination based on the data sources we have already described in this final rule with comment period, as to what screening level assignment is most appropriate for such new entities. As previously discussed, we will publish notice of these new provider category assignments in the **Federal Register** prior to making final any such assignment.

Comment: One commenter recommended that non-physician owned medical facilities and groups be considered a higher risk than physician-owned medical facilities.

Response: In the proposed rule, we solicited comments on whether non-practitioner owned facilities and suppliers should be subject to a higher level of screening than practitioner-owned facilities and suppliers. We received several comments suggesting that the former category should be subject to higher screening than the latter. We are declining to adopt this suggestion in this final rule with comment period, however. As previously stated, the ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to risk levels that determine screening requirements—rather than determining individual risk—is consistent with the statute.

Comment: Several commenters stated that extending the enhanced screening requirements to MAOs will prove duplicative and unnecessarily increase costs for providers. Identifying those providers participating in multiple health programs and coordinating their screening and monitoring could, the commenters contended, avoid unnecessary administrative burden for all involved. Otherwise, by extending the screening requirements to MAOs, providers will be forced to undergo the same screening process multiple times, for each MAO with whom they contract. One commenter stated that it would be more efficient for CMS and the States to perform the screenings and make that data available to the MAO plans through a centralized process. Another commenter recommended that fingerprinting and background checks be restricted to State and Federal law enforcement agencies, adding that there is no legitimate purpose for MA or Medicare managed care plans to collect and maintain this information.

Another commenter opposed applying the proposed requirements to MAOs and other managed care organizations (MCOs) for several reasons. First, there are already appropriate screening tools for MAOs for their providers and suppliers pursuant to § 422.204(b)(3). Second, MAOs have other requirements, as established in § 422.204, to access certain data bases to verify licensure, licensure sanctions and other limitations. Third, traditional Medicare has a greater population to serve and a wider network of providers and suppliers to process and screen than individual MA plan networks. Therefore, the processes should stem from those with oversight and administration of traditional Medicare, with a trickledown effect and benefit for MAOs. Fourth, if a limited, moderate or high risk provider has an enrollment verification letter from Medicare issued after March 25, 2011, the provider has been appropriately credentialed and needs no further credentials for a MAO. Fifth, Medicare's enrollment application captures certain elements that are not currently captured by some insurers' enrollment applications, such as delegated representative, authorized representative, and owners. This information would be difficult to capture and verify, and the workload would increase substantially on the part of MCOs to credential numerous individuals who may not have a significant role within the providers/supplier entity.

Response: Because there are a large number of other regulatory provisions that form the framework for oversight of managed care plans, and we do not want to duplicate these requirements by imposing additional screening and enrollment criteria on these organizations, we have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter stated that MCOs design their anti-fraud initiatives based on the risks they encounter, which may be unique and different from the risks faced by FFS programs. Consequently, CMS should give MCOs the flexibility to decide whether to adopt any of the proposed new screening requirements and, if so, how to do so; CMS should not extend the screening requirements to MCOs. The commenter stated that MCOs should be allowed to: (1) Assign providers and suppliers to a level that is higher or lower than the level assigned by Medicare FFS or the State FFS Medicaid programs, and (2) deem a provider as having satisfied its screening requirements if the provider is enrolled in Medicare FFS and/or a Medicaid FFS program, and has gone through their screening procedures.

Response: As explained previously, we are concerned that the application of the screening provisions to MCOs would duplicate existing oversight and regulatory authority. We therefore have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations. This will, as the commenter suggests, allow MCOs to develop provider screening requirements that are unique to their circumstances, including (1) assign providers and suppliers to a level that is higher or lower than that assigned by Medicare or the State Medicaid program, and (2) deem a provider as having satisfied their screening requirements if the provider is enrolled in Medicare and/or a State Medicaid program.

Comment: A commenter stated that applying consistent risk management

practices throughout an organization fosters a culture of program integrity. As such, the commenter recommended that MAOs be required to implement the same enhanced screening processes that CMS is considering for the original Medicare program.

Response: As mentioned earlier, we have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter recommended that CMS explain what type of screening process will be used for Medicare Advantage, managed care organizations or health maintenance organizations.

Response: As previously stated, there are a large number of other regulatory provisions that form the framework for oversight of managed care plans. We do not want to duplicate these requirements by imposing additional screening and enrollment criteria on these organizations. We therefore have decided not to apply the provisions of this final rule with comment period to managed care plans and organizations.

Comment: A commenter recommended that CMS establish screening criteria for slide preparation facilities and competitive acquisition program/Part B vendors.

Response: We will not be establishing screening criteria or prescribing screening levels for slide preparation facilities in this final rule with comment period. Slide preparation facilities do not enroll in Medicare at this time; thus, we do not believe it is appropriate to assign a level of screening to such entities. As for competitive acquisition program/Part B vendors, these will be assigned to the limited screening level. It has not been our experience that this supplier type poses an elevated risk of fraud, waste or abuse to the Medicare program.

In addition, we are adding portable x-ray suppliers to the moderate screening level. In support of this classification, we note that the OIG has analyzed Medicare claims data to identify suppliers with questionable billing patterns. The unusual claims patterns that were found raise concerns about the integrity of payments to certain portable x-ray suppliers. Based on this, and combined with the fact that there are low barriers to entry for this type of supplier, portable x-ray suppliers will be placed in the moderate screening level.

Comment: A commenter recommended that CMS establish higher levels of screening when: (1) A provider or supplier changes ownership on a frequent basis; (2) a physician or non-physician practitioner is enrolled in different States; (3) a physician has a large number of reassignments or when reassignments cross States; (4) a physician is engaging or billing in a reciprocal billing or locum tenens billing arrangement; (5) owners have businesses in different States; and (6) when owners establish banking relationships in different States from where their practice is located.

Response: In the proposed rule, we sought comment on what factors should permit us to elevate an individual provider or supplier to a higher level of screening. We appreciate the commenter's suggestion. While we are not adopting these recommendations at this time, such suggestions may form the basis of future rulemaking. We would first like to evaluate how the factors we will finalize as part of this rule will work prior to adopting new factors such as the ones the commenter has identified.

Comment: One commenter recommended that CMS assign to the higher screening level any owner or physician who had an final adverse action within the previous 10 years; has an unrepaid overpayment with Medicare, Medicaid or CHIP; has a Medicare or Medicaid payment suspension; exclusion or debarment; a felony conviction; unpaid taxes; or a Medicare revocation. Another commenter stated that in Table 1, CMS appears not to consider previous payment suspensions, overpayments, OIG exclusions, or Medicare revocations in establishing higher risk levels. The commenter recommended that CMS explain why such actions are not an indicator of higher program risk and the need for enhanced screening.

Response: As in the proposed rule, we state in § 424.518(c) of the final rule with comment period that a provider or supplier will be moved from the "limited" or "moderate" category to the "high" level if it has been excluded by the OIG, or has had its Medicare billing privileges revoked in the previous ten years. We have added in the final rule with comment that a provider or supplier that has been subject to any final adverse action as defined at § 424.502 would also be moved to the high level of screening. With regard to these commenters' other proposals, we are generally supportive of them, and may examine the possibility of future rulemaking to include some of them as factors that may elevate a provider or supplier to a higher level of risk. As previously mentioned, however, we would first like to evaluate how the factors we will finalize as part of this rule will work prior to adopting new factors.

Comment: A commenter recommended that CMS propose a definition for the term "tax delinquency," as it is used in Table 1 of the proposed rule, and clarify whether the term refers to Federal, State and/or local taxes.

Response: We have removed tax delinquency from the list of database checks in this final rule with comment period. Though we do have new authorities to obtain tax information as part of ACA and other recently enacted statutes, we are not prepared to operationalize this provision at this time.

Comment: A commenter stated that CMS' categorical risk approach did not address the individual risk associated with certain owners and individual practitioners. The commenter recommended that CMS issue a new proposed rule to establish specific risk factors would increase/decrease a provider or supplier's screening level.

Response: The ACA requires levels of screening according to the risk of fraud, waste and abuse posed by categories of providers and suppliers. The approach taken in the final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by risk of fraud, waste and abuse is consistent with the requirements of the statute. Furthermore, we believe the approach taken in this final rule with comment period is objective and allows us to avoid subjective assessments of a provider's or supplier's risk to the programs.

Comment: A commenter supported the use of background checks to ensure the identity and integrity of owners and senior managers of home health and hospice agencies. While supporting the maintenance of the confidentiality of this information, the commenter believes it should be used to: (1) Target agencies for special oversight, (2) alert owners of patterns of criminal behavior on the part of their managers, and (3) disqualify owners or managers that have criminal histories.

Response: We intend to use this tool in a way that safeguards personal information and also helps prevent fraud, waste and abuse. The criminal history record will verify whether a provider, supplier, or an individual with a 5 percent or greater direct or indirect ownership interest in such provider or supplier has been convicted of certain types of felonies that could result in the denial or revocation of billing privileges under § 424.530 or § 424.535, respectively. We believe that

criminal history record checks will confirm the accuracy of information submitted in enrollment applications, and the discovery of false or misleading information could result in denial or revocation of billing privileges under § 424.530 or § 424.535. Providers or suppliers who have been denied on these bases are afforded all applicable appeals rights.

While in some instances, such a denial may result in alerting a provider or supplier of an individual's criminal history, this is not the purpose or intention of this enrollment screening tool. Rather we will use this authority for the purpose of verifying eligibility for Medicare enrollment. We will disseminate guidance and instructions to providers, suppliers and our enrollment contractors shortly after the publication of this final rule with comment period regarding the implementation of the criminal history record check requirement.

Comment: A commenter opposed the proposal to move those who have previously been placed on a payment suspension or subject to a denial or revocation in the past year, into a higher screening level. The commenter stated that a payment suspension may be imposed upon a mere or false suspicion of wrongdoing, and that the denial or revocation could have been based on an innocent mistake.

Response: We agree with this commenter with respect to the denial of billing privileges. Many denials occur simply because the provider does not meet the requirements to enroll as a particular provider type or other clerical errors. We have therefore removed the denial of billing privileges as a basis for moving a provider or supplier into a higher risk screening level. We have retained revocations of Medicare billing privileges as such a basis because we believe that such a provider poses a heightened risk of fraud, waste or abuse to the Medicare Trust Fund.

Payment suspension is used as a fraud fighting tool only in instances where facts available point to possible fraud, waste, or abuse. Consequently, because of the risk to the program posed by individuals and entities upon which a payment suspension has been imposed, we believe we are justified in placing them in the high risk screening level.

Comment: One commenter suggested that in lieu of fingerprinting, each owner or physician should submit: (1) A U.S. Passport or a Foreign Passport with their enrollment application, and/or (2) copies of their Federal Tax Returns.

Response: We agree with the commenter that there may be alternatives to fingerprint-based criminal history record checks to verify identity; however information on U.S. or foreign passports and Federal Tax Returns, such as name, date of birth and Social Security number are duplicative of information that is captured in the Medicare enrollment application. Information that would be obtained from a U.S. or foreign passport or Federal Tax Returns could only be used to process a name-based criminal history record check, and the FBI does not process name-based requests for non-criminal justice purposes. The submission of fingerprints is the only way to obtain a criminal history record check from the FBI.

Additionally, the National Task Force on the Criminal Backgrounding of America concluded that fingerprint-based criminal history record checks are more accurate than name-based checks because "names tend to be unreliable because: people lie about their names; obtain names from false documents; change their names; people have the same name; people misspell names; people use different versions of their names * * * people use aliases * * *" The suppliers assigned to the high screening level have been so assigned because, in CMS, and its law enforcement partners' experience, such supplier types have, as a category, not undergone sufficient scrutiny in the enrollment process. Some may have gained entry in the past through falsification of an enrollment application that may have passed a name based check. As a result, the extra level of screening provided by the submission of fingerprints for the purposes of an FBI database check has the potential to deny enrollment to individuals whose sole intent is to defraud the Medicare program. We believe fingerprint-based criminal history record checks will be an effective tool to prevent fraud, waste, and abuse in Federal health care programs by independently verifying information provided on applications of potential providers and suppliers in the high screening level.

If, after a sufficient period of evaluation, we conclude that fingerprint-based FBI criminal history record checks do not fulfill our program integrity objective of identifying applicants who pose a heightened risk of fraud, waste, and abuse prior to enrollment or we determine that supplementary actions are needed, we may pursue additional rulemaking that seeks to adopt alternative or additional safeguards consistent with authorities given to the Secretary in the ACA.

Comment: A commenter stated the screening process described by CMS does little to ensure that a provider or supplier is submitting legitimate claims for eligible individuals, since there is no linkage between the enrollment process and claim submission process. The commenter contended that it did not appear that CMS considered the alternative approach of linking its proposed screening requirements to section 1866(j)(3) of the Act. The commenter recommended that CMS establish a link between the screening process and the payment process by establishing payment caps and prepayment claims review as described in section 1866(j)(3) of the Act.

Response: The commenter references new section 1866(j)(3) of the Act, which addresses a provisional period of enhanced oversight for new providers or suppliers of services. We believe that the payment caps and prepayment claims processes should supplement, but not be used in lieu of, the procedures outlined in this proposed rule. Payment caps and prepayment claims processes will be addressed in separate vehicles. Clearly, the provisions of section 1866(j)(3) of the Act are an important complement to the pre-enrollment screening provisions in this rule. We intend to use both to fight fraud. However, this provision is not part of this final rule with comment period. In fact, the ACA authorizes the Secretary to implement the provisions of section 1866(j)(3) of the Act through instruction or otherwise.

Comment: A commenter contended that with respect to the limited risk screening requirements, the language in proposed § 424.518(a)(2)(i) may be overly broad. The commenter believes the intent of this provision is for the contractor to verify that the provider or supplier meets only the applicable regulations or requirements that qualify it for the appropriate provider or supplier type. However, the commenter stated that, as written, § 424.518(a)(2)(i) could be construed to require the Medicare contractor to verify the provider or supplier's compliance with virtually every Federal regulation and State requirement that applies to the provider or supplier type. This, the commenter argued, could subject limited categorical risk providers and suppliers to an overly broad, burdensome, and time-consuming verification process.

Response: As explained in the proposed rule, the verification process for limited risk providers and suppliers will be that which is currently used for most providers and suppliers. The verification will be limited to enrollment requirements, and will not examine compliance with all other State

and Federal regulations unless the other State and Federal regulations have an impact on whether the provider or supplier meets the requirements for enrolling or revalidating enrollment in Medicare. The table that describes the types of screening to be performed for each of the three screening levels explains clearly the kinds of verification processes that CMS contractors will be using to verify a provider's or supplier's eligibility to enroll or remain enrolled in Medicare.

Comment: One commenter requested that CMS explain why it did not consider compliance plans in establishing its screening criteria.

Response: We solicited comments regarding the use of compliance plans in combating fraud, waste, and abuse. Because there are a several complex policy and implementation issues we are pursuing separate additional rulemaking in this area.

Comment: One commenter stated that CMS did not include a discussion of low quality of care when it established its screening criteria.

Response: Quality of care is the subject of several other CMS regulations. Accordingly, we did not include quality consideration in our development of levels of categorical screening. We believe that the factors we included in the proposed rule for establishing the screening criteria support our classifications.

Comment: A commenter recommended that CMS increase the level of screening for any provider using a billing agent or clearinghouse convicted of health care fraud. The commenter also recommended that, similar to the provisions found in section 6503 of the ACA, CMS establish enrollment standards for clearinghouses and billing agents for Medicare. CMS, the commenter stated, mentioned in the proposed rule that "based on our data analysis including analysis of historical trends and CMS' own experience with provider screening and enrollment we believe the following providers and suppliers pose a limited risk." The commenter also recommended that CMS furnish the data analysis used to assign each provider type in the limited screening levels and the moderate screening levels.

Response: As for the commenter's recommendation regarding billing agents and clearinghouses, the commenter references section 6503 of ACA, which calls for billing agents and clearinghouses to register under Medicaid. The implementation of 6503 of the ACA, is not part of this rule; however, we will be addressing that provision in the future. We do not propose to screen billing agents and/or clearinghouses as part of this rule because such entities do not enroll in Medicare as providers or suppliers.

With respect to the data analysis we used, we furnished information in the proposed rule regarding our reasons for assigning certain provider and supplier types to limited, moderate or high level of screening. We relied on our experience to identify categories of providers with a higher incidence of fraud as well as our familiarity with types of fraudulent schemes that are currently prevalent in Medicare. In addition, we used the expertise of our contractors charged with identifying and investigating instances of fraudulent billing practices in making our decisions regarding the appropriate risk assessment of various providers. In some instances, we also relied on the data analysis and expertise of the OIG, GAO, and other sources to develop screening levels designed to increase scrutiny for specific categories of providers and suppliers as the risk posed to the Medicare and Medicaid programs increases.

Comment: A commenter asked whether CMS, in grouping all hospital types—including specialty hospitals, physician-owned hospitals, short-term hospitals, and acute hospitals—into one risk level, is stating that all hospitals have the same risk. If so, the commenter requested that CMS provide data to support this assertion and to explain why it believes that all hospitals pose the same risk

Response: Our assignment of hospitals to the limited screening level should not be construed as meaning that every type of hospital poses the same exact degree of risk. We did, however, base our assignment on the premise that all hospital provider types have certain features in common that make them less likely to be a program integrity concern on the whole. For example, such entities have significant start up costs and capital and infrastructure costs. In addition, such entities are subject to significant government oversight, at both the State and Federal levels. Finally, such entities often are subject to oversight from other accrediting bodies through deeming authority. These features are, in general, less apparent with other provider and supplier types. We note that these are not the only features we considered when evaluating hospitals and that these features, by themselves, are not sufficient to cause us to place a provider or supplier type in the limited screening category.

Comment: A commenter stated that in Table 1, CMS appears not to consider previous payment suspensions, overpayments, OIG exclusions, or Medicare revocations in establishing higher risk levels. The commenter recommended that CMS explain why such actions are not an indicator of higher program risk and the need for enhanced screening.

Response: As mentioned previously, we state in this final rule with comment period that a provider or supplier will be placed into the high screening level if the provider or supplier (or an individual who maintains a 5 percent or greater direct or indirect ownership interest in such provider or supplier) has had a final adverse action—as that term is defined in § 424.502—imposed against it within the previous 10 years.

Comment: A commenter stated that because of the wide variation in DMEPOS items and services and differing levels of behavior, CMS should subdivide the general category of DMEPOS suppliers and assign appropriate screening levels to each product category, rather than to DMEPOS suppliers as a whole.

Response: We think the commenter's suggestion might lead to an overly complex system of provider screening and related oversight tools. Accordingly, we have decided not to create such a distinction based on such sub-categories. At this time, we are not determining the risk of fraud, waste, and abuse by product category.

Comment: Several commenters requested CMS to change the proposed rule to state that both publicly traded entities and their wholly-owned subsidiaries are afforded "limited categorical risk" status.

Response: As stated previously, publicly traded status is not being included as a criterion for assigning provider or supplier categories to screening levels. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by the categorical risk of fraud—rather than determining individual risk—is consistent with the requirements of the ACA.

Comment: One commenter supported CMS's proposal to place new HHAs into the high screening level. The commenter stated that much of the fraud and abuse that has been detected in the home health benefit is associated with new providers, particularly in areas not subject to certificate of need (CON) or other State controls on provider development.

Response: We appreciate this commenter's support.

Comment: One commenter recommended that the proposed rules for assigning screening levels for

existing home health and hospice providers be modified so as to more accurately focus enforcement efforts on certain existing providers within a particular category. More specifically, the commenter stated that CMS can use its ample data resources to more precisely differentiate between agencies with proven histories of good performance and those that are either untested or have demonstrated irregular patterns of performance. The commenter recommended that any nonprofit home health or hospice agency that was certified in Medicare or Medicaid before October 1, 2000, and has not been identified as having program integrity problems, be placed in the limited risk screening level. The commenter added that CMS should also create a scoring algorithm that would identify those HHAs and hospices at moderate risk based on criteria such as: (1) Years of program participation; (2) ownership type; (3) number of medical review requests; (4) pattern of selectively serving highly profitable cases; (5) frequent changes in ownership; (6) geographic location; (7) relationship to other stable (for example, hospital) or less stable provider types (DMEPOS); and (8) current accreditation status.

Response: We did not base our development of levels of screening on provider-specific risk assessments. As described previously, the statutory requirements set forth in ACA guided our approach in assigning categories of providers and suppliers to screening levels appropriate to the risk of fraud, rather than pre-screening individuals prior to the assignment of a screening level. Adopting the type of scoring algorithm suggested by the commenter would automatically provide for individual breakdowns of each HHA's or hospice's risk, which we believe would be inconsistent with the statute and constitute a pre-screening step in the enrollment process. We do not rule out the possibility of using scoring algorithms in the future for other program integrity functions or for provider and supplier enrollment, but we decline to adopt this suggestion for enrollment screening purposes at this time. For the reasons stated previously, we believe that the moderate risk screening level is appropriate for currently enrolled HHAs and hospices.

Comment: A commenter did not believe that site visits were necessary to ensure that ambulance providers and suppliers were in compliance with applicable program requirements. The commenter expressed concern that the time associated with conducting pre-enrollment site visits could slow down the enrollment process. The commenter added that ambulance services are already subject to site inspections by the State licensing agency (as well as other State and Federal requirements), and that the existing procedures are sufficient to ensure that ambulance providers and suppliers are operating in compliance with program requirements. Another commenter stated that in this proposed rule, CMS states that it only conducts a limited number of unscheduled or unannounced site visits for certain provider types. If this is based on a policy decision, the commenter requested that CMS explain why it now believes that unscheduled or unannounced site visits will reduce fraud, waste, and abuse. The commenter also requested a cost/benefit analysis for its previous onsite efforts to show the effectiveness of this new strategy. If a fiscal constraint, the commenter requested that CMS explain: (1) Why it is spending $9 million on grants to Senior Medicare Patrol (SMP) and millions in advertising to promote "Stop Medicare Fraud" in lieu of conducting unscheduled and unannounced site visits, and (2) where the additional funds will come from to conduct thousands of unannounced site visits.

Response: We have been conducting site visits of one kind or another for years, and have found such visits to be an extremely effective tool in fighting fraud. We plan to conduct site visits pursuant to the authorities provided in the ACA and as outlined in this final rule with comment period. We have received many valuable tips and other information from SMP volunteers across the country. We believe that site visits are appropriate for ambulance companies, especially considering that we have uncovered several instances where an enrolling ambulance company—contrary to the information it furnished on the CMS–855B—had no base of operations. Regarding the commenters concern about the Senior Medicare Patrol initiative, we believe the SMP program is outside the scope of this regulation.

Comment: With respect to whether non-practitioner-owned facilities and suppliers should be subject to a higher level of screening than their practitioner-owned counterparts, a commenter urged CMS to exempt dually-enrolled physicians from enrollment screening requirements applicable to entities only enrolling as DMEPOS suppliers. The commenter believes it would make no sense to consider physicians "limited risk" while simultaneously labeling them either "moderate risk" or "high risk" when they provide DMEPOS to their own patients.

Response: We disagree. As stated previously, the approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determines by the assessed categorical risk of fraud—rather than determining individual risk—is consistent with the requirements of the ACA. We believe that each provider and supplier category must be considered on its own merits as an entire class, rather than be sub-categorized based on whether or not a particular provider is owned by provider subject to the limited screening level. For reasons we have stated, both in this final rule with comment period and in the past, newly enrolling DMEPOS suppliers are currently subject to a higher level of scrutiny and revalidating DMEPOS suppliers are subject to the moderate level of screening—such as through the need to comply with the supplier standards in § 424.57(c)—because of the heightened risk posed by this class of suppliers as a whole. We therefore decline to exempt certain types of DMEPOS suppliers from either the moderate level of screening for revalidating suppliers or the high level of screening for newly enrolling suppliers.

Comment: A commenter suggested that CMS revise the enrollment applications to include language in the certification statement so that CMS' contractors can conduct a criminal background check on any owner, authorized official, delegated official, managing employees and individual practitioners during the initial enrollment process or subsequently thereafter. The commenter believes that CMS is needlessly limiting its ability to conduct criminal background checks.

Response: We appreciate this comment but decline to adopt this approach. We will perform fingerprint-based criminal history record checks of the FBI's Integrated Automated Fingerprint Identification System consistent with the methodology specified in this rule. We do not intend to amend the CMS–855 to include language that would expand the use of such criminal history record checks beyond the requirements set forth in this final rule with comment period. We think that to conduct the same screening for all provider categories without taking into account the variation in risk of fraud, waste or abuse would be an inappropriate allocation of resources and would be inconsistent with the provisions of the ACA. As stated previously, if CMS re-assigns additional categories of providers to the high level of screening, or expands the use of FBI

criminal history record checks to the other screening levels, CMS will publish a notice in the **Federal Register**.

Comment: A commenter suggested that Medicare, Medicaid, and CHIP consider bankruptcy and credit report scores during the screening process and that CMS deny enrollment where an owner, authorized official, or delegated official has a credit score of less than 720 or has had a personal or business bankruptcy within the last 5 or 10 years. The commenter stated that credit score is indicative a person's ability to manage financial assets.

Response: We decline to adopt this approach in this final rule with comment period. We would need to perform additional study to determine whether credit scores correlate with program integrity risk. Because we do not have evidence to support such a relationship, we decline to adopt this approach at this time.

Comment: Several commenters requested clarification on whether a Federal agency or a private company will process the fingerprint card, how CMS will safeguard this information, and how much additional time fingerprinting will add to the screening process of new applicants. Another commenter urged CMS to ensure that documentation concerning fingerprints be tracked from origination to delivery to prevent loss, and that all information be protected from FOIA disclosure.

Response: The FBI requires that fingerprints be collected and submitted by FBI-approved "authorized channelers." The FBI currently has approved 15 such private companies to collect and submit fingerprints to the FBI CJIS Division's Wide Area Network (WAN), receive the criminal history record information, and submit the record to authorized recipients, in this case CMS (or its FBI approved outsourced contractors) for the determination of eligibility for enrollment. CMS will use of one or more of the pre-approved authorized channelers to collect and submit fingerprints directly to the FBI, and CMS will ensure the written proposal(s) provided by the selected channeler(s) contains the appropriate assurances of compliance with privacy and security considerations mandated by the Compact Council (the national independent authority that regulates and facilitates the exchange of noncriminal justice criminal history record information) and as required by 28 CFR part 906. Additionally, CMS will adhere to the Compact Council's Security and Management Control Outsourcing Standard for Channelers. The use of authorized channelers effectively means CMS never has custody of the submitted fingerprints, only the resulting criminal history record. CMS will, of course, protect the information in the criminal history record according to existing Federal standards and procedures that govern personally identifiable information.

After further consideration of the proposed requirement that all required applicants submit their fingerprints on the FD–258 card, CMS has removed the requirement to use only the FD–258 card from this final rule with comment period. CMS strongly encourages all required applicants to provide electronic fingerprints to the CMS-selected authorized channeler, but will also accept the FD–258 card. As stated previously, CMS and the authorized channeler will safeguard the information as required by the existing requirements of the Compact Council, and specifically the Compact Council's Security and Management Control Outsourcing Standard for Non-Channelers and Channelers and the FBI's Criminal Justice Information System's Security Policy.

We believe the additional time for a contractor's processing of the application in light of the fingerprint-based criminal history record check will be minimal for those applicants who submit electronic fingerprints. Applicants who submit the FD–258 card will experience an extended processing time as the authorized channeler selected by CMS will have to convert the paper print into a electronic submission so that the FBI can quickly process all requests. The FBI processing of the electronic prints occurs within 24 hours of receipt from the authorized channeler, and the authorized channeler will receive and transmit the report to CMS. The report will be reviewed for disqualifying felonies and omitted information as outlined in existing regulations at § 424.530(a) for enrollment and at § 424.535(a) for revalidation and once the fitness determination has been made, the appropriate contractor will process the enrollment application as before. CMS believes this process will not cause significant delays to the enrollment process.

As stated previously, CMS and our Medicare contractors will protect individuals' information under the Privacy Act, 5 U.S.C. 552a and the Privacy Act system of records notice for this information. We recognize that the safeguarding of individual privacy and ensuring the security of fingerprints collected under this regulation is a serious concern. We will ensure that these concerns are addressed and that all necessary safeguards are implemented to protect this information –from both privacy and security standpoints—when we issue guidance on fingerprint-based criminal history record checks following the publication of this final rule with comment period. We will ensure that fingerprint documentation is fully protected to the extent required by Federal law.

As stated previously, the fingerprint-based criminal history record check will be required 60 days following the publication of subregulatory guidance. All other screening requirements are effective on March 25, 2011 for those in the "high" screening level. The delay in the effective date for the fingerprint-based criminel history check will permit CMS to coordinate the implementation of this new process with our law enforcement partners, ensure that all concerns related to privacy are addressed, educate our providers and suppliers about the new process, and ensure that our contractors are adequately prepared to implement this new process so that the implementation of this new process does not cause any undue delay.

Comment: A commenter stated that while CMS assigns CMHCs to the moderate screening level, CMS has not taken steps to implement section 1301 of the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act), which requires that CMHCs provide at least 40 percent of its services to individuals who are not eligible for benefits. The commenter recommended that CMS consider CMHCs as a "high" categorical screening risk until CMS implements section 1301 of the ACA.

Response: For reasons already explained, we believe that CMHCs are most appropriately assigned to the moderate screening level. Section 1301 of ACA is not a part of this rule.

Comment: Several commenters requested that CMS consider establishing criteria for making assignments to screening levels before moving forward with this rule.

Response: We explain in the preamble the criteria and factors we used for our placement of various provider and supplier types into particular levels. These factors include our experience with claims data used to identify fraudulent billing practices, as well as the expertise developed by our contractors charged with investigating and identifying instances of Medicare fraud across multiple categories of providers. In addition, we have relied on insights gained from numerous studies conducted by the HHS OIG, GAO, and other sources.

Comment: A commenter requested that a fourth level of "no risk" be established. This is to reflect positively on providers who have had no incidents of fraud, waste or abuse.

Response: We do not believe it is appropriate to create a "no risk" level as the limited level of screening represents the baseline screening requirements for entry into the Medicare program. We believe that fraud, waste and abuse can occur at any time and among any provider or supplier category. Our screening methodology is designed to match an appropriate level of screening to provider or supplier categories based on level of risk of fraud, waste or abuse posed by the provider or supplier category.

Comment: A commenter requested clarification regarding whether CMS will conduct TIN matches with the IRS via an automated match or whether the provider will be required to sign an I–9 verification form. The commenter also asked whether CMS will conduct tax delinquency database matches with the IRS and the authority for such a match. In both cases, the commenter recommended that CMS establish new denial and revocation reasons if the TIN does not match or there is a tax delinquency.

Response: We currently verify the provider's TIN as part of the enrollment process; if the TIN does not match the provider's legal business name, the application will be denied, or, if enrolled, the provider's billing privileges will be revoked. However, we have removed references to tax delinquencies as a component of the screening methodology from this rule. While we do plan to implement provisions that will allow us to coordinate enrollment decisions with data obtained from the Internal Revenue Service—for instance, potentially denying an application based on tax delinquency information from the IRS—such an effort is not a part of this rule.

Comment: A commenter stated that CMS's proposed "limited risk" classification for publicly traded companies does not explicitly afford the same treatment to subsidiaries of publicly traded providers and suppliers. Several commenters recommended that majority owned subsidiaries of publicly traded providers and suppliers be treated the same as their publicly traded parents. Specifically, since subsidiaries of publicly traded providers and suppliers are subject to substantially similar oversight and scrutiny, the commenter proposed that all providers and suppliers—regardless of whether the parent is enrolled—that are at least majority owned, directly or indirectly, by a publicly traded provider or supplier be assigned to the limited risk level for screening. The commenter suggested that proposed § 424.518(a)(2) be revised to read as follows: "(2) When CMS designates a provider or supplier into the "limited" categorical level of screening, the provider or supplier is publicly traded on the New York Stock Exchange (NYSE) or the National Association of Securities Dealers Automated Quotation System (NASDAQ), or the provider or supplier is majority owned, directly or indirectly, by an organization publicly traded on the NYSE or NASDAQ * * *.". Another commenter stated that subjecting different providers under a hospital to different levels of scrutiny could cause confusion and unnecessary hardship.

Response: For reasons already stated, we have eliminated the distinction between publicly traded and private companies and have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: A commenter stated that while subjecting newly enrolling DMEPOS suppliers to stringent screening may be proper, an enrolled DMEPOS supplier that reenrolls following an ownership change should not be subject to the same screening as a newly established supplier. It should instead be treated as moderate risk, just as enrolled suppliers that revalidate their enrollment information. The commenter contended that the seller's business, much of which remains after the purchase, has already been verified and authenticated; if CMS and the NSC subject the purchaser to stringent enrollment screening, they will duplicate the work that they have already done to validate and inspect the purchased business, wasting resources. It could also delay the new owner's receipt of a Medicare number, which could disrupt the continuity of business and patient care. The commenter added that if CMS does not agree that an enrollment following an ownership change of an enrolled DMEPOS supplier should be moderate risk, CMS should formally state that purchasers of enrolled DMEPOS suppliers will receive new Medicare numbers with billing privileges retroactive to the purchase date. In closing, the commenter stated that the proposed rule is a dramatic change to the existing methods of Medicare enrollment; while change to prevent fraud and abuse is advisable, such change should not harm honest providers and suppliers who strive to provide high quality service to Medicare beneficiaries. Another comment stated the purchaser of an existing community pharmacy DME supplier store should be screened as a moderate (not a high) risk supplier during reenrollment.

Response: We disagree that a DMEPOS supplier undergoing a change of ownership should be assigned to the as moderate screening level. For purposes of enrollment, a DMEPOS supplier undergoing a change of ownership is treated and must enroll as a new supplier. Hence, since all newly-enrolling DMEPOS suppliers are subject to a "high" level of screening, we believe DMEPOS suppliers undergoing a change of ownership should also be subject to a "high" level of screening. Further, the screening requirements in the high screening level include a fingerprint-based criminal history record check of any individual with direct or indirect ownership of 5 percent or greater. Therefore, enrollment screening after a change in ownership has clear value to the enrollment process, and we disagree that it would be a waste of resources. Currently-enrolled (revalidating) DMEPOS suppliers are assigned to the moderate level of screening.

Comment: A commenter stated that certified orthotic and prosthetic DMEPOS suppliers and American Board for Certification in Orthotics and Prosthetics (ABC)-accredited DMEPOS suppliers should be assigned to the limited screening level. The commenter stated that accreditation is not an easy standard to meet, and asked CMS to investigate whether there are any studies or other evidence that indicate that ABC Accredited Facilities and/or ABC Certified practitioners as a DMEPOS subcategory pose an elevated risk to the Medicare program. If there are not, such suppliers should be subject to limited screening.

Response: We believe the commenter is asserting that accreditation bodies perform a sufficient level of oversight to ensure that the entities they accredit are a low program integrity risk. We do not believe this is true. The accreditation bodies help verify the supplier's compliance with DMEPOS standards, rather than assess the supplier's risk of fraud, waste and abuse. Accordingly, we decline to assign entities accredited by ABC or any other accrediting organization to the limited screening level solely on that basis.

Comment: A commenter contended that in States without licensure, if a DMEPOS supplier is practitioner-owned and one or more of the practitioners is certified by ABC (accrediting body referenced in section 427 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)), or if the facility itself has been accredited by one of these entities, it should be as assigned

to the limited screening level. The practitioner being credentialed in either of these ways has demonstrated a commitment to quality.

Response: As already stated, we decline to subcategorize individual providers and suppliers based on their ownership and do not believe accreditation—standing alone—should be the foremost indicator of fraud and abuse risk.

Comment: One commenter stated that chain pharmacies should be exempt from the increased screening levels and screening procedures, as they are already subject to significant regulation within their respective States.

Response: We disagree. For the same reason that we cited for eliminating the distinction between publicly traded and non-publicly traded or public or non-public ownership status as a basis for determining screening level, state regulation of chain DMEPOS suppliers is not in itself a sufficient indicator of the risk of fraud, waste or abuse posed by a particular category of provider or supplier. The fact that a particular provider or supplier type may be regulated by the State is not adequate grounds for placing it in a lower screening level.

Comment: A commenter stated that the proposed provisions punish legitimate providers and that the most egregious fraud is committed by scam artists and organized crime. The commenter expressed concern that small practices will be driven out of business. In light of CMS's proposed exemption for public companies, one or two large national companies may be the only ones "left standing" and will have a monopoly. CMS, the commenter argued, will then be unable to objectively compare "best practices" or to objectively evaluate trends in care, and that patients will not have a choice for their care.

Response: As already stated, we have eliminated the distinction between publicly held and private companias. In addition, we believe that the proposed provisions will help stem the fraud that both the commenter and we are concerned about.

Comment: A commenter recommended that CMS provide the analysis for which it based its risk assignment decisions for limited and moderate screening levels. The commenter also recommended that CMS consider the Medicare and Medicaid error rates for each provider or supplier in establishing its screening levels. Finally, the commenter also requested the following data for each type of Medicare provider and supplier for 2008, 2009, and 2010:

- Number of Medicare revocations.
- Number of Medicare payment suspension.
- Number of Medicare overpayment.
- Medicare error rate.
- Medicaid error rate.
- CMPs.
- Convictions by the Department of Justice.
- HHS OIG mandatory exclusions under 1128 of the Act.
- HHS OIG permissive exclusions under 1128 of the Act.

Response: We based our risk assessments on a variety of factors, including some of those listed by the commenter as well as others. However, because our conclusions were not based on any one factor nor any specific combination of factors, but rather on CMS's aggregate experience with each provider and supplier type, providing the data requested by the commenter would not serve to clarify the determinations of risk.

Comment: A commenter stated that the proposed screening approach in the proposed rule is simplistic at best and flawed at worst. The commenter did not believe provider type is the only measure of risk of fraud. To address those individuals and organizations who intend to enroll for the sole purpose of committing fraud, CMS must: (1) Consider the provider's past experience with Medicare, Medicaid, or CHIP; (2) coordinate enrollment and billing issues with commercial health plans, Medicaid and CHIP; and (3) establish more stringent program requirements. The commenter believes that CMS did not offer any enhanced program requirements in the proposed rule, the rule does not reduce the "pay and chase" approach used by CMS and OIG today.

Response: We disagree, and believe that the program safeguard measures outlined in this final rule with comment period will greatly assist in reducing fraudulent activity. We believe several of the elements proposed by the commenter are inherent in this rule. First, under the final rule with comment period, final adverse actions will lead to a high screening level assignment and the use of additional screening tools. Second, with regard to more stringent program safeguards, we believe there is much in this final rule with comment period to bolster our efforts at combating fraud, waste, and abuse For example, in this final rule with comment period, we are expanding the instances in which we can impose a payment suspension. Furthermore, for the first time in the history of the programs, we will be able to impose an enrollment moratorium in order to combat fraud, waste, and abuse. Accordingly, we believe the new authorities that we are implementing under the ACA will assist us in strengthening our program integrity efforts.

Comment: A commenter recommended that the following be placed into the high screening level: (1) Any provider or supplier that is not State licensed, and (2) any owner, authorized official, delegated official, physician or non-physician practitioner who has ever been excluded by the OIG, revoked by Medicare, or had a State license revocation or suspension.

Response: We stated previously that merely because a particular provider or supplier type may be regulated by the State is not in and of itself adequate grounds for placing it in a lower screening level. By the same token, we do not believe that a failure to be licensed by the State should automatically place the provider or supplier in a high screening level, as the State may not have licensure requirements for that particular provider or supplier type. In addition, the standards for licensure vary among the States and Territories such that these are largely out of our control. With regard to the commenter's second suggestion, we again note that § 424.518(c) of the final rule with comment period states that a provider or supplier will be moved from the "limited" or "moderate" level to the "high" level if it has had final adverse actions imposed against it.

Comment: A commenter recommended that CMS explain why it did not consider comments regarding publicly traded companies in the final rule with comment period; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices, when developing the proposed policy found in the proposed rule to this final rule with comment period.

Response: This rule and the rule that the commenter references deal with different issues. Each was developed and considered on its own merits.

Comment: A commenter supported CMS's placement of hospitals and physicians into the limited screening level. However, the commenter disagreed that publicly traded DMEPOS suppliers or HHAs would have less risk. The commenter also stated that the providers and suppliers that are designated as "high risk" or "moderate risk" but which are members of, operate as a part of, or are owned by a hospital or a health system, should instead fall under the same risk assignment as the hospital. Such providers and suppliers

are part of larger established organizations that have high levels of accountability to their internal governance structures and have longstanding relationships with and responsibility to their local communities.

Response: For reasons already stated, we have eliminated the distinction between publicly traded and private companies and have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters requested greater specificity regarding what level of managing employees would be subject to the screening requirements for high risk providers and suppliers. Some of them requested that for large provider organizations, only the highest-level managing employees who operate or manage, or who oversee the operation of the entire healthcare organization—and not lower-level managers of individual departments or functions—should be subject to the enhanced screening procedures.

Response: In this final rule with comment period, we will only apply the screening requirements for high screening level providers and suppliers to individuals with a 5 percent or greater direct or indirect ownership interest. Officers, directors, and managing employees—to the extent that they do not have a 5 percent or greater ownership interest—will not be subject to fingerprint-based criminal background checks. However, we intend to monitor the situation and may seek to extend the scope of fingerprint-based criminal background checks in the future if circumstances warrant.

Comment: A commenter stated that hospitals should be exempted from all screening levels—even the limited screening level—if they are State-licensed and accredited.

Response: We disagree with this commenter. To exempt a provider or supplier from any screening level would be the equivalent of stating that the provider need not undergo even the most basic verification requirements used under the limited risk level of screening.

Comment: Several commenters supported site visits as a tool to improve program integrity, but believes that they could disrupt or administratively burden a legitimate provider or supplier's business operations. They recommended that CMS limit the purpose of these site visits to verifying that the provider/supplier exists and is operational; other matters that would require significant management and clinical staff time should be handled through separately scheduled site visits. Several other commenters believe that site visits were appropriate, but said that the number of such visits must be reasonable for the circumstances and should only increase if inappropriate activity is suspected. In addition, another commenter suggested that as part of a DMEPOS site visit, the auditor should confirm with the owner of the warehouse or facility the terms of the lease; for HHAs, the auditor should confirm that the HHA has been using the OASIS form and that a sample of Patient Plan of Care medical records/files can be directly linked to an OASIS document.

Response: We decline to state that site visits will always be limited to verifying whether the provider or supplier is operational. We must retain the flexibility to conduct a closer on-site review if warranted.

Comment: One commenter stated that classifying DMEPOS suppliers that are physician-owned as high risk could pose a significant disincentive to office-based physicians to continue offering DMEPOS supplies to their patients. The commenter stated that there has been little to no documentation of fraud, waste, or abuse in this category of DMEPOS, and that these suppliers should be exempted from the high risk level of screening.

Response: For reasons already stated, we have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters stated that the risk assessments of specific providers should not be made public.

Response: To the extent allowed by Federal law, we will not release to the general public the risk assessment of an individual provider or supplier. Thus when an individual provider or supplier is elevated in screening level as a result of a triggering event in § 424.518 and § 455.450, we will not publish the individual provider's or supplier's name.

Comment: Several commenters supported the creation of limited, moderate, and high screening levels, as well as the proposal to place physicians into the limited screening levels. They added that CMS should use public notice and comment prior to modifying the process or revising level assignments based on new criteria.

Response: We appreciate the commenters support and will publish notice in the **Federal Register** regarding changes in assignment or levels of screening specified at § 424.518 and § 455. 450. However, as mentioned previously, we will not publish information about an individual provider or supplier that meets certain triggering events as described in these sections.

Comment: A commenter opposed "geographical circumstances" as a possible criterion for adjusting a provider or supplier's screening level. This would deny all providers and suppliers in the specified geographic area basic due process and could seriously damage beneficiary access to health care providers and services in the impacted area.

Response: We are not adopting "geographic circumstances" as a criterion for adjusting a provider or supplier's screening level at this time. We believe that should circumstances arise where we have concerns about a provider or supplier type in a geographic area, the authority to impose an enrollment moratorium, as detailed in this rule, will provide program integrity protection. However, we do retain the authority to add geographic location as a criterion for adjusting a provider or supplier's screening level through future rulemaking.

Comment: Several commenters opposed the proposal to re-assign physicians from the "limited" or "moderate" screening level to the "high" screening level when CMS has evidence from or concerning a physician that another individual is using their identity within the Medicare program. Classifying physicians who have been the victims of identity theft to the high screening level would stigmatize the physician and create a presumption that he/she has engaged in conduct warranting heightened scrutiny. They urged CMS to establish a fourth level, which signifies a heightened level of risk to Federal health care programs as a result of compromised physician identity or identity theft. Another commenter requested that CMS clarify that it will be the offender who is subjected to additional scrutiny and that the victim will not be penalized for the actions of the offender. Another commenter, however, supported CMS's proposal to adjust the categorical screening level if a practitioner notifies CMS or its contractor that another individual is using his or her identity within the Medicare program, and to require fingerprinting of high risk provider and supplier types (but not of individual practitioners who have been the victim of identity or provider number theft).

Response: We stress that we will work closely with law enforcement against those individuals who are perpetrating Medicare identity theft. We do not plan to use screening tools to address identity theft concerns as it would not be an adequate response. We believe

identity theft concerns are most appropriately handled by our law enforcement partners.

Comment: A commenter requested clarification as to the screening level assignment of in-home supportive services (IHSS). If they fall into the "moderate" level, as do home health agencies, the commenter expressed concern that site visits could burden program recipients.

Response: Medicare does not recognize "in home supportive services" as a specific category of provider or supplier. To the extent that the IHSS supplier is or will be enrolling in Medicare or Medicaid as a HHA, it will be subject to the same requirements and standards as all other HHAs. As for the site visits, they will generally be conducted at the HHA's physical locations.

Comment: Several commenters expressed concern with the proposal to re-assign physicians (and other providers/suppliers) from the "limited" or "moderate" screening levels to the "high" screening level if a physician has had billing privileges revoked by a Medicare contractor within the previous ten years. Billing privileges can be revoked for a number of reasons unrelated to fraud, waste, or abuse, such as a failure to respond to a request for revalidation documentation within stringent contractor imposed deadlines. They urged CMS to differentiate between a temporary revocation of billing privileges and revocations based on actual misconduct by a provider or supplier.

Response: As stated earlier, revocation is undertaken as an administrative remedy only if clearly justified. Also, there is an appeals process in place for provider revocations. Should a revocation be rescinded, the provider or supplier would be restored to its previous screening level.

Comment: A commenter urged CMS to exercise the temporary moratorium authority judiciously and to exempt physicians from re-assignment from level I (limited) to level III (high) if physicians are ever subject to the temporary moratorium; this would include an exemption for physicians enrolled as DMEPOS suppliers if the latter are subject to a moratorium.

Response: We believe this commenter is addressing a concern that if a moratorium is imposed on a category of providers that includes physicians or physician-owned DMEPOS suppliers, that when the moratorium is lifted the provider or supplier category to which the moratorium applied would be moved to the high screening level for 6 months following the lifting of the moratorium. The commenter is asking for an exception to this proposal. A moratorium may be imposed if there is a heightened risk of fraud, waste or abuse in a particular geographic area or involving a certain provider or supplier type. If a particular provider or supplier type posed such a risk as to warrant a moratorium, it would be inappropriate for us to automatically exempt it from enhanced screening once the moratorium ends. In the event that we were to impose a temporary moratorium on physicians or physician-owned DMEPOS suppliers, the moratorium would be as narrowly tailored as possible to address specific fraudulent activity.

Comment: A commenter believes that the moderate and high screening level assignments for community pharmacies are inappropriate and contended that: (1) all existing community pharmacy DME suppliers, as well as new locations of existing community pharmacy DME suppliers, should be designated as limited risk, and (2) newly enrolling community pharmacy DME suppliers should be treated as posing a moderate risk. The commenter stated that community pharmacies are already heavily regulated by the States and Federal government through State boards of pharmacy, CMS supplier standards and surety bonds, and argued that community pharmacies are not a major source of fraud. The commenter also urged CMS to incorporate into its final rule the same exemption criteria that CMS's uses to exempt certain community pharmacies from DME supplier accreditation requirements. In addition, the commenter stated that CMS should designate community pharmacies as limited risk suppliers if: (1) They have had a supplier number for at least 5 years; (2) their DME sales are less than 5 percent of their total sales over the last 3 years; and (3) they have not received a final adverse action against them in the past 5 years. Another commenter stated that DMEPOS sales are but a small portion of genuine community pharmacy sales. Accordingly, the proposal regarding unannounced pre- and/or post-enrollment site visits for moderate risk suppliers and criminal background checks and fingerprinting for high risk suppliers may prove unbearably costly and burdensome to community pharmacies. The commenter added that it could lead to community pharmacies to stop supplying DME products, causing access problems.

Response: As already stated, all newly-enrolling DMEPOS suppliers, regardless of sub-type or ownership, will be placed in the high level of categorical screening. This includes new DMEPOS locations, which have long been treated as initial enrollments. Moreover, we do not believe it is appropriate to apply the community pharmacy exemption for accreditation to the risk classifications, as the standards for accreditation are different from the criteria we are using for the risk classifications.

Comment: A commenter urged CMS to more narrowly tailor its risk assignments of provider or supplier types by geography, so that DMEPOS suppliers in many areas of the country are not unfairly grouped into a higher screening level merely because those same DME supplier types pose major fraud risks in other limited areas of the country.

Response: We disagree. While some areas of the country are undeniably more prone to fraud than others, fraudulent activity can occur anywhere. Furthermore, we believe it most objective to apply the same standard to all parts of the country and use other tools to narrowly tailor our approach when necessary, including the enrollment moratoria provision set forth in this final rule with comment period.

Comment: A commenter requested clarification on whether an existing commnnity pharmacy DME supplier that seeks to add a new DMEPOS supplier store would fall under the moderate or high screening level under the proposed rule. The commenter believes this should fall within the moderate screening level.

Response: As already stated, the addition of a new DMEPOS location would be subject to the level or screening specified for providers and suppliers assigned to the high screening level.

Comment: A commenter expressed concern that the Medicare contractor may not know which companies are publicly traded.

Response: We have eliminated the distinction between publicly traded and non-publicly traded companies; as such, this comment is no longer applicable.

Comment: One commenter stated that on June 23, 2010, the Director of the Office of Management and Budget published a memorandum titled, "Enhancing Payment Accuracy" through a "Do Not Pay List"; this Presidential document stated that, "At a minimum, agencies shall, before payment and award, check the following existing databases (where applicable and permitted by law) to verify eligibility: the Social Security Administration Death Master File, the GSA's EPLS, the Department of the Treasury's Debt

Check Database, the Department of Housing and Urban Development's (DHUD) Credit Alert System or Credit Alert Interactive Voice Response System and the DHHS OIG LEIE." The commenter stated that CMS should explain why the proposed rule does not mention these verification sources.

Response: Medicare contractors have long been required to review the EPLS and the LEIE prior to enrolling a provider or supplier in Medicare. In addition, providers, suppliers and their owners and managers are currently reviewed against the SSA Death Master File. As for the DHUD Credit Alert System and the Department of the Treasury's Debt Check Database, we understand the Presidential memorandum requires review of these systems prior to payment or award and will integrate their use as appropriate in our protocols.

Comment: Several commenters supported the placement of hospitals in the limited screening level. However, they added that high risk or moderate risk providers and suppliers that are members of, operate as a part of, or are owned by a hospital or a health system, should instead fall under the same limited risk assignment that CMS proposes for hospitals.

Response: Again, for reasons already mentioned, we have declined to subcategorize individual providers and suppliers based on their ownership.

Comment: Several commenters stated that in States with orthotic and prosthetic licensure, orthotic and prosthetic DMEPOS suppliers should be designated as limited risk, as there is no evidence of significant elevated risk for such licensed professionals. In States without orthotic and prosthetic licensure, several commenters stated that the supplier should be treated as limited risk if: (1) One or more of the supplier's practitioners are certified by the American Board for Certification of Orthotics, Prosthetics and Pedorthics or the Board of Certification/Accreditation International, or (2) the supplier itself has been accredited by one of these entities. Other commenters stated that if the orthotic and prosthetic supplier is not practitioner owned, but has been in business at least 3 years, it should be considered limited risk due to a demonstrated lack of inappropriate billings over time; if it is not practitioner-owned and has not been in business at least 3 years, it should be rated as a moderate risk. Finally, the commenters objected to the proposed risk provision for this risk assignment provision because: (1) Orthotics and prosthetics is not part of DME, and has significantly lower fraud and abuse risks; and (2) there has not been sufficient consideration of the impact of number of years in business, or accreditation/certification status as factors that diminish risk.

Response: As stated earlier, we do not believe certification or accreditation to be dispositive of risk for fraud and decline to adopt this suggestion. While we appreciate the commenter's suggestion that we should look at length of time in business as a means of supporting the assessment of risk, we believe that OIG and GAO reports and experiences are instructive and rely on those as well as our own data to support the assignment to levels of screening that we finalize in this rule.

Comment: A commenter expressed concern that the time and cost necessary to comply with the requirements in the proposed rule is a significant burden on small providers, in light of all of the other requirements they are subjected to. The commenter stated that for reasons of reduced risk, time in business and demonstrated commitment to quality, no certified practitioner or accredited orthotist or prosthetist facility should be subject to background checks and fingerprinting.

Response: We decline to adopt this suggestion; to do so would foreclose the possibility that any high risk practitioner or orthotic or prosthetic facility would be subject to enhanced scrutiny.

Comment: A commenter questioned whether requirements such as fingerprinting will accomplish CMS's goal of tracking violators, since CMS will have no way to ensure that the person providing the fingerprints is the person rendering the care. The commenter also questioned whether fingerprinting will help prevent identity theft for physicians.

Response: We are confident that fingerprint-based criminal history record checks will enable us to identify individuals who violate CMS existing regulations at § 424.530(a) and § 424.535(a), and appropriately deny or revoke Medicare billing privileges in these circumstances. This screening tool is intended to prevent individuals who pose an elevated risk of fraud, waste, and abuse from enrolling in the programs. Physicians will not be subject to the fingerprint-based criminal history check if they are not in the high screening level. Physicians as a category are in the limited screening level and providers and suppliers in the limited screening level are not subject to fingerprint-based requirements as are individuals and entities in the high screening level. The submission of fingerprints for the purposes of an FBI criminal history record check is not intended to address identity theft concerns.

Comment: A commenter stated that raising a supplier's screening level seems reasonable only if the supplier has come under a payment suspension or if after investigation, the type of provider and the services it will render are not congruent on its enrollment application.

Response: We disagree. There are, as explained in this final rule with comment period, a variety of final adverse actions that we believe warrant the placement of a provider or supplier in a higher screening level. Payment suspensions and inconsistent information on the enrollment application should not be the only two grounds for elevating a provider's screening level.

Comment: A commenter stated that with regard to the "high" screening level, although government enforcement efforts to date have shown fraud, waste and abuse issues with HHAs and DMEPOS suppliers in certain geographical regions (for example, South Florida, Texas, and California), it is not clear that issues with such entities are national. Because the criminal background checks and fingerprints are onerous requirements that are not currently used by Medicare, the commenter stated that CMS should limit itself to introducing such requirements in high risk geographic areas, rather than nationally, at least at this stage. Moreover, the commenter stated that CMS has neither provided the data nor made the convincing case that its proposed changes will deliver results to justify the extent to which the rules would intrude on normal patient care and business practices. With respect to orthotic and prosthetic suppliers, the commenter urged CMS to adopt a more realistic approach that cracks down on fraudulent providers, without either considering every provider to be a crook, or adding huge regulatory burdens that could put honest, legitimate, hard-working orthotic and prosthetic suppliers out of business.

Response: We disagree that our enhanced screening procedures should initially be restricted to high risk geographical areas. While some regions of the country evidence fraud, waste and abuse more than others, fraudulent activity can occur anywhere. In addition, we believe that a national approach is most objective in implementing the screening provisions herein. We will rely on other program integrity tools, including, without limitation, the enrollment moratoria authority contained within this rule, to

address concerns in particular locales. Moreover, CMS will monitor implementation of the final requirements on provider and supplier screening with respect to patient care and business practices.

Comment: A commenter stated that with respect to changing a health care provider's level of screening, the basis for this determination should be on information released during 2011 and beyond.

Response: We disagree. We have found that long-term trends (for example, data from 2005 through 2009) are often good indicators of potential fraudulent activity.

Comment: A commenter suggested that CMS establish certain exemptions to DMEPOS suppliers prior to a company being deemed a moderate or high risk supplier, such as: (1) A multiple year history as a DMEPOS provider; (2) award of a DMEPOS competitive bidding contract (where CMS itself has extensively reviewed the financials of contracted suppliers); and (3) accreditation by a CMS-approved third party.

Response: We did not base our development of levels of screening and the assignment of provider and supplier categories to these levels of screening of fraud, waste or abuse on the past experience of specific individual providers. Rather, it is based on collective experience of provider and supplier categories. Furthermore, we do not believe length of time in business is an appropriate determination of fraud risk. Similarly, as described previously, we do not believe accreditation is—in and of itself—an indication that a provider or supplier should be assigned to the limited screening level. Finally, we decline to accept the commenter's suggestion that the award of a DMEPOS competitive bidding contract should provide an exemption from the assignment specified in this rule. The criteria for competitive bidding are different than those that we are using to determine the appropriate screening level appropriate to particular categories of provider or supplier.

Comment: A commenter stated that any criteria utilized by CMS to assign screening levels should be made public, and that CMS should regularly review its assignment to screening levels. The commenter questioned whether automatically applying the proposed additional screening measures for providers and suppliers assigned to the moderate and high levels will be effective in shutting-out sham suppliers and past violators from participating in Medicare, particularly since these safeguards do not protect Medicare against criminals who use a shell as the owner of record to avoid detection. The commenter believes that the recently implemented accreditation and bonding requirements for DMEPOS suppliers are a stronger deterrent in ensuring that fraudulent suppliers are not able to participate in Medicare, and recommended that CMS first determine whether these requirements adequately deter fraud before imposing additional and arguably less effective safeguards, especially considering the cost and burden of these new requirements.

Response: Criteria for the risk assessments were discussed in the proposed rule and this final rule with comment period. The criteria will be reviewed on a consistent and ongoing basis, and in the event we decide to update the assignment of screening levels, we will publish a regulatory document in the **Federal Register**. We do not believe, though, that we should wait for the results of the accreditation and surety bond requirements before taking additional steps to address program integrity problems related to DMEPOS suppliers. Indeed, it could take several years for the full impact of the surety bond and accreditation requirements to take effect on our anti-fraud efforts. As such, we do not believe it to be premature to assign newly-enrolling DMEPOS suppliers to the high screening level and require enhanced screening pursuant to this rule. It is our expectation that all of these program integrity protections together will lessen the risk of fraud and abuse in the Medicare program.

Comment: A commenter stated that the language in § 424.500, *et seq.*, does not define "Medicare contractor," and the verbiage in the preamble is somewhat vague. The commenter requested clarification as to: (1) The contractors that will be conducting the on-site visits, (2) whether this approach will be uniform across the country, and (3) the training and experience the individuals conducting these visits will have.

Response: Since the term "Medicare contractors," as used strictly in the provider enrollment context, is generally understood and recognized by the provider community to mean the entities that process CMS–855 provider enrollment applications, we do not believe it is necessary to include a formal definition of this term in this final rule with comment period. The contractors that will conduct site visits will vary, as will the scope and breadth of individual visits; however, such site visits will be in accordance with guidance issued by CMS. Those who will conduct site visits will receive appropriate instructions and oversight regarding the performance of the visits.

Comment: Several commenters stated that HHAs and hospices are already subject to a State survey prior to enrollment—as well as on a periodic basis thereafter—thus making a site visit superfluous. As such, initially enrolling HHAs and hospices should be included in the limited screening level rather than in the moderate screening level. A commenter also stated that including all revalidating HHAs, hospices and DME suppliers in the moderate screening level is unfair and inappropriate, as they are already established providers; the commenter believes it should be exempt from the site visit requirement if it has been in existence for at least 5 years and there is no reason to suspect fraudulent activity. The commenter added, however, that additional site visits and increased medical review during the provider's first 5 years of enrollment could be performed to ensure compliance. Another commenter stated that it would be better to conduct HHA site visits, if they had to be performed, with existing or recent patients in their homes, since most care is provided to patients in their homes; care is not provided in the HHA or hospice office.

Response: We do not believe that a site visit is superfluous. Due to the length of the enrollment, survey, and certification processes, we believe it is important for us to institute verification activities at multiple points during this period, and not to restrict its validation efforts to the enrollment process and the State survey. Moreover, we do not believe that site visits should be limited to providers who have been enrolled for less than 5 years, as we do not have data to suggest that those who have been enrolled for 5 years or more present less of a fraud, waste, and abuse concern than newly enrolled providers and suppliers. Finally, and as mentioned earlier, provider enrollment site visits will be conducted at the HHA's physical locations.

Comment: A commenter asked CMS to describe the process the Medicare contractors are using to review State licensing data on a monthly basis. The commenter also requested clarification as to whether the reference to "non-public, non-government owned" applies only to affiliated ambulance services suppliers, or extends to the other provider types listed in the moderate level.

Response: The contractors use various processes to review licensure data; frequently, this is an automated process. With regard to the clarification requested, the term as used in the NPRM applied only to ambulance

suppliers. However, as we have eliminated the distinction between public and non-public ambulance service providers, this comment is no longer applicable.

Comment: A commenter suggested that CMS consider reclassifying providers and suppliers in the "moderate" and "high" screening level to the "limited" risk level if the provider or supplier is subject to State licensure requirements. In addition, the commenter opposed reclassifying providers or suppliers from one screening level to another based strictly on their geographical location. To do so would be arbitrary, and would not reflect the risk associated with particular provider or supplier types.

Response: As already mentioned, we do not believe that State licensure is, in and of itself, indicative of a limited risk of fraud. In addition, we do not plan to reclassify providers or suppliers based solely on geographical location. As stated earlier, if we identify a concern among provider and supplier categories in a particular geographic location, our authority to impose a temporary moratorium will help to address those concerns. However, we do retain the authority to add geographic location as a criterion for adjusting a provider or supplier's screening level through future rulemaking.

Comment: A commenter expressed concern that fingerprinting: (1) Could be very costly; (2) raises privacy and security concerns once an organization begins to collect, maintain, administer access and store a database of fingerprints; and (3) is technologically being replaced by much more modern and reliable identification techniques. The commenter urged CMS to avoid requirements for fingerprinting in screening requirements and to use more modern techniques.

Response: As already mentioned, we believe that fingerprint-based criminal history record checks will be an effective tool in combating Medicare waste, fraud, and abuse. In our view, such criminal history record checks—more effectively than a name-based background check—will prevent ineligible individuals from enrolling in the Medicare program. CMS believes that the cost to both the applicants for the collection of fingerprints, and to CMS for the processing of the prints is not unduly burdensome either to the providers and suppliers or the agency. We would like to clarify that CMS will not be collecting and storing any fingerprints. As mentioned earlier, the selected authorized channeler will collect and transmit the prints electronically directly to the FBI CJIS Division's Wide Area Network to check against the IAFIS, the FBI maintained database. CMS will only receive the criminal history record information, and will protect that information as the Privacy Act requires—both from a privacy and security standpoint. In response to the commenter's third remark, while CMS is aware of the advances in technology in the biometric market, the FBI and State law enforcement standard is currently the fingerprint. Once the FBI or State law enforcement requires a new standard of identification to access the criminal history record information, we will comply with that standard.

Comment: A commenter suggested that in implementing the screening requirements, CMS should minimize duplication of effort. Often the same providers who participate in traditional Medicare are also participating in other plans, such as Medicaid. Having separate screenings could be burdensome and inefficient.

Response: We agree with the commenter that every possible attempt should be made to avoid duplication of effort. To that end, we have attempted to address this concern by providing that the States may rely upon a screening performed by the Medicare program.

Comment: A commenter supported the concept of applying geographical circumstances when adjusting providers or suppliers from one screening level to another, and recommended that anti-fraud efforts be coordinated with other payers—such as through information sharing—because providers and suppliers perpetrating fraud do so across the spectrum of payers, and that reality should be integrated into CMS's overall strategy.

Response: We agree that anti-fraud efforts should be coordinated among payors and we are taking steps to promote greater coordination. As stated previously, we believe our temporary moratoria authority described later in this rule will be an effective tool in particular geographic locations. We may revisit as a factor for enrollment screening level in future rulemaking.

Comment: Several commenters stated that new locations of currently enrolled Medicare DMEPOS providers should be distinguished from other providers that do not have an established record with the Medicare program. CMS should therefore screen new locations of Medicare enrolled suppliers in the same manner as it proposes to screen currently enrolled providers.

Response: We disagree. As previously stated, the addition of a new location is considered an initial enrollment. Consequently, a new DMEPOS location will be subject to the "high" level of categorical screening.

Comment: Several commenters requested that occupational and physical therapists, including those enrolled or applying to enroll as DMEPOS suppliers, be placed in the limited risk level.

Response: As stated earlier, all newly-enrolling DMEPOS suppliers (including those with new practice locations), regardless of sub-type, and including those that are owned by occupational and/or physical therapists, will be subject to a high level of categorical screening. For physical therapists enrolling as individuals or group practices via, respectively, the CMS–855I and CMS–855B applications, these suppliers will be placed in the moderate level of screening. As we explained earlier with respect to physical therapy providers, we believe the classification of physical therapists in the moderate level is supported by a recent OIG report entitled "Questionable Billing for Medicare Outpatient Therapy Services" (December 2010) (*http://oig.hhs.gov/oei/reports/oei-04-09-00540.pdf*), which found, among other things, that Miami-Dade County had three times, and nineteen other counties had at least twice, the national level on five of six questionable billing characteristics.

Comment: A commenter asked whether CMS will identify the contractors that will perform these screenings, or whether it will accept screenings performed by commercial screening services widely used by large employers outside the health care industry.

Response: We believe the commenter is referring to criminal background screenings. To comply with the FBI requirements that only authorized channelers submit fingerprints to the Wide Area Network, and receive the criminal history record information from the FBI, CMS will contract with a pre-approved FBI authorized channeler. In the future guidance, CMS will identify the selected authorized channeler(s) where individuals may have their fingerprints collected, or to whom they may submit the FD–258 card that was completed at a local law enforcement agency. In addition to ensuring compliance with FBI security requirements, such authorized channelers have vendors all over the country where individuals can have their fingerprints electronically collected. In addition, individuals may have their prints taken on the FD–258 paper card at a local law enforcement agency, and then have it sent to the

authorized channeler to have it digitized and submitted to the FBI.

Comment: A commenter had several suggestions for screening levels. The commenter recommended that the limited screening level include providers affiliated with non-profit acute care hospitals or health systems; any not-for-profit providers who have been in existence for at least 20 years and who have filed annual cost reports (if required) for their line of business; and any for-profit providers in business for 20 years as a single site provider. The moderate screening level should include all other providers except those indicated in the high screening level, plus any provider who has entered into a settlement with a government agency (Federal, State or local) within the past 20 years, up through the most recent 5 years, where such settlement covered any over-charge allegations. The high screening level should include any provider who has entered into a settlement with a government agency (Federal, State or local) for any overpayment in the past 5 years; and any provider or group of providers which may currently be under review for possible billing overcharges or other violations who is seeking either a new provider number or seeking a new provider location.

Response: We appreciate these suggestions, and may consider them as part of a future rulemaking effort should circumstances warrant. However, for now, and for the reasons described previously, we believe that the screening level assignments discussed in this preamble will best implement the statute.

Comment: A commenter recommended that CMS refrain from publicly posting risk levels, particularly as they relate to individual providers or group practices. The commenter believes that in some instances this could give a false impression as to the level of risk of any provider or supplier, and that CMS has not clarified how this action will assist the agency with fraud prevention.

Response: To the extent permitted by Federal law, we do not plan to publish risk assessments and the corresponding screening level of individual providers or suppliers.

Comment: A commenter urged CMS to provide contractors with sufficient and targeted resources to handle identity theft screening to ensure that the additional screening precipitated by identity theft will not delay processing of new enrollment applications.

Response: As mentioned throughout this rule, we do not plan to use fingerprint-based criminal history record checks to address identity theft concerns. Identity theft is within the purview of law enforcement and we will make referrals to our law enforcement partners whenever appropriate.

Comment: A commenter requested clarification as to whether a revalidating provider would need to resubmit fingerprints with its application. The commenter believes this would be burdensome, costly, and unnecessary, since fingerprints do not change.

Response: If an individual has provided fingerprints on one occasion, we will not ask such individual to furnish fingerprints a second time unless required by FBI protocols.

Comment: A commenter disagreed that in all cases publicly traded entities pose a "limited" risk while all HHA companies that are not publicly traded pose a "moderate" risk to the program. The commenter supported the "high" risk assignment for those new to the program, but stated that the proposed rule does not consider that companies that have operated successful and compliant HHAs for years would fall into the high screening level if they were to open a new location or branch simply based on the arbitrary assignment of the screening level.

Response: As stated earlier, we believe that newly enrolling HHA locations (for which a CMS–855 is submitted) should be subject to the enhanced scrutiny of the high risk screening level. Further, as stated earlier, we have eliminated the distinction between publicly traded and non-publicly traded companies.

Comment: A commenter urged CMS to expand the definition of limited risk to include entities that file with the Securities and Exchange Commission (SEC), even though they do not have securities traded on the NYSE or NASDAQ. By reason of their debt obligations, such entities are subject to the same disclosure and reporting requirements under Federal securities laws as a company that is subject to section 13 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Response: As stated earlier, we have eliminated the distinction between publicly traded and non-publicly traded companies, and the comment is no longer applicable.

Comment: A commenter stated that adjusting HHAs from the "limited" or "moderate" screening level to "high" risk simply because they reside in an area for which CMS imposes a moratorium is arbitrary and punishes good HHAs with no consideration of their compliant service to the Medicare beneficiaries and the program.

Response: As explained elsewhere in this section and also later in the general discussion regarding moratoria, a moratorium may be imposed if there is a heightened risk of fraud, waste, or abuse in a particular area or involving a certain provider or supplier category. If a particular provider or supplier type posed such a risk as to warrant a moratorium, it would be inappropriate for us to automatically exempt it from enhanced screening once the moratorium ends. To do so would, in effect, require us to state that once the moratorium ends, that provider or supplier type no longer poses a risk, a conclusion that we could not necessarily draw.

Comment: A commenter stated that the assignment of risk should be based on defined criteria beyond those proposed, such as compliance history related to billings, medial review, and history of negative audits from the program safeguard contractors. The commenter added that defined criteria should also be used to identify when providers are moved to different screening levels. For instance, brand new HHAs with no previous enrollment history should be part of the high screening level; however, upon 5 years of compliant operation, they should be moved to the moderate screening level. If a company with a 5 year compliance history opens a HHA, it should not be assigned to the high screening level; instead, it should be assigned to the moderate screening level based on its good history with Medicare. Agencies that have a 7 year or more compliance history should be assigned the limited screening level.

Response: Though we do not at this point believe that length of time as a Medicare provider should be a criterion for reducing a provider's or supplier's screening level, we may consider this as part of a future rulemaking effort should circumstances warrant.

Comment: A commenter believes that the phrase "Indian Health Service facilities" should be deleted in favor of "health programs operated by an Indian Health Program (as that term is defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as that term is defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act." Such language would encompass all Indian and tribal programs that are carried out pursuant to the Indian Health Care Improvement Act (IHCIA) and Indian Self-Determination and Education Assistance Act (ISDEAA). Moreover, to

ensure that all Indian and tribal health programs are treated as limited risk, the exception in (b)(1) and (c)(1) should be amended to refer to Indian and tribal health programs. The commenter stated that the burden on Indian and tribal providers of meeting new screening requirements would be significant and duplicative of screening requirements imposed already under the Indian Child Protection and Family Violence Act on many of the providers.

Response: We will revise the language in the final regulation as requested by the commenter to ensure that Indian and tribal health programs are described accurately and are assigned to the limited screening level.

Comment: A commenter stated that CMS should designate provider screening levels in the final rule with comment period, and should require changes in the risk level for a provider type to be subject to the rulemaking process.

Response: We have specified the different screening levels in this final rule with comment period. Should a change in a particular provider or supplier type's classification be warranted and should it necessitate a change in existing regulatory language, we will publish notice of it in the **Federal Register**. However, we will not publish notice of the circumstances under which an individual provider or supplier has been moved to an elevated level of screening as described in § 424.518(c) and § 455.450(e).

Comment: A commenter stated that ophthalmologists, optometrists, and opticians who only bill as DMEPOS suppliers for post-cataract glasses and lenses should fall into the limited screening level.

Response: As detailed previously, currently enrolled DMEPOS suppliers will be placed in the moderate level of categorical screening and newly-enrolling DMEPOS suppliers will be assigned to the high level of screening.

Comment: A commenter opposed CMS' proposal to consider assigning all providers or suppliers in a specific geographic location to a higher level of screening, solely because others in that area may be considered moderate or high risk. The commenter believes this type of action was arbitrary, and could cause new, limited risk providers to think twice before entering a geographic market, thus potentially blocking beneficiary access to needed services.

Response: We did not assign any provider or supplier category to a screening level based on geography.

Comment: A commenter did not believe independent laboratories should be placed in the moderate screening level, due to their high level of regulation. The commenter stated that the sheer volume has no bearing on risk and that they are already subject to regular site visits.

Response: We disagree. Based on our experience, we believe that independent laboratories are appropriately assigned to the moderate screening level. We note that newly-enrolling DMEPOS suppliers are, too, subject to site visits, yet they are assigned the high screening level.

Comment: A commenter stated that all physicians should not be placed in the limited screening level. Several specialties are increasingly engaging in abusive self-referral arrangements.

Response: For the reasons stated previously, we believe that physicians and non-physician practitioners are appropriately classified in the limited screening level. Moreover, we note that the final rule with comment period contains provisions for elevating a particular physician's or practitioner's screening level in certain circumstances.

Comment: One commenter disagreed that geographical circumstances should justify the adjustment of FQHC providers and suppliers to elevated screening levels based upon this criterion alone. The commenter stated that FQHC entities are in an entirely different classification and should not be subject to the same categorical movement.

Response: We assume this commenter is concerned about our ability to reassign providers or suppliers after a temporary moratorium is lifted such that FQHCs could be classified as high risk in the event they are located in an area in which a temporary moratorium is lifted. We intend to finalize the elevated risk factors. We believe it important to closely monitor all providers and suppliers in the event a temporary moratorium is imposed—and for a period thereafter. We note that this would only apply to providers and suppliers to which the moratorium applied. Unless the moratorium that was lifted had applied to either all providers and suppliers in a geographic area or to a category of providers or suppliers that included FQHCs or to FQHC specifically, the elevation to the high screening level would not apply to FQHCs or any other provider or supplier category not originally subject to the moratorium.

Comment: A commenter: (1) Expressed concern about potential application delays if the Medicare contractors have insufficient funds to conduct these visits; (2) requested assurances from CMS that adequate funds will exist; and (3) recommended that CMS provide guidance to the Medicare contractors on the timeframes within which enrollment inspections shall occur.

Response: We believe that adequate funds will exist to perform the required site visits, and we will issue guidance to our contractors regarding processing times.

Comment: A commenter expressed concern that tax-exempt, faith-based HHAs will be subject to a higher level of scrutiny than publicly traded for-profit HHAs. The commenter believes that such faith-based HHAs should be placed in the limited screening category.

Response: We have eliminated the distinction between publicly traded and non-publicly traded HHAs. We decline to adopt the commenter's suggestion to assign faith-based HHAs in the limited level of screening as it has not been our experience that faith-based HHAs present a different risk of fraud and abuse than non-faith-based HHAs.

Comment: A commenter stated that the inclusion of CMHCs in the "moderate" risk group seems appropriate given the history of fraud in "for profit" CMHCs. The commenter believes, however, that in the future, "not for profit" CMHCs be considered for status as a "limited" screening level.

Response: We decline to adopt the commenter's suggestion, as it has not been our experience that non-profit CMHCs pose a different risk than for-profit CMHCs. We will monitor CMHCs and other provider and supplier types after this final rule with comment period is implemented and, if need be, make adjustments to various risk classifications.

Comment: A commenter stated that the fingerprint requirement is problematic. The FD–258 fingerprint card could be fairly easy to obtain and complete without the involvement of government officials or by manipulating the form before forwarding it to the concerned government representative which could lead to fraudulent data being accepted by CMS contactors. In order to ensure the validity and acceptability of fingerprint data, the commenter stated that a clear chain of custody will be required for the FD–258 cards, providing for uninterrupted and secure forwarding of the completed cards from an originating law enforcement office to the CMS contractor. The commenter believes that consultation with the FBI and other expert agencies on this subject could prove valuable.

Response: CMS has consulted and will continue to consult with the FBI regarding the use of the FD–258 card. As noted previously, CMS has found that in addition to a longer processing time for

the FD–258, there is a higher cost to CMS for the processing of such cards. However, individuals who have their prints collected by a local law enforcement agency must use the FD–258 card and submit it to CMS' authorized channeler. The authorized channeler will digitize such FD–258 cards obtained at a local law enforcement agency for submission to the FBI. The chain of custody will conform to the FBI Security and Management Control Outsourcing Standard for Channelers and Non-Channelers and the FBI's Criminal Justice Information Services (CJIS) Division's Security Policy.

Comment: A commenter recommended that the proposed screening procedures be applied across the board for all providers and suppliers in or being introduced into any aspect of the Medicare, Medicaid or CHIP system.

Response: We disagree with this comment. Different categories of providers and suppliers pose different risks that must be addressed in distinct ways.

Comment: A commenter recommended that when determining whether to adjust an individual DMEPOS supplier's screening level, CMS should consider the supplier's: (1) Experience in furnishing services; (2) experience in the geographic area; (3) accreditation status and compliance with quality standards; and (4) compliance program, as well as any past fraudulent activity by the supplier or its employees and the category of DMEPOS it furnishes.

Response: We decline to adopt this approach. First, we believe that this could be subject to inherently arbitrary implementation. Second, as has been described previously, we believe the ACA requires us to assign categories of providers and suppliers to a level of screening based on the risk for fraud. The criteria the commenter proposes would necessitate a level of pre-screening that is not feasible for every applicant CMS must process.

Comment: A commenter stated that providers and suppliers should be individually notified of the screening level into which they will be placed and the reasons for such designation. The categorizations should not be made public because that could easily lead to irreparable damage to reputations and the companies' business.

Response: The publication of this final rule with comment period serves as notification to suppliers and providers of the assignment of their category to a particular screening level. The only new screening requirement that requires action on the part of a provider or supplier is the fingerprint-based criminal history record check. As stated, there will be an additional 60 day period after the publication of subregulatory guidance prior to its implementation for DMEPOS and HHAs. In instances where an individual provider or supplier has been reassigned to a higher level of scrutiny under § 424.518(c)(3), we anticipate that each provider or supplier will be individually notified of its newly assigned screening level prior to revalidation. This process will be clarified in the subregulatory guidance that CMS will issue as described in this final rule with comment period. Moreover, to the extent permitted by Federal law, we do not intend to make public a particular provider or supplier's screening level assignment.

Comment: A commenter requested that CMS expand the limited screening level defined in the proposed regulation to include the term "non-physician practitioner." This term is frequently used to describe nurse practitioners, clinical nurse specialists, and physicians' assistants.

Response: This regulation uses the term "non-physician practitioner" in describing categories of providers assigned to a level of screening. *See* § 424.518(a)(1)(i).

Comment: A commenter recommended that, to the extent allowed under law, CMS disclose limited information about the risk model so as to avoid reverse-engineering by individuals intent on defrauding the Medicare program.

Response: We appreciate this comment, but believe it is important that the provider and supplier communities be made aware of what will be required as part of the enrollment process.

Comment: A commenter recommended that reimbursement be provided for the cost of the background check and fingerprint card. With budget cuts and regulatory mandates, providers are struggling to meet the increasing costs of delivering health care services in an environment with decreasing resources. Another commenter suggested, however, that fingerprinting be done at the cost of the provider prior to the Medicare contractor receiving the enrollment application.

Response: A fingerprint-based criminal history record check is part of the Medicare enrollment screening process for specified applicants. The cost of the having the fingerprints taken and supplying the fingerprints to the authorized channeler, whether electronic or on the card, will be borne by the provider or supplier. There will be no cost to the provider or supplier for the subsequent processing of the prints or the background check, as CMS will pay for the processing of the prints and the criminal history record check.

Comment: A commenter recommended that providers be able to have their fingerprints electronically scanned with a vendor contracting with the Federal government.

Response: Shortly after the publication of this final rule with comment period, we will be issuing guidance to the provider and supplier communities regarding the processes for obtaining fingerprints. We anticipate that CMS will contract with an FBI-approved authorized channeler for the collection and transmission of fingerprints. It is our understanding that such authorized channelers use electronic technology to collect and process fingerprints. We will provide more information regarding available technologies and vendors prior to the implementation of this requirement, as announced 60 days prior to the effective date through the publication of subregulatory guidance.

Comment: A commenter stated that CMS needs to ensure that information used in the classification of suppliers is correct and appropriate. Thus, CMS should require that only final agency actions be used as a basis for assigning suppliers. Decisions overturned on appeal should have no bearing or effect on the supplier's screening level.

Response: We do not believe it is appropriate to wait until a particular action is final before shifting a provider into a different screening level. The appeals process can take an extended period, during which a provider intent on defrauding the Medicare program could have more time to do so if permitted to remain in a lower screening level. As already mentioned, should a particular action be rescinded, the provider will be restored to its previous screening level.

Comment: A commenter stated that pharmacies licensed by the State—whether newly enrolling or as part of an additional location—should be specified as limited risk providers.

Response: As we mentioned earlier, State licensure is not automatically indicative of the screening level that should be ascribed to a category of provider or supplier.

Comment: A commenter questioned whether hospice organizations are correctly included within the moderate screening level and should instead be included in the limited screening level. The commenter did not believe that sufficient data exists to justify placing

hospices in the moderate screening level.

Response: For the reasons we explained, we believe that hospices are most appropriately as assigned to the moderate screening level.

Comment: A commenter stated that if an enrollment moratorium were placed on a particular geographic area and then lifted, the Medicare contractor would be required to conduct background checks and fingerprints on all physicians in that area. The commenter urged CMS to reconsider the burdens and costs of doing so for large groups of providers. The delays in processing these applications would deter physicians from enrolling and revalidating their enrollments. The commenter also stated that CMS should limit those physicians placed in the highest level of screening to individuals previously found guilty of crimes against Medicare or where there is publicly available evidence to justify such intrusions.

Response: The situation described in the commenter's first sentence would only apply in the unlikely event that physicians in that area were subject to a moratorium. As stated earlier, CMS does not believe that the collection of the fingerprints for the FBI fingerprint-based criminal history record check will substantially impact the time to process an enrollment application by the relevant Medicare contractor. If, as will most likely be the case with any temporary enrollment moratorium, the moratorium only applies to non-physician provider or supplier types, physicians would not be affected by the lifting of the moratorium. We believe we have clarified this point in the final rule with comment period.

Comment: Regarding fingerprinting and background checks, a commenter requested clarification regarding: (1) How the information will be stored and whether it will be destroyed after a period of time; (2) how the information will be used; (3) what constitutes background information that rises to the level of a threat to Medicare; (4) whether the physician or non-physician practitioner be afforded a copy of the results; (5) the policies that will ensure that the information is protected and secure and, in the event of a security lapse, whether the practitioner will be notified; (6) who will be conducting the background checks; (7) whether the information will be added to State or Federal databases for other purposes; and (8) whether practitioners will know prior to or at the time of application submission that they will be subject to these additional requirements.

Response: We have clarified in this final rule with comment period that the fingerprint requirement will be used in the context of obtaining FBI criminal history record information. This information will be stored according to all Federal requirements as well as the FBI's Security and Management Control Outsourcing Standard for Channelers and Non-Channelers and the CJIS Security Policy. CMS will rely on existing authority to deny and revoke enrollment at § 424.530(a) and § 424.535(a) if an individual who maintains a 5 percent or greater direct or indirect ownership interest in a provider or supplier has certain prior felony convictions, or if an enrollment application contains false or misleading information. The FBI will send the results of the criminal history record check only to the authorized channeler, who will be permitted to send the results only to the authorized recipient, or an FBI approved outsourced third party. In the event of loss of the criminal history record reports, CMS will follow the established protocol for communicating with the public and individuals regarding the loss of personally identifiable information. The criminal history record information is compiled when the FBI receives the fingerprint and links it to an existing record(s) of arrest and prosecution in State and FBI databases. Individuals or entities do not conduct criminal background checks. CMS, through an authorized channeler, will be accessing existing law enforcement data on fingerprinted individuals as required by this final rule with comment period. CMS will inform all relevant individuals of their requirement to submit fingerprints for the purposes of an FBI criminal history check as a condition of enrollment. While we are finalizing this screening method, we do not plan to implement this provision upon the effective date. Instead, we will be issuing additional guidance to providers, suppliers, the general public, and our contractors after the publication of this final rule with comment period to explain the operational aspects of the fingerprint-based criminal history record check requirement. As stated previously, we will delay implementation until 60 days after the publication of subregulatory guidance.

Comment: A commenter asked who will pay the fee for the fingerprinting and, if the physician or practitioner must pay it, whether he or she will be reimbursed, given the restrictions on application fees for certain non-institutional providers.

Response: The relevant individuals who are required to undergo the criminal history record check will incur the cost of having their fingerprints taken. Providers and suppliers will not be reimbursed by Medicare, Medicaid or CHIP for the fingerprint collection costs. CMS will bear the cost of processing the fingerprint-based criminal history record check for providers and suppliers that enroll in Medicare. For Medicaid-only and CHIP-only providers, the States and Federal government will share these costs.

Comment: A commenter stated that fingerprinting is generally limited to certain hours of the day. Due to the demands of physicians' schedules, the commenter asked how CMS will ensure the availability of fingerprinting for those physicians placed in the high screening level.

Response: Physicians who are enrolled in Medicare as practicing physicians will generally not be subject to fingerprinting. Fingerprint-based criminal history record checks will only be required in the case of providers or suppliers that are assigned to the high screening level. Physicians are generally assigned to the limited screening level.

Comment: A commenter urged CMS to ensure that fingerprinting and background checks do not delay the enrollment of legitimate and honest physicians.

Response: Physicians are generally assigned to the limited screening level and, as such, will not be subject to fingerprinting based on their enrollment as a physician. Physicians who choose to enroll as DMEPOS suppliers or HHAs will be required to undergo a fingerprint-based criminal history record check as a requirement of the high screening level but, as stated previously, CMS does not believe this requirement will significantly delay the enrollment of any provider or supplier.

Comment: A commenter stated that hospital-owned HHAs and hospices should be designated as limited risk and, therefore, should not be subject to unannounced and unscheduled pre-enrollment and/or post-enrollment onsite visits.

Response: For the reasons already discussed, newly enrolling HHAs will be placed in the high screening level, regardless of ownership.

Comment: Several commenters stated that implementing the new screening procedures by March 23, 2011 is not feasible due to the coordination efforts required between Medicare and Medicaid. They recommended that the implementation date be moved to March 23, 2012.

Response: We disagree, and believe that all screening procedures except the fingerprint-based criminal history record check required for those in the high level of screening will be in place

beginning on March 25, 2011. As noted previously, we will delay implementation of such high screening level until 60 days after the publication of subregulatory guidance on how this provision will be implemented. Further, we believe the statute requires the implementation dates that we have specified.

Comment: A commenter recommended that CMS reconsider the risks associated with allowing existing enrollees to be exempted from the new screening procedures until March 23, 2012. The commenter believes this creates a potential gap in program integrity.

Response: The ACA specifies the effective dates for the new screening provisions. For newly enrolling providers and suppliers, and for those currently enrolled whose revalidation is scheduled between March 25, 2011 and March 23, 2012, the effective date is March 23, 2011 or the date scheduled for the revalidation. For providers and suppliers assigned to the high screening level, the fingerprint-based criminal history record check requirement will be implemented through subregulatory guidance and will be effective 60 days following the publication of the guidance. All other screening requirements are effective on March 25, 2011 for those in the high screening level. For all other currently enrolled providers and suppliers, the statute established an effective date of March 23, 2012.

Comment: A commenter recommended simplifying the screening process such that all enrolling providers and suppliers are put into the moderate level, and then adjust screening interventions based on specific circumstances related to elevated risk of fraud.

Response: We decline to base the assignment of provider and supplier types to a level of screening on the assumption that every provider or supplier is of equal risk upon enrollment into the Medicare. We see clear differences in risk among categories of providers and snppliers. Therefore, we do not plan to assign all provider and supplier categories to the same screening level. In response to the suggestion that we adjust screening interventions based on specific circumstances, we believe this process is both unwieldy and burdensome to implement for every provider as the baseline screening methods. Although we have identified certain events that will cause a provider to move from "limited" or "moderate" to "high" screening, we do not believe we should conduct individual assessments. As stated previously, CMS will assess an individual provider's risk and potential actions based on the individual provider's enrollment application and may continue to use existing program integrity tools that are not addressed by this rule. We believe this approach is the most objective approach and is consistent with the ACA.

Comment: A commenter requested clarification on how States will be notified of providers' risk classifications and any changes thereto.

Response: We will disseminate guidance to the States on this topic shortly after the publication of this final rule with comment period.

Comment: A commenter recommended that CMS explain whether it is replacing or removing the current revalidation basis in § 424.535(a)(6) with the proposed new § 424.535(a)(6).

Response: We are neither replacing nor removing the current revalidation basis. We simply proposed an additional reason at § 424.535(a)(6)(i) for the revocation of Medicare billing privileges. Specifically, we proposed that billing privileges may be revoked if "An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application," or the hardship exception is not granted. We will renumber the subsections in § 424.535(a) accordingly.

The commenter refers to the current revalidation basis but cites to the revocation regulation. To clarify, as stated previously, the proposed rule proposed to require that a provider or supplier revalidate its enrollment at any time pursuant to § 424.515. This new authority to permit off-cycle revalidations does not replace the current cycle for revalidation (3 years for DMEPOS and 5 years for all other providers).

Comment: To reduce the paperwork burden imposed on providers and suppliers and to reduce the administrative expense associated with processing a revalidation application, several commenters recommend that CMS allow providers and suppliers in good standing to submit an annual attestation, rather than a full revalidation application. The attestation, in other words, would be used in lieu of revalidation, and would require the provider or supplier to notify CMS of eny changes or to attest that there were no changes within the prior year. This approach would promote compliance without requiring the provider or supplier to submit a full revalidation application and a fee.

Response: The burden associated with submitting Medicare enrollment applications A, B, I, R and CMS–855S is currently approved under Office of Management and Budget (OMB) control numbers 0938–0685 and 0938–1057, respectively. Such an attestation, as proposed by the commenter, would not fulfill the screening requirements of this final rule with comment period, as re-screening is a condition of revalidation. The screening requirement and associated application fee are required by the ACA to minimize the risk of fraud, waste and abuse to the Medicare, Medicaid programs and CHIP, and cannot be circumvented by a process that would limit the scope of such screenings.

Comment: One commenter stated that CMS did not furnish sufficient justification or rationale for its proposal in § 424.515 that CMS may require a provider or supplier to revalidate its enrollment at any time. The commenter added that the proposed revision seems punitive and overly broad because CMS does not furnish ample discussion for the public to fully evaluate the proposal. The commenter recommended that CMS remove its proposal because CMS did not: (1) Justify its reasons for establishing this new authority, (2) describe its existing authorities and how this proposal is different, and (3) explain or justify the number of times that CMS can require revalidation within a given period of time.

Response: We proposed at § 424.515 that we have the ability to require that a provider or supplier revalidate its enrollment at any time, and stated that this proposal was designed to help ensure that the statutory effective date of March 23, 2013 is met. We fully intend to implement the new authorities provided by the ACA by the deadlines that have been set out by the Congress.

We stated in the proposed rule that DMEPOS suppliers are required to re-enroll every 3 years, and other providers and suppliers are required to revalidate their enrollment every 5 years. For purposes of clarity, we also proposed language at § 424.57(e) that changes all references to "re-enroll" or "re-enrollment" to "revalidate" or "revalidation." We have existing authority at § 424.515(d) to require off-cycle validations in addition to the regular 5 year revalidations and may request that a provider or supplier recertify the accuracy of the enrollment information when warranted to assess and confirm the validity of the enrollment information maintained by us. Such off-cycle revalidations may be triggered as a result of random checks, information indicating local health care

fraud problems, national initiatives, complaints, or other reasons that cause us to question the compliance of the provider or supplier with Medicare enrollment requirements. Off cycle revalidations may be accompanied by site visits. The new authority to conduct off-cycle validations of providers and suppliers will enable us to apply the new screening requirements to all currently enrolled providers and suppliers by the statutory effective date.

The proposed rule stated that once a provider has been subject to an off-cycle validation under § 424.515(e), the current cycle for revalidation would apply. This means that if a provider subject to the 5-year revalidation cycle had to revalidate in 2013, the provider or supplier would next have to revalidate in 2018. However, a provider or supplier may be required to revalidate under § 424.515(d) during that time period if there are indicators of the noncompliance for a particular provider.

Comment: A commenter stated that CMS currently requires contractors to review State licensing board data on a monthly basis. As such, it would be more efficient to access a centralized, federated database to provide CMS with the most comprehensive data on physician licensure status.

Response: As previously mentioned, we are currently in the process of re-assessing the provider enrollment process and systems that are used to support screening and enrollment. We are exploring a number of options to take advantage of technological advances to improve the provider screening process. Increased automation of the process is one of the areas on which we are focusing.

Comment: A commenter stated that, given the ongoing Medicare backlogs, CMS should provide information regarding: (1) The number of revalidations started and completed by CMS or its contractors in 2007, 2008, 2009, and 2010, (2) how an estimated 93,000 revalidations per year beginning in 2010 will impact the processing of new applications by providers and suppliers, and (3) the amount of money obligated on provider screening activities for each fiscal year between 2005 and 2010, and (4) how much money CMS expects to obligate for these activities in 2011. Another commenter recommended that CMS furnish the number of revalidation applications processed by the National Supplier Clearinghouse, MACs, carriers, and fiscal intermediaries for each of the last 5 years.

Response: This final rule with comment period specifically increases the number of providers and suppliers that will be revalidated through the use of off-cycle revalidations, for the explicit purpose of applying the new screening requirements to currently enrolled providers. Therefore, the number of revalidations processed in the past 4 or 5 years and the money obligated to that process is irrelevant to the evaluation of our ability to process additional revalidations as required by this final rule with comment period. Additionally, we have undertaken steps to streamline the enrollment process, both for newly enrolling and revalidating providers and suppliers. We recognize that there have been challenges in implementing the new authorities to safeguard the integrity of Medicare, Medicaid and CHIP, and have demonstrated a willingness to work with providers and suppliers to reduce unnecessary burdens and risks that may have accompanied the enrollment processes in the past. We have communicated with providers via Medicare Learning Networks and provider Open Door Forums, and will continue to do so throughout the implementation of the ACA.

We believe that additional resources will be available to enable the processing of the increased numbers of enrollment applications. We have actively taken steps to reduce processing times as much as feasible. Furthermore, we have undertaken many activities to streamline the enrollment process to reduce the burden upon providers and suppliers.

Comment: A commenter recommended that CMS employ an expanded data-driven screening process by using open-source data during the enrollment and re-enrollment business processes. Such data could include the current operational status of the firm; chain of ownership or corporate family linkages; identification of tax liens; presence of open bankruptcies; and records of government enforcement actions. The commenter also suggested that each provider and supplier be registered for post-enrollment data monitoring, which "pushes" one or more high risk updates (for example, bankruptcy filing; a criminal filing involving a provider executive; or sudden increase in the risk of financial failure) to CMS automatically. CMS could use such high risk alerts for the selection and prioritization of unscheduled and unannounced site visits. Finally, the commenter recommended additional database checks that would vary by screening level. These included, but were not limited to, verifying: (1) Corporate chain of ownership, (2) tax liens, (3) non-HHS government enforcement actions, (4) extent of any government contracting, and (5) any open lawsuits.

Response: As stated previously, we are continually exploring additional improvements to our data systems. We are committed to working with both private and public partners to continue to evaluate technologies that can provide the scalability and safeguards to beneficiary access that we need to ensure accurate payments to legitimate providers for appropriate services.

Comment: A commenter urged CMS to release a proposal for comment that provides additional detail regarding what CMS believes should constitute background information relevant to Medicare provider enrollment that would prevent a practitioner from enrolling in the Medicare program.

Response: At some point it may be necessary to modify our existing regulations that address felonies that are relevant to enrollment of billing privileges. However, we have not yet proposed expansion of our existing authorities codified in the Code of Federal Regulations. The requirements for Medicare enrollment are established in other regulations and manual instructions, and are not—unless otherwise stated herein—being modified in this final rule with comment. The criminal background check is intended to verify certain information provided on the Medicare enrollment application. Under our existing regulatory authority, we could impose a denial of enrollment or a revocation of billing privileges based upon the results of the background check in certain instances. Illustratively, if, through the background check, CMS learned of a felony conviction that met the criteria at § 424.530(a)(3) or § 424.535(a)(3), billing privileges could be denied or revoked, respectively.

Comment: One commenter stated that in its FY 2011 performance budget, we say that we will create a limited number of MACs to carry out provider enrollment, and that each contractor would enroll providers for designated regions of the country. Given the publication of the proposed rule, the commenter recommended that we explain how reducing the number of MACs and increasing the workload will help providers and suppliers and reduce Medicare fraud, waste, and abuse in the Medicare program. The commenter also requested that CMS furnish an update on this consolidation effort. Another commenter asked CMS to explain how it will consolidate provider enrollment activities, conduct 93,000 ravalidations, and handle initial applications without disrupting the provider enrollment

process and creating additional backlogs and processing delays for providers of service and suppliers.

Response: We recognize that provider enrollment is a large and complicated task that requires not only internal consistency but also understanding and ease of interaction with the provider and supplier community. As a result, we are currently engaged in a thorough assessment of the provider enrollment process and in making improvements as needed to eliminate delays in enrollment and improve overall system performance. As part of this process, we are working toward consolidation of the number of enrollment contractors as a means to achieve economy of scale and greater consistency in the enrollment process. In developing the provisions of this final rule with comment period and other regulatory and subregulatory policies, we are mindful of the overall re-assessment of the provider enrollment process and supporting systems.

Comment: A commenter urged CMS to refine its provider enrollment specialty categories to accurately reflect the existing varieties of practitioners—particularly the categories for dentistry and the dental specialties—in order to reduce the likelihood that practitioners such as dentists will be inappropriately categorized and subject to unwarranted higher levels of screening.

Response: We do not believe it is necessary to further refine the provider enrollment specialty. Dentists should submit the CMS–855I if they intend to submit claims directly to Medicare. Further, dentists would be in the limited screening level.

Comment: A commenter stated that the proposed rule does little to prevent: (1) Identity theft; (2) health care fraud; (3) money laundering; and (4) bank fraud. The commenter believes that the screening levels were too broad and simplistic. To prevent fraud and abuse, the commenter recommended that CMS: (1) Implement section 6401(a)(3) of the ACA immediately; (2) consider and adopt distinct screening criteria and program requirements for non-physician owners of medical clinics and that these providers be placed into a high screening level, and (3) use the statutory authority in section 6401(a)(3) of the ACA to make sure that the claims being submitted are valid.

Response: We believe the commenter is referring to new section 1866(j)(3) of the Act, which addresses a provisional period of enhanced oversight for new providers of services or suppliers. We will implement all authorities granted under the ACA using the proper procedures. We disagree with the commenter that the proposed rule and this final rule with comment period will do little to prevent health care fraud, and believe that issues of money laundering and bank fraud are beyond the scope of this final rule with comment period. We strongly believe that additional site visits, both announced and unannounced, will help to identify fraudulent providers and suppliers before they are permitted to enroll in Medicare, Medicaid or CHIP. The temporary moratoria and payment suspension provisions give us the ability to act as soon as a problem is detected, preventing money from being paid while balancing the rights and needs of providers, suppliers, and beneficiaries.

Comment: One commenter stated that CMS's proposed ability to reenroll DMEPOS suppliers more frequently than every three years could be burdensome for CMS and the DMEPOS supplier, and suggested that CMS revalidate every 3 years from the most recent revalidation, rather than every 3 years from the date billing privileges were granted.

Response: As stated previously, the proposed rule and this final rule with comment period permit us to require revalidation of DMEPOS suppliers on or after March 23, 2012 to meet the statutory effective date for the screening requirements; after that, DMEPOS suppliers would then be subject to revalidation every 3 years. DMEPOS could be subject to off-cycle revalidation under existing authority at § 424.515(d) when CMS has reason to question the compliance of the provider or supplier with Medicare enrollment requirements.

Comment: One commenter stated that identity theft is a huge problem in the United States and that Medicare, Medicaid and CHIP should do everything possible to protect physicians' identities. The commenter recommended that CMS provide data on the number of physicians and non-physician practitioners who have practice locations in multiple States—including States with connecting State boundaries and States without connecting State boundaries. The commenter also suggested that CMS explain what efforts, if any, are used to verify a physician that is establishing a practice location in multiple States and that the individual's identity is authenticated. Another commenter stated that it is unclear how fingerprinting and background checks will achieve the goal of preventing identity theft for physicians.

Response: We agree with the comment that Medicare, Medicaid and CHIP should use all available authorities to protect physicians' identities. However, as we have noted previously, we will not use this screening regulation to identify instances of identity theft. We disagree that the publication of the number of physicians and non-physician practitioners who have practice locations in multiple States will address the issue of identity theft. We also have a process in place to verify a physician is legitimately establishing practice locations in multiple States, and have found there are multiple legitimate reasons why this may be the case.

We believe that criminal history record checks will enable us to verify information that has been submitted on an enrollment application is accurate and complete. As stated previously, using fingerprints to perform such a record check is the only accepted method by the FBI for non-criminal justice purposes, as it is believed to be the most accurate link between an individual and their criminal history record.

Comment: A commenter stated that in the proposed rule, CMS does not justify or explain the rationale for many of its positions, such as: (1) Placing providers and suppliers into various screening categories, and (2) its rationale for creating a new revalidation reason (*see* § 424.515(e)). The commenter recommended that CMS not finalize this proposed rule, but rather publish a new proposed rule using the information from this rule.

Response: We disagree that the proposed rule did not explain our rationale for our approaches. As mentioned earlier, we relied on our extensive experience to identify categories of providers with a higher incidence of fraud, waste and abuse. In addition, we used the expertise of our contractors charged with identifying and investigating instances of fraudulent billing practices in making our decisions regarding the appropriate risk classification of various providers. In some instances, we also relied on the data analysis and expertise of the OIG, GAO, and other sources to develop a process designed to increase scrutiny for specific categories of providers and suppliers that represent a higher risk to the Medicare program. Furthermore, we stated the new reason for off-cycle validation is to enable us to apply the new screening requirements to all applicable providers and suppliers by the statutory effective date of March 23, 2013.

Comment: In response to a request for comments, a commenter stated that harmonization between Medicare, Medicaid, and MA would be beneficial

only to the extent that the programs have enrollment and re-validation reciprocity and that adequate resources and time were allocated to ensure that harmonization does not wreak havoc among state Medicaid programs and MA plans. Reciprocity would ensure that physicians are not subject numerous times to the same or similar onerous requirements; this would also represent significant savings for Federal health care programs.

Response: We agree that harmonization between program requirements will be beneficial for State Medicaid agencies, providers, and CMS. This final rule with comment period implements several changes that minimize the burden on States and providers, including the reciprocity of Medicare screening for dually enrolled providers and State responsibility to screen only Medicaid and CHIP-only providers.

Comment: A commenter requested special consideration and/or exemptions for States with comprehensive licensure statutes for orthotists and prosthetists.

Response: We do not agree that licensed orthotists and prosthetists should receive special consideration or exemptions as compared to orthotists and prosthetists that happen to be located in a State without what could be deemed 'non-comprehensive' licensure statutes. CMS did not make a distinction based on licensure requirements for any other category of provider.

Comment: A commenter opposed the proposed language at § 424.515(e) allowing CMS to require additional off-cycle revalidations, stating it could allow CMS to initiate revalidations frequently and on a whim. At a minimum, off-cycle revalidations should be exempt from the $500 application fee.

Response: We disagree with this comment. Section 424.515(e) was added for a specific purpose and we could not require a provider or supplier to revalidate off-cycle pursuant to § 424.515(e) more than once. The application fee was included in the statute to cover exactly the type of screenings that will be performed during the revalidations, and we do not believe it is appropriate or necessary to exempt the revalidations from the fee.

Comment: A commenter suggested that CMS tie an enrollment ban to those who are trying to enroll in the Medicare program and not just for those who are already enrolled. That way, fraudulent providers would never be allowed to enter the program.

Response: We believe the commenter is referring to an enrollment bar for providers and suppliers whose applications are denied, similar to that which is currently in place for providers and suppliers whose Medicare billing privileges are revoked. We appreciate this suggestion. We are currently not in a position to adopt it, as additional research is needed to determine its potential effectiveness and the various circumstances under which it might apply. That said, we may consider it as part of a future rulemaking effort.

c. Final Screening Provision—Medicare

This final rule with comment period finalizes the provisions of proposed rule in regards to the Medicare screening requirements with the following modifications:

- In § 424.518(a)(1), we are adding Competitive Acquisition Program/Part B Vendors to the limited risk screening level.
- In § 424.518(a)(1), we are adding pharmacies that are newly enrolling or revalidating via the CMS–855B to the "limited" level of screening.
- In § 424.518(a)(1), in response to comments, we have changed the description for Indian health service providers to state, "health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act, hereinafter (IHS facilities)."
- In 424.518(a)(2), we are clarifying that occupational therapy and speech pathology providers are assigned to the limited screening level.
- In 424.518(a)(1), we are removing physical therapists and physical therapist groups from the category of non-physician practitioners that are within the limited screening level.
- In 424.518(a)(1), we are removing non-public, non-government owned or affiliated ambulance suppliers from the limited screening level.
- In § 424.518(a)(2), we are adding portable x-ray suppliers to the moderate screening level.
- In 424.518(a)(2), we are adding physical therapists and physical therapist groups to the moderate screening level.
- In 424.518(a)(2), we are assigning all ambulance suppliers to the moderate screening level, regardless of whether they are public or government affiliated.
- In § 424.518(a)(1), we are adding pharmacies that are newly enrolling or revalidating via the CMS–855B to the limited screening level.
- In § 424.518, we also eliminated the distinction between: (1) Publicly traded and non-publicly traded, and (2) publicly owned and non-publicly owned as criteria for assignment of any provider type to a level of screening.
- In § 424.518(c)(2)(ii)(A), we have removed the requirement that fingerprints must be submitted using the FD–258 fingerprint card. Also, the fingerprints must be collected from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.
- In § 424.518(c)(2)(ii)(B), we have replaced "conducts a criminal background check" with "Conducts a fingerprint-based criminal history report check of the Federal Bureau of Investigations Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier."
- In § 424.518(d), we have identified owners with a 5 percent or greater direct or indirect ownership as responsible for providing fingerprints, and the methodology of how to submit the fingerprints.
- § 424.518(c)(3), we have added "final adverse action" as a basis for reassigning a provider or supplier to the high screening level at § 424.518(c)(3)(iii)(B).
- In § 424.518(c)(3), we have added six months as the length of time a provider or supplier category will be assigned to the high screening level following the lifting of a temporary enrollment moratorium.
- Finally, in § 424.518(c)(3), we have removed denial of Medicare billing privileges in the previous ten years as a basis for reassigning a provider or supplier to the high screening level at § 424.518(c)(3)(iii)(B).

As we have stressed throughout this preamble, we will monitor these new procedures and their effectiveness and may reconsider or modify our approach in the future as we gain experience with these procedures. We further reiterate that nothing in this rule is intended to abridge our established screening authority under existing statutes and regulations, or to diminish the screening that providers and suppliers currently undergo. The provisions specified in this final rule with comment period are intended to enhance—not replace—our existing authority. The screening laid out here reflects the minimum requirements. For example, a contractor may undertake database checks in addition to the ones listed below as deemed appropriate. Nothing in this rule should be interpreted as limiting the amount of scrutiny CMS or its

contractors may give to an applicant. Tables 5 through 8 below outline the levels of screening by category that we are finalizing.

TABLE 5—FINAL LEVEL OF REQUIRED SCREENING FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X
Conduct license verifications, (may include licensure checks across States)	X	X	X
Database Checks (to verify Social Security Number (SSN); the National Provider Identifier (NPI); the National Practitioner Data Bank (NPDB) licensure; an OIG exclusion; taxpayer identification number; death of individual practitioner, owner, authorized official, delegated official, or supervising physician	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Fingerprint-Based Criminal History Record Check of law enforcement repositories			X

TABLE 6—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "LIMITED" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Physician or non-physician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapist groups.
Ambulatory surgical centers, competitive acquisition program/Part B vendors, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B, radiation therapy centers, religious non-medical health care institutions, rural health clinics, and skilled nursing facilities.

TABLE 7—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "MODERATE" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Ambulance suppliers, community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; physical therapy including physical therapy groups and portable x-ray suppliers.
Currently enrolled (revalidating) home health agencies.

TABLE 8—FINAL MEDICARE PROVIDERS AND SUPPLIERS CATEGORIES DESIGNATED TO THE "HIGH" LEVEL FOR SCREENING PURPOSES

Provider/supplier category
Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of DMEPOS.

4. General Screening of Providers—Medicaid and CHIP—Proposed Provisions and Analysis of and Responses to Public Comments

Section 1902(kk)(1) of the Act requires that States comply with the process for screening providers established by the Secretary under section 1866(j)(2) of the Act.[4] Section 2107(e)(1) of the Act provides that all provisions that apply to Medicaid under sections 1902(a)(77) of the Act,[5] the State plan mandate for compliance with provider and supplier screening, oversight, and reporting requirements in accordance with 1902(kk), and 1902(kk) of the Act, the specific State plan requirements regarding provider and supplier screening, oversight, and reporting, shall apply to CHIP. We proposed in new § 457.990 that all the provider screening, provider application, and moratorium regulations that apply to Medicaid providers will apply to providers that participate in CHIP. In addition, in this final rule with comment period, we refer to State Medicaid agencies as responsible for screening Medicaid-only providers. In some States, CHIP is not administered by the Medicaid agency. Throughout this final rule with comment period, with respect to those instances, "State Medicaid agency" should be read to encompass "Children's Health Insurance Program agency" where the two are separate entities.

Because it would be inefficient and costly to require States to conduct the same screening activities that Medicare contractors perform for dually-enrolled providers, we proposed that a State may rely on the results of the screening conducted by a Medicare contractor to meet the provider screening requirements under Medicaid and CHIP. Similarly, we proposed in § 455.410 that State Medicaid agencies may rely on the results of the provider screening performed by the State Medicaid programs and CHIP of other States. For Medicaid-only providers or CHIP-only providers, we proposed that States follow the same screening procedures that CMS or its contractors follow with respect to Medicare providers and suppliers.

As previously noted, section 1902(kk)(1) of the Act requires that State screening methods follow those performed under the Medicare program. For the sake of brevity, we will not restate those methods verbatim. We proposed that States follow the rationale that we have set forth for Medicare in section II.A.3. of this final rule with comment period, and that we use as the basis for § 455.450. For the types of providers that are recognized as a provider or supplier under the Medicare program, States will use the same screening level that is assigned to that category of provider by Medicare. For those Medicaid and CHIP provider types that are not recognized by Medicare, States will assess the risk posed by a particular provider or provider type. States should examine their programs to identify specific providers or provider types that may present increased risks of fraud, waste or abuse to their Medicaid programs or CHIP. States are uniquely qualified to understand issues involved with balancing beneficiaries' access to medical assistance and ensuring the fiscal integrity of the Medicaid programs and CHIP. However, where applicable, we expect that States will assess the risk of fraud, waste, and abuse using similar criteria to those used in Medicare. For example, physicians and non-physician practitioners, medical groups and clinics that are State-licensed or State-regulated would generally be categorized as limited risk. Those provider types that are generally highly

[4] As noted previously, we believe that the reference to section 1866(j)(2) of the Act in section 6401(b)(1) of the ACA is a scrivener's error, and that the Congress intended to refer instead to section 1866(j)(2) of the Act.

[5] Section 1902(a)(77) is only broadly referenced in the final regulations under section § 455.400, as a statutory section being implemented by the regulation.

dependent on Medicare, Medicaid and CHIP to pay salaries and other operating expenses and which are not subject to additional government or professional oversight would be considered moderate risk, and those provider types identified by the State as being especially vulnerable to improper payments would be considered high risk. States will then screen the provider using the screening tools applicable to that risk assigned. However, we did not propose to limit or otherwise preclude the ability of States to engage in provider screening activities beyond those required under section 1866(j)(2) of the Act, including, but not limited to, assigning a particular provider type to a higher screening level than the level assigned by Medicare.

As with the proposed screening provisions for Medicare, we solicited comments on the applicability of these proposals for Medicaid as well. We solicited comment on the proposed assignment of specific provider types to established risk categories, including whether such assignments should be released publicly, whether they should be reconsidered and updated according to an established schedule, and what criteria should be considered in making such assignments.

Based on the level of screening assigned to a provider or provider type, we proposed that States conduct the following screenings:

TABLE 9—PROPOSED LEVEL OF RISK AND REQUIRED SCREENING FOR MEDICAID AND CHIP PROVIDERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicaid/CHIP	X	X	X
Conduct license verifications (may include licensure checks across State lines)	X	X	X
Database Checks (to verify SSN and NPI, the NPDB, licensure, a HHS OIG exclusion, taxpayer identification, tax delinquency, death of individual practitioner, and persons with an ownership or control interest or who are agents or managing employees of the provider)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X

Not all States routinely require persons with an ownership or control interest or who are agents or managing employees of the provider to submit SSNs or dates of birth (DOBs). Without such critical personal identifiers, it is difficult to be certain of the identity of persons with an ownership or control interest or who are agents or managing employees of the provider, and it may be difficult for States to conduct the screening proposed under this rule. Accordingly, and to be consistent with Medicare requirements, pursuant to our general rulemaking authority under section 1102 of the Act, we proposed in § 455.104 to require that States will require submission of SSNs and DOBs for all persons with an ownership or control interest in a provider. In addition to the amendment to § 455.104, we proposed to revise that section for the sake of clarity both for the disclosing entities' provision and the States' collection of the disclosures. We recognize that there may be privacy concerns raised by the submission of this personally identifiable information as well as concerns about how the States will assure individual privacy as appropriate; however, we believe this personally identifiable information is necessary for States to adequately conduct the provider screening activities under this final rule with comment period. We solicited comment specifically on this issue.

Although the level of screening may vary depending on the risk of fraud, waste or abuse the provider represents to the Medicaid program or CHIP, under section 1866(j)(2)(B)(i) of the Act, all providers would be subject to licensure checks. Therefore, we proposed that States be required to verify the status of a provider's license by the State of issuance and whether there are any current limitations on that license.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers would apply to providers that participate in CHIP, these requirements for provider screening and assigning of categories of risk of fraud, waste, or abuse, as well as verification of licensure, under § 455.412 and § 455.450 will apply in CHIP.

Comment: Commenters expressed concerns about new and existing disclosure requirements under § 455.104, including our proposal to add to the disclosure requirements collection of SSNs and DOBs of persons with an ownership or control interest in the disclosing entity. Some States support the proposal, already having instituted the disclosure requirement in their enrollment application procedures. Other States support the proposal but request additional time for implementation, including forms and system changes. Two States expressed concern about the impact the requirement might have upon beneficiary access to providers.

Response: We will not address the comments directed at the existing language of § 455.104. The regulation was rearranged for ease of application by States and disclosing entities, but with the exception of the addition of SSNs and DOBs, as well as changes suggested by a few commenters regarding corporate entity addresses and familial relationships, the language is substantially unchanged from the language currently in effect. We acknowledge the commenters' concerns about collection of SSNs and DOBs, however, collection of SSNs and DOBs is necessary to complete the screening process and be certain of the identity of the party being screened. We recognize that the addition of SSNs and DOBs and other improvements in disclosure collection will require systems and forms changes and States will need time for implementation. We encourage States to contact us about their specific timeframes. Furthermore, we do not believe that this requirement will have an adverse impact on beneficiary access as the majority of disclosure requirements have not changed, and our experience with the same requirement in Medicare indicates that such a requirement does not adversely impact beneficiary access.

Comment: Other commenters made recommendations on language changes that would clarify § 455.104(b)(1)(i) regarding the address of corporate entities with ownership or control of disclosing entities; § 455.104(b)(2) regarding familial relationships; and § 455.104(b)(4) regarding SSNs and DOBs of managing employees.

Response: We agree with the commenters that § 455.104(b)(1)(i) should be clarified regarding addresses

of corporate entities with ownership or control of disclosing entities and accordingly will revise § 455.104(b)(1)(i) to clarify from whom the name and address must be provided and to require the disclosing entity to supply primary business address as well as every business location and P.O. Box address, if applicable. We agree that § 455.104(b)(2) should be clarified regarding to whom the spouse, parent, child, or sibling is related, and we are revising § 455.104(b)(2) accordingly. We agree that § 455.104(b)(4) should be clarified to require managing employees to provide SSNs and DOBs, as that was the intent of the proposal, and we are revising § 455.104(b)(4) accordingly.

Comment: Several commenters expressed concern regarding collection of disclosures under § 455.104. One commenter expressed concern about the confidentiality and privacy of board member identity and the protection from disclosure to the general public. Other commenters were concerned that not-for-profit board members were volunteers and might not serve were they compelled to provide their SSNs and DOBs as a condition of the entity being enrolled.

Response: We have previously provided guidance to States that § 455.104 requires disclosures from persons with ownership and control interests in the disclosing entity, which includes officers and directors of a disclosing entity that is organized as a corporation, without regard to the for-profit or not-for-profit status of that corporation. That guidance is available at *http://www.cms.gov/FraudAbuseforProfs/Downloads/bppedisclosure.pdf.* We are sensitive to the concerns related to confidentiality of identifiable information such as SSNs. We are also concerned about issues that arise out of identity theft. We encourage States to institute appropriate safeguards to protect the information they gather as required by these rules. However, collection of disclosures including the SSNs and DOBs of persons with ownership and control interests in a disclosing entity, and of managing employees, is necessary to protect the integrity of the State Medicaid programs. Therefore, we are finalizing the proposal requiring provision of SSNs and DOBs.

Comment: One commenter sought clarification whether the disclosure requirements in § 455.104 apply to IHS providers.

Response: This rule does not make any changes about whom disclosures must be provided, but rather simply adds additional items of information that must be disclosed. The boards of IHS facilities were not previously subject to the—disclosure requirements in § 455.104, and accordingly, are not subject to the additional disclosure requirements imposed by this rule.

Comment: Commenters expressed concern about the applicability of § 455.104 to public school districts. Public schools deliver Medicaid school based health services to Medicaid eligible children and therefore are enrolled as Medicaid providers. The commenters objected to the proposed requirement in § 455.104 that the schools provide the SSNs and DOBs of persons with controlling interests of the provider, which they interpreted to include the SSNs and DOBs of school board members. The majority of the commenters stated that the public school districts were closely regulated by numerous checks and balances and there was a low likelihood that fraud would be perpetrated in schools, therefore, the collection of SSNs and DOBs from public school districts was unnecessary.

Response: As previously noted, this rule does not change about whom disclosures must be provided, but rather what information must be disclosed. Except to the extent that any public school districts may be organized as corporations, they were not previously required to make disclosures about their boards, nor are they required to under this new rule.

Comment: Several commenters expressed concern regarding the license verification requirement in § 455.412. One commenter noted that it would be administratively inefficient, costly, and unrealistic for States to verify each provider applicant's licensure status in another State. Another commenter offered that searching its database containing multi-State licensure data would be more efficient than requiring States to search State by State.

Response: Holding a valid professional license should be a prerequisite in any State prior to assignment of a Medicaid provider identification number. Medicaid beneficiaries have a right to be treated only by those providers that have been deemed by the licensing boards of their States to be eligible to treat them. As a matter of public policy, it is not unreasonable to expect that licensure status of all in-State and out-of-State providers be checked prior to enrollment, and that any limitations on their licenses be checked as well. Out-of-State provider applicants submit licensure information including status to the Medicaid agency with their application. While verification of out-of-State licensure may be challenging, all those Medicaid agencies that enroll out-of-State providers have the obligation to verify licensure status of out-of-State providers as well. We appreciate the commenter's suggestion of its database of provider information. We are aware that State licensing boards maintain publicly available information that neighboring States may access. It is within the States' discretion which databases to check.

Comment: A commenter requested clarification of whether license verification was required when the chart at 75 FR 58214 states that license verification "may include licensure checks across State lines" thereby implying that licensure checks across State lines are permissive, not mandatory.

Response: The State Medicaid agency must verify the licensure of a provider applicant in the State in which the provider applicant purports to be licensed. If an out-of-State provider submitted an application for enrollment, the State Medicaid agency would be required to verify license across State lines.

a. Database Checks—Medicaid and CHIP

States employ several database checks, including database checks with the Social Security Administration and the NPPES, to confirm the identity of an individual or to ensure that a person with an ownership or control interest is eligible to participate in the Medicaid program.

A critical element of Medicaid program integrity is the assurance that persons with an ownership or control interest or who are agents or managing employees of the provider do not receive payments when excluded or debarred from such payments. Accordingly, in § 455.436, we proposed that States be required to screen all persons disclosed under § 455.104 against the OIG's LEIE and the General Services Administration's EPLS. We proposed that States be required to conduct such screenings upon initial enrollment and monthly thereafter for as long as that provider is enrolled in the Medicaid program.

We also proposed at § 455.450, as well as § 455.436, that database checks be conducted on all providers on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type.

As previously stated, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act also apply to CHIP. Because we proposed a new regulation in Part 457

under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for database checks under § 455.436 and § 455.450 apply in CHIP.

We received many comments on the database requirements in § 455.436 from States concerned about the administrative burden presented by searching several databases upon enrollment, and both the LEIE and the EPLS on a monthly basis by the names of both the provider and those with ownership or control interests in the provider and managing employees of the provider.

Comment: Some commenters questioned whether there were costs associated with accessing the databases. The commenters suggested that CMS establish a centralized database that States could access, including using an automated, rather than manual, search, all at no cost to States. One State suggested that the databases be accessible through automated data exchanges and that any cost to the States be waived to avoid barriers to compliance with the rule. Two other States questioned whether there were costs associated with accessing the databases that must be considered. Other commenters suggested a delay or elimination of the proposed requirement at § 455.436(c)(2) until CMS established such a centralized database.

Response: We are aware that there may be costs to the State Medicaid agency associated with checking some databases. However, § 455.436 enumerates databases that most State Medicaid agencies already check in their routine provider enrollment operations. In addition, we have previously issued guidance to State Medicaid Directors recommending searching the LEIE on a monthly basis by the names of enrolled providers and for providers, by the names of their employees and contractors. Those guidance documents are available here: *http://www.cms.gov/smdl/downloads/SMD061208.pdf* and *http://www.cms.gov/SMDL/downloads/SMD011609.pdf*. Many States have already adopted the recommendations in their enrollment policies. More recently, in September 2010, we provided guidance to program integrity directors on the availability of the LEIE and EPLS for exclusion searches. That guidance document is available here: *http://www.cms.gov/FraudAbuseforProfs/Downloads/bppedisclosure.pdf*.

Accordingly, we are finalizing § 455.436 to require State Medicaid agencies to conduct Federal database checks.

Comment: A commenter questioned whether other databases will be prescribed in the final rule with comment period or whether States will be notified of requirements in another fashion.

Response: In § 455.436(b), we proposed that the States be required to check "any such other databases as the Secretary may prescribe." We are not prescribing additional databases in the final rule with comment period. However, in response to evolving circumstances, the Secretary may issue guidance to States regarding checking specific databases.

Comment: One commenter sought clarification on which of a provider's managing employees the State Medicaid agency must search in the exclusions databases. The commenter noted that some large providers like hospitals have many managing employees that may be subject to the proposed database checks.

Response: We recognize the burden that conduct of database checks of managing employees may pose for providers with managing employees at multiple levels or locations in its organizations. Nevertheless, database checks must be conducted for all persons disclosed under § 455.104, including managing employees who could compromise or place in jeopardy a provider's compliance with Medicare, Medicaid, or CHIP requirements.

Comment: One commenter noted that State vital statistics information may be more accurate than the Social Security Administration's Death Master File. The commenter suggested allowing States to check against their own vital records systems and not require the States to check against the Social Security Administration's file.

Response: While on an anecdotal basis State records may be more accurate than the Social Security Administration's Death Master File, it is the Death Master File that is the national file of record. Therefore, we are finalizing the requirement that State Medicaid agencies check the Social Security Administration's Death Master File. However, under § 455.436(c)(1) a State may also consult other appropriate databases to confirm identity upon enrollment and reenrollment.

Comment: Another commenter noted that the Social Security Administration only allows SSN verification for W–2 purposes. The commenter recommended removing the reference to checks of "applicable" Social Security Administration databases from the database check requirement.

Response: We express no opinion as to the accuracy of the commenter's statement regarding SSN verification, but agree with the commenter that the database check requirement in this rule should be more explicit. Accordingly, we are revising § 455.436 to indicate a check of the "Social Security Administration's Death Master File" rather than "applicable databases".

Comment: A few commenters requested clarification regarding which database States must check for verification of tax identifications and tax delinquencies and how the States would use that information as a tool for screening providers.

Response: Although we believe that verifying taxpayer identification and checking for tax delinquencies may be useful indicators of fraud to a State Medicaid program, access to that information is limited and may not be feasible in the short term. Therefore, we are not finalizing those requirements as suggested by Table 5 under "Type of Screening Required".

Comment: One commenter asked whether it was our intention to require providers also to check their employees for exclusions on a monthly basis. The proposed regulation at § 455.436 does not require providers to check their employees for exclusions.

Response: We issued guidance on June 12, 2008, to State Medicaid Directors recommending that they check their enrolled providers for exclusions on a monthly basis. We followed up that guidance on January 16, 2009, with guidance to State Medicaid Directors recommending that they require their enrolled providers to check the providers' employees and contractors for exclusions on a monthly basis. Those letters are available at: *http://www.cms.gov/smdl/downloads/SMD061208.pdf* and *http://www.cms.gov/SMDL/downloads/SMD011609.pdf*. Many States made our recommendations their policy.

Section 455.436 does not mandate that States require their providers to check the LEIE and EPLS on a monthly basis to determine whether the providers' employees and contractors have been excluded. We do, however, recommend that States consider making this a requirement for all providers and contractors, including managed care contractors in their Medicaid programs and CHIP.

b. Unscheduled and Unannounced Site Visits—Medicaid and CHIP

Section 1866(j)(2)(B)(ii)(III) of the Act states that the Secretary, based on the risk of fraud, waste, and abuse, may conduct unscheduled and unannounced

site visits, including pre-enrollment site visits, for prospective providers and those providers already enrolled in the Medicare and Medicaid programs and CHIP.

Some States already require site visits, often for provider categories at increased risk of fraud, waste or abuse such as home health and non-emergency transportation. According to FY 2008 State Program Integrity Assessment (SPIA) data, at least 16 States report that they perform some type of site visits. However, such efforts vary widely across the country and are subject to budget shortfalls.

We proposed to require in § 455.432 and § 455.450(b) that States must conduct pre-enrollment and post-enrollment site visits for those categories of providers the State designates as being in the "moderate" or "high" level of screening.

Further, in § 455.432, pursuant to our general rulemaking authority under section 1102 of the Act, we proposed that any enrolled provider must permit the State Medicaid agency and CMS, including CMS' agents or its designated contractors, to conduct unannounced on-site inspections to ensure that the provider is operational at any and all provider locations.

We maintain that site visits are essential in determining whether a provider is operational at the practice location found on the Medicaid enrollment agreement. We expect these requirements to increase the number of both pre-enrollment and post-enrollment site visits for those provider types that pose an increased financial risk of fraud, waste, or abuse to the Medicaid program.

We proposed that failure to permit access for site visits would be a basis for denial or termination of Medicaid enrollment as specified in § 455.416.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for site visits under § 455.432 apply in CHIP.

Comment: Some commenters were supportive of the proposal for pre-enrollment and post-enrollment site visits in § 455.432, although they noted that they would need additional funding for travel or for contractors to conduct the site visits. Some commenters stated that the States should have the discretion to define which providers are subject to pre- and post-enrollment site visits and when the site visits are conducted, for example, by established risk categories or an automatic flag that demonstrates that billing has gotten to a certain threshold thus requiring an onsite visit. A few commenters stated that the site visits were an undue burden on States. One commenter stated that the site visits were unnecessary given that other more cost-effective methods could prevent enrollment of providers who are using fraudulent identity, such as annual re-enrollment, license verification, and follow-up when a duplicate provider ID or address is used. Another commenter noted that pre-enrollment site visits could delay enrollment as a result of inclement weather.

Response: We recognize that conduct of site visits will place a burden on State budgets and staff time, and may be difficult to accomplish in rural areas or in inclement weather. However, site visits are a requirement depending on the risk the provider represents to the Medicaid program. In response to the commenters that suggested that States should have the discretion to define which providers are subject to pre- and post-enrollment site visits: The site visits are required for those providers that are determined to be a moderate or high categorical risk of fraud, waste, or abuse. In addition to the required site visits for providers in the moderate and high screening levels, the State may also conduct site visits at its discretion. While there may be other means to verify whether a provider is a going concern or whether a provider has a business location, conduct of site visits is one method that is required by this regulation. The State has the discretion to utilize other additional methods to prevent enrollment of non-existent providers or to ensure that spurious applications are not processed.

Comment: A few commenters sought clarification on what the expectations were for site visits when the provider performed services in the beneficiary's home, for example, personal care services; or for out-of-State providers or rural providers.

Response: If a Medicaid-only provider is in the moderate or high screening level, the State Medicaid agency does not have the discretion whether to conduct a site visit: It is required under § 455.432(a) and § 455.450(b). However, pursuant to § 455.452, States are permitted to establish additional or more stringent screening measures than those required by this final rule with comment period. Thus, for providers that are in the limited screening level, the State has the discretion to determine whether to conduct site visits, based on whatever factors the State deems appropriate. We recognize that the appropriate location of the site visit may differ based upon the provider type. For example, the personal care services agency is the enrolled provider, so its location would likely be subject to a site visit. While its employee the personal care attendant may not be an enrolled provider with the State Medicaid agency, it may also be appropriate to conduct a site visit in a beneficiary's home where the personal care attendant is providing services to ensure that services are in fact being provided appropriately. It would be within the discretion of the State Medicaid agency to determine whether to conduct an additional site visit for a provider in the limited screening level. With respect to providers in rural locations, the mere fact that the provider is in a rural location does not absolve the State Medicaid agency of its responsibility to conduct site visits. Similarly, for out-of-State providers, the mere fact that a provider in the moderate or high screening level is located in another State would not negate the requirement for a site visit, although we note that § 455.410 permits States to rely upon the screening performed by Medicare and by other State Medicaid programs and CHIP. Therefore, no additional site visit would be required if the provider is also enrolled by Medicare or in Medicaid or CHIP in its home State.

c. Provider Enrollment and Provider Termination—Medicaid and CHIP

States may refuse to enroll or may terminate the enrollment agreement of providers for a number of reasons related to a provider's status or history, including an exclusion from Medicare, Medicaid, or any other Federal health care program, conviction of a criminal offense related to Medicare or Medicaid, or submission of false or misleading information on the Medicaid enrollment application. Failure to provide disclosures is another reason for termination from participation in the Medicaid program.

Federal regulations beginning at § 455.100 require certain disclosures by providers to States before enrollment. States require additional disclosures prior to enrollment. Some States require periodic re-enrollment and disclosure at that time. However, States vary in the frequency of such re-disclosures. Providers are also inconsistent in keeping their enrollment information current, including items as elementary as their address.

We proposed, at § 455.414, pursuant to our general rulemaking authority

under section 1102 of the Act, that all providers undergo screening pursuant to the procedures outlined herein at least once every 5 years, consistent with current Medicare requirements for revalidation.

In § 455.416, we proposed to establish termination provisions, requiring States to deny or terminate the enrollment of providers: (1) Where any person with an ownership or control interest or who is an agent or managing employee of the provider does not submit timely and accurate disclosure information or fails to cooperate with all required screening methods; (2) that are terminated on or after January 1, 2011 by Medicare or any other Medicaid program or CHIP (*see* section II.F. of this final rule with comment period); and (3) where the provider or any person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit sets of fingerprints within 30 days of a State agency or CMS request. We proposed to permit States to deny enrollment to a provider if the provider has falsified any information on an application or if CMS or the State cannot verify the identity of the applicant. We also proposed to require States to deny enrollment to providers, unless States determine in writing that denial of enrollment is not in the best interests of the State's Medicaid program, in these circumstances: (1) The provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to provide accurate information; (2) the provider fails to provide access to the provider's locations for site visits, or (3) the provider, or any person with an ownership or control interest, or who is an agent or managing employee of the provider has been convicted of a criminal offense related to that person's involvement in Medicare, Medicaid, or CHIP in the last 10 years. We believe that providers can significantly reduce the likelihood of fraud, waste or abuse by providing and maintaining timely and accurate Medicaid enrollment information. We believe the Medicaid program will be better protected by not allowing persons with serious criminal offenses related to Medicare, Medicaid, and CHIP to serve as providers.

We proposed at § 455.416 that the State be allowed to deny an initial enrollment application or agreement submitted by a provider or terminate the Medicaid enrollment of a provider, including an individual physician or non-physician practitioner, if CMS or the State is not able to verify an individual's identity, eligibility to participate in the Medicaid program, or determines that information on the Medicaid enrollment application was falsified.

In § 455.420, we proposed to require that any providers whose enrollment has been denied or terminated must undergo screening and pay all appropriate application fees again to enroll or re-enroll as a Medicaid provider.

We proposed at § 455.422 that in the event of termination under § 455.416, the State Medicaid agency must give a provider any appeal rights available under State law or rule.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for provider enrollment, provider termination, and provider appeal rights under § 455.414, § 455.416, § 455.420, and § 455.422 apply in CHIP.

Comment: Several commenters expressed concern regarding the requirement under § 455.414 related to a 5 year re-screening process. Some commenters stated that they already required a periodic re-enrollment process and CMS should take into consideration the States' existing processes and grant the States the flexibility to employ those existing processes.

Other commenters noted that the additional enrollments would place administrative and fiscal burdens on the States. Several commenters noted that they would need an extended period to implement the new requirements of the proposed rule, including the requirement set forth at § 455.414.

One commenter sought clarification whether all providers currently enrolled and that have been enrolled for 5 years would be up for revalidation when the regulation became effective; and whether currently enrolled providers could be revalidated over a 5-year timeframe to diminish the administrative burden on State Medicaid agency staff.

Another commenter sought clarification whether the requirement was for re-screening or for re-enrollment at least every 5 years; whether the requirement would apply to all enrolled providers including rendering providers, or just to ordering or referring physicians and other professionals who are the subject of the requirements set forth at § 455.410 and § 455.440; and whether CMS would give affected providers notice of the need to re-enroll.

Response: Periodic re-validation of enrollment information affords States the opportunity to ensure their provider rolls do not contain providers that have been excluded from participation in the Federal health care programs. The State Medicaid agencies can cull from their provider rolls those providers that have not submitted claims for payment or referred claims for payment in several years. Without removing those providers' numbers during a periodic re-enrollment process, those providers' numbers might be used at a later date in a fraudulent scheme: The providers may have been unwitting victims of identity theft or may have participated in selling their provider numbers.

The proposed requirement at § 455.414 describes screening of all providers at least every 5 years. Screening, as performed by the Medicare Administrative Contractors for all dually participating providers, and by the State Medicaid agency or CHIP for those providers that are not also participating in the Medicare program, should be distinguished from enrollment, a function performed by the State Medicaid agency or CHIP to participate in the Medicaid program or CHIP of a given State. Screening would involve various assessments commensurate to the risk the provider posed to the Medicaid program or CHIP, including license verification, database checks, site visits, background checks, and fingerprinting. Enrollment may involve all of those, as well as collection of disclosures required under § 455.104, § 455.105, and § 455.106, and a host of State-specific requirements.

We applaud States that already require periodic re-enrollment of Medicaid providers. For the sake of consistency with the Medicare program, however, we are finalizing § 455.414 as a 5 year re-validation of enrollment information, which includes re-screening as well as the collection of updated disclosure information, for providers regardless of provider type, including, but not limited to, rendering, ordering, and referring physicians, and other professionals. The screening component of the 5 year re-validation will be conducted by either the Medicare Administrative Contractors (for dually-participating providers) or by the States (for Medicaid-only or CHIP-only providers). The collection of updated enrollment information, including, but not limited to, disclosure information will be the province of the State Medicaid agencies, and subject to their existing procedures, therefore, we will not issue notices of the need to

revalidate enrollment information to the affected providers.

State Medicaid agencies should complete the first re-validation cycle by 2015, with 20 percent of providers being re-validated each year beginning 2011. State Medicaid agencies have the discretion to determine which providers or provider types to re-validate enrollment first. However, they may want to consider re-validating enrollment in the first years of the cycle those providers or provider types that pose the greatest risk of fraud, waste or abuse to the Medicaid program and CHIP.

Comment: We received comments from States supportive of the proposed bases for denial of enrollment or termination of enrollment in § 455.416, but concerned about the time they would need for implementation to amend State laws and rules and to amend provider agreements. One State commented that it would be administratively inefficient, costly, and unrealistic for each State to independently confirm providers' enrollment status or termination history in another State's Medicaid program or CHIP.

Response: We believe that the bases for denial of enrollment or termination of enrollment in § 455.416 are necessary to protect the integrity of the Medicaid program. Therefore, prompt implementation of these additional bases for denial or termination will serve each State and Medicaid programs nationally. We acknowledge the additional burden that new bases for denial and termination will create for State Medicaid programs, for example, in changes to systems and forms, and changes to provider agreements. We are currently examining to what extent we can support a centralized information sharing solution for provider enrollment across programs and across States. However, we note that termination based on termination by Medicare or by another State's Medicaid program is a statutory requirement effective January 1, 2011.

Comment: One commenter recommended that the reasons for provider termination should be outlined and given to the provider upon denial or termination. The commenter noted that the provider would then have the ability to address or correct deficiencies prior to resubmitting its enrollment application. This requirement, the commenter noted, would be in addition to any appeal rights.

Response: We have provided for a right of appeals to the extent they are available under a State's existing laws or rules. While we recognize that the commenter's suggestion may be helpful, and States may elect to adopt it, we will not be disrupting a State's procedures under its existing laws or rules with this regulation.

Comment: One State recommended an addition to the language of § 455.416(g)(1) to recognize that a provider's omissions may be as egregious as its falsified statements.

Response: We appreciate the commenter's suggestion to cover all possible situations when a provider may have misled the State in the application process. However, § 455.416(d) addresses termination for a failure to submit timely and accurate information which would include omissions to provide information. Therefore we decline to revise section § 455.416(g)(1).

Comment: A State requested clarification on how rigorous the State's efforts must be to verify the identity of the provider applicant or whether a background check is sufficient.

Response: The State Medicaid agencies have the discretion to determine the steps that are appropriate to verify the identity of the provider applicant, which may include, but would not be limited to, verification of licensure, database checks, and criminal background checks.

d. Criminal Background Checks and Fingerprinting—Medicaid and CHIP

Section 1866(j)(2)(B)(ii)(II) of the Act allows the Secretary to use fingerprinting during the screening process; and while several States have implemented procedures to require fingerprinting of physicians and non-physician practitioners as a condition of licensure, we maintain that if a State designates a provider as within the high level of screening as described previously, each person with an ownership interest in that provider should be subject to fingerprinting.

Adding fingerprinting to State screening processes for those providers that pose the greatest risk to the Medicaid program will allow CMS and the State to: (1) Verify the individual's identity; (2) determine whether the individual is eligible is participate in the Medicaid program; (3) ensure the validity of information collected during the Medicaid enrollment process; and (4) prevent and detect identity theft. Ensuring the identity of "high" risk Medicaid providers through fingerprinting protects both the Medicaid program and providers whose identities might otherwise be stolen as part of a scheme to defraud Medicaid.

In addition, while § 455.106 requires providers to submit information to the Medicaid agency on criminal convictions related to Medicare and Medicaid and title XX, current regulations do not require States to verify data submitted as part of the Medicaid enrollment application and they are sometimes not able to verify information that was purposefully omitted or changed in a manner to obfuscate any previous criminal activity. According to fiscal year (FY) 2008 SPIA data, at least 20 States report that they conduct some type of criminal background check as part of their Medicaid enrollment practices.

Elements of a robust criminal background check could include, but not are necessarily limited to: (1) Conducting national and State criminal records checks; and (2) requiring submission of fingerprints to be used for conducting the criminal records check and verification of identity.

We proposed in § 455.434 and § 455.450 for those categories of providers that a State Medicaid agency determines is within the high level of screening, the State must: (1) Conduct a criminal background check of each provider and each person with an ownership or control interest or who is an agent or managing employee of the provider, and (2) require that each provider and each person with an ownership or control interest or who is an agent or managing employee of the provider to submit his or her fingerprints. The State Medicaid agency has the discretion to determine the form and manner of submission of fingerprints.

At § 455.434, we proposed that the State Medicaid agency must require providers or any person with an ownership or control interest or who is an agent or managing employee of the provider to submit fingerprints in response to a State's or CMS' request.

We solicited public comment on the appropriateness of using criminal background checks in the provider enrollment screening process, including the instances when such background checks might be appropriate, the process of notifying a provider or individual that a criminal background check is to be performed, and the frequency of such checks.

We also solicited comment on the use of fingerprinting as a screening measure. We recognize that requesting, collecting, analyzing, and checking fingerprints from providers are complex and sensitive undertakings that place certain burdens on affected individuals. There are privacy concerns and operational concerns about how to assure individual privacy, how to check fingerprints against appropriate law enforcement fingerprint data bases, and how to store

the results of the query of the databases and also how to handle the subsequent analysis of the results. As a result, we solicited comments on how CMS or a State Medicaid agency should maintain and store fingerprints, what security processes and measures are needed to protect the privacy of individuals, and any other issues related to the use of fingerprints in the enrollment screening process. We expressed interest in comments on this and other possible circumstances in which fingerprinting would be potentially useful in provider screening or other fraud prevention efforts. Our proposed screening approach contemplated requesting fingerprints from providers assigned to the high level for screening. We solicited comments on whether this is an appropriate requirement, the circumstances under which it might be appropriate or inappropriate, and any alternatives to the proposed approach regarding fingerprints. Our proposed approach would allow States to deny enrollment to newly enrolling providers and to terminate existing providers if the provider or if individuals who have an ownership or control interest in the provider or who are agents or managing employees of the provider refuse to submit fingerprints when requested to do so. We solicited comments on this proposal including its appropriateness and utility as a fraud prevention tool.

In addition, we solicited comment on the applicability and appropriateness of using, in addition to or in lieu of fingerprinting, other enhanced identification techniques and secure forms of identification including but not limited to passports, United States Military identification, or Real ID drivers licenses. As technology and secure identification techniques change, the tools we or State Medicaid agencies use may change to reflect changes in technology or in risk identification. We solicited comment on the appropriate uses of these techniques and the ways in which we should notify the public about any tools CMS or State Medicaid agencies would adopt. We also welcomed comments on whether there should be differences allowed between Federal and State techniques, or among States, and if so, on what basis.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for criminal background checks and fingerprinting under § 455.434 will apply in CHIP.

Comment: A number of commenters noted the undue and significant burden on the States and providers that the criminal background check requirement in § 455.434, and specifically the fingerprint requirement, would pose. These commenters noted that State Medicaid agencies do not have the staff or expertise to conduct the checks. One commenter stated that enforcement of this provision will have deleterious effects on the Medicaid provider network and act as a barrier to care, and recommended removing the fingerprinting and background check requirements for high risk providers.

Other commenters were supportive of the proposal to conduct criminal background checks and collection of fingerprints, noting that the proposal was intended to screen out unscrupulous providers. One commenter recognized that the proposal to add fingerprinting of high risk entities was a way to evaluate the background of potential providers, to identify fraud and prevent individuals with known criminal backgrounds from participating in Medicaid.

Other commenters were concerned about the relative cost and efficiency of conducting the criminal background checks. Several commenters suggested that the background checks be at the States' discretion. One commenter suggested that CMS conduct any necessary fingerprinting, regardless of whether the person or entity is enrolled in Medicare. Another commenter recommended that CMS consider limiting FBI criminal background checks to cases in which there is reasonable cause to believe the subject may have a criminal record in another State.

Response: We have considered all the comments received and are sensitive to the burden the criminal background checks and fingerprinting will pose to the State Medicaid agencies and the affected providers. However, we believe that criminal background checks are an effective means of evaluating a high risk provider. Furthermore, we believe that fingerprinting high risk providers and their owners are worthwhile endeavors to determine identity and whether the provider and other individuals have been involved in criminal activities that would adversely impact the Medicaid program. While we are finalizing the requirement to conduct criminal background checks and collect fingerprints for high risk providers, the requirement will be limited to providers and persons with a five percent or more direct or indirect ownership interest in the provider. There will be no requirement to conduct criminal background checks on, or collect the fingerprints of, persons with a control interest in the provider or the agents or managing employees of high risk providers. However, we intend to monitor the situation and may seek to extend the scope of fingerprint-based criminal background checks in the future if circumstances warrant. We are making the appropriate changes to § 455.434. States will not be required to implement criminal background checks and fingerprinting until we issue additional guidance. To the extent that States have the ability to conduct background checks and collect fingerprints at this time, it is within their discretion to do so prior to the delayed implementation date. States have the discretion to impose more stringent requirements for Medicaid-only and CHIP-only providers than those we are requiring.

Comment: One commenter asked how results of criminal background checks would be communicated in data available to States from CMS.

Response: We are currently examining to what extent we can support a centralized information sharing solution for provider screening results across programs and across States. The individual results of a criminal background checks performed, however, would likely be sent directly to the agency requesting the background check from the entity that performed the check.

Comment: One commenter asked whether there would be standard criteria that define the types of convictions that warrant denial of a provider's application.

Response: Whether to deny enrollment or to terminate enrollment are decisions that are within the discretion of each State Medicaid agency in accord with § 455.416. Thus, the types of convictions that warrant denial of enrollment would be at the discretion of the State Medicaid agency.

Comment: Some commenters asked what level of background check was required, for example, were State Medicaid agencies expected to do a Federal criminal background check or a State criminal background check.

Response: While it is within the State Medicaid agency's discretion to decide whether to conduct State or Federal background checks for Medicaid-only providers, we recommend that the State conduct Federal criminal background checks which would provide information that is national in scope and therefore would be more complete.

Comment: A few commenters questioned which databases a States should consult to compare fingerprints against in order to do the screening under this provision, in the event that law enforcement is not available to review the fingerprints?

Response: We are not aware of databases that the State Medicaid agencies might search, however, there are vendors that provide the service for a fee.

Comment: One commenter questioned whether the State Medicaid agency must perform a criminal background check in its State only or in the neighboring State for a provider applicant that only provides services in the neighboring State.

Response: The States have the discretion to decide, however, we would recommend conducting a FBI criminal history record check, which would provide information that is national in scope and therefore would be more complete and would be preferable to a State background check in either the enrolling State or the neighboring State.

Comment: Some commenters noted that fingerprints created a logistical concern for the State Medicaid agencies. Once they have obtained the fingerprint cards from the providers, should the States maintain the files, how should they maintain the cards, and for how long? If electronic files, how should the States maintain those files?

Response: The State Medicaid agencies should follow their existing records retention laws and procedures, however we recommend that the State Medicaid agencies retain the files for at least 5 years, until the provider's revalidation. To the extent that a State Medicaid agency itself receives the fingerprints submitted, we expect them to maintain those files in a secure manner to protect the privacy of the individual who submitted the fingerprints.

Comment: One commenter suggested that the provision be revised so that it does not require two copies of the fingerprint card but allows for collection of two copies if the State determines that two copies are needed.

Response: We agree, and are making that change to § 455.434.

e. Deactivation and Reactivation of Provider Enrollment—Medicaid and CHIP

Section 1902(kk)(1) of the Act requires the screening of Medicaid providers to ensure they are eligible to provide services and receive payments. In an effort to further protect the Medicaid program and to be consistent with longstanding Medicare requirements, we proposed in § 455.418 that any Medicaid provider that has not submitted any claims or made a referral that resulted in a Medicaid claim for a period of 12 consecutive months must have its Medicaid provider enrollment deactivated. Further, under § 455.420, we proposed that any such provider wishing to be reinstated to the Medicaid program must first undergo all disclosures and screening required of any other applicant. In addition, we proposed that the provider must pay any associated application fees under § 455.426.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, the proposed requirements for deactivation and reactivation of provider enrollment under § 455.418 and § 455.420 would apply in CHIP.

Comment: A few commenters supported the proposed requirement as written. A number of commenters were supportive of the spirit of this proposed requirement but suggested that we lengthen the timeframe to 24 months. Other commenters expressed concern regarding the applicability of the application fee when reactivating enrollment and suggested that Medicaid follow a streamlined reactivation process similar to what occurs in the Medicare program.

One State commenter expressed concern that the requirement to deactivate providers would necessitate deactivating one third of the State's enrolled providers. Other State commenters noted that out-of-State providers would routinely be deactivated because their billings are so infrequent.

Response: We recognize that many out-of-State providers provide occasional emergency treatment to Medicaid beneficiaries, and that requiring States to deactivate those providers after a year without billings would cause administrative burdens for the States and the providers. We believe States should have the discretion to police their own provider enrollment, although we recommend that States deactivate provider numbers that have not been used for an extended period of time.

After reviewing the comments received and other operational considerations we are not finalizing the requirement for deactivation of provider numbers after 12 months in § 455.418 at this time.

f. Enrollment and NPI of Ordering or Referring Providers—Medicaid and CHIP

Section 1902(kk)(7) of the Act provides that States must require all ordering or referring physicians or other professionals to be enrolled under a Medicaid State plan or waiver of the plan as a participating provider. Further, the NPI of such ordering or referring provider or other professional must be on any Medicaid claim for payment based on an order or referral from that physician or other professional.

Providers and suppliers under Medicare and providers in the Medicaid program are already subject to the requirement that the NPI be on applications to enroll and on all claims for payment, pursuant to section 6402(a) of the ACA, amending section 1128J of the Act, and under § 424.506, § 424.507, and § 431.107, as amended by the May 5, 2010 interim final rule with comment period (75 FR 24437).

In § 455.410, we proposed that any physician or other professional ordering or referring services for Medicaid beneficiaries must be enrolled as a participating provider by the State in the Medicaid program. We proposed that this would apply equally to fee for service providers or MCE network-level providers.

Additionally, we proposed to amend § 438.6 to require that States must include in their contracts with MCEs a requirement that all ordering and referring network-level MCE providers be enrolled in the Medicaid program, as are fee for service providers, and thus are screened directly by the State.

Although the NPI requirements in section 6402(a) of the ACA did not extend to CHIP providers, section 6401 of the ACA does apply equally to CHIP, and the proposed requirement for ordering and referring physicians or other professionals under the Medicaid program apply equally under CHIP.

In addition, in § 455.440, we proposed that all claims for payment for services ordered or referred by such a physician or other professional must include the NPI of the ordering or referring physician or other professional. We proposed that this would apply equally to fee for service providers or MCE network-level providers.

It is essential that all such claims have the ordering or referring NPI and that the State has properly screened the ordering or referring physician or other professional. Without such assurances,

it is difficult for CMS or the State to determine the validity of individual claims for payment or to conduct effective data mining to identify patterns of fraud, waste, and abuse.

As stated previously, pursuant to section 2107(e)(1) of the Act, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation in Part 457 under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, these requirements for provider enrollment and NPI under § 455.410 and § 455.440 apply in CHIP.

Comment: Many commenters expressed concern regarding whether the ordering and referring requirements in the proposed rule applied in the managed care environment. Many State, MCO, and association commenters also expressed concern regarding the impact that mandatory enrollment under § 455.410 would have upon Medicaid beneficiary access to providers. These commenters stated concerns about the ability to contract with providers and other professionals if there was a requirement for those providers to be enrolled with the State as participating providers. The MCO and association commenters also cited their concerns about network level providers wanting to control their practices and not being mandated to participate in the Medicaid program when their preference was to serve in a Medicaid MCO. In addition, a State commenter expressed the concern that they be able to attract MCOs to their programs to provide choice to beneficiaries.

Several State commenters also noted that adding managed care ordering and referring providers to their rolls in addition to the proposed requirement for re-enrollment every 5 years, as well as the other proposed screening requirements would impose administrative and fiscal burden on State resources.

A few association commenters suggested that States implement a registration process whereby MCO network level providers would engage in a process short of full enrollment with the Medicaid agency, solely for the purpose of screening. Several commenters also expressed concerned related to: (1) Consistency of screening across Medicare and Medicaid, and across the MAOs and Medicaid managed care; and (2) who would conduct the screening. There was some confusion about whether the MAOs and MCOs would conduct the screening of the network level providers, or whether Medicare contractors and State Medicaid agencies would conduct the screening. There was also the issue of MAO providers not being specifically required to be enrolled to order or refer for the items and services they ordered or referred for Medicare beneficiaries to be paid.

A few commenters noted the adequacy of current credentialing performed by Medicaid MCOs and the absence of any statement to the contrary justifying enrollment of network level ordering and referring providers.

Several State commenters questioned how the NPI requirement would apply in a managed care environment, when risk-based health plans file claims for payment for the services of their subcontracted network level providers based on the contract between the State and the risk-based health plan. The network level providers ordering or referring items or services do not file claims for payment as fee-for-service providers do.

Response: After careful consideration of the comments we received, as well as the statutory language, we have determined that the new requirements for ordering and referring physicians should not apply in a risk based managed care context. We do not believe it was the intent of the Congress to impose stricter requirements on the Medicaid program than are imposed in Medicare. To require Medicaid managed care providers that order or refer items or services for Medicaid beneficiaries to enroll as Medicaid participating providers when MAO providers are not also required to enroll in the Medicare program to order or refer items or services for Medicare beneficiaries would be to treat the programs unequally.

In consideration of the concerns for beneficiary access and the administrative burden that enrollment of MCO ordering and referring physicians and other professionals would impose on State Medicaid agencies, and in consideration of the parity of requirements for the Medicaid and Medicare programs, we are not requiring that ordering and referring physicians and other professionals in managed care risk based health plans enroll as participating providers by State Medicaid programs. Consequently, we are not finalizing the proposed change to § 438.6 that would have required State managed care contracts to require network level providers enroll with the Medicaid agency as participating providers.

We are limiting the exemption to risk based managed care. Section 1902(kk)(7) requires that States must require all ordering or referring physicians or other professionals to be enrolled under a Medicaid State plan or waiver of the plan as a participating provider. We want to give the greatest effect to the statute while creating the least adverse impact on beneficiaries. Had we extended the exemption to all forms of managed care, for example, we would have allowed physicians or other professionals that participate in primary care case management programs that operate under State plan waivers to avoid enrollment with a State's Medicaid program; or we would have allowed home and community based services program providers that order or refer to avoid enrollment, to the extent that a State requires such enrollment. We also gave consideration to the comments we received regarding access, burden on State processes, and credentialing. The State and managed care organization commenters expressed concerns about beneficiary access to managed care networks and providers, which would be likely to occur in the risk-based forms of managed care, but not in primary care case management, for example. The States also expressed concerns about the burden of enrolling as participating providers those physicians and other professionals in managed care. Again, we interpret their concerns to be about risk-based forms of managed care, rather than forms of managed care in which the provider or entity bears no risk, because in the vast majority of States network level providers in risk-based forms of managed care are not enrolled with the Medicaid agency. Primary case care managers, however, are already enrolled with the Medicaid agency as fee-for-service providers. In addition, risk-based managed care entities conduct credentialing required under Federal regulations and subject to the terms of the contracts between the States and the MCOs, PIHPs, or PAHPs. Providers that participate in non-risk-based forms of managed care are subject to the various enrollment requirements that each State may designate.

Given that managed care services are recorded in encounter claims, we recognize that it is not always possible for such an ordering or referring physician's or other professional's NPI to be reflected on such a claim. We leave it to the State's discretion, based in part on the capability of the State's systems, to require entrance of the NPI on the encounter record.

Comment: A commenter requested clarification on whether the requirement for ordering and referring physicians or other professionals to be enrolled with a State Medicaid agency would apply to professionals who may not be eligible to

enroll in a State's Medicaid program but who provide services under the supervision of an enrolled provider and whose services are billed under the provider identification number of that eligible Medicaid enrolled provider.

Response: The requirement for other ordering or referring professionals to enroll with a State's Medicaid program as a participating provider would depend on whether a State's Medicaid program recognized the professional as a Medicaid provider. If it did not, there would be no requirement to enroll.

Comment: Several commenters expressed concern about the applicability of § 455.410 and § 455.440 to public school districts. Public schools deliver Medicaid school based health services to Medicaid eligible children and therefore are enrolled as Medicaid providers. Commenters expressed concern about public school-based providers, for example, speech language therapists, school psychologists, occupational therapists, and physical therapists, employed by public school districts being required to enroll with the Medicaid agency as ordering and referring physicians or other professionals. The commenters noted that public school based providers are able, but have not been required in the past, to get an NPI. Public school districts have included their NPI on claims and the clinicians are assigned unique provider identification numbers to facilitate identification of providers and services. Therefore, the commenters encourage an exemption for public school based providers from the NPI requirement.

Response: Public school based providers are subject to the ordering and referring requirements set forth in § 455.410 and § 455.440. However, as a way to minimize the administrative burden of enrolling additional providers, State Medicaid agencies may implement a streamlined enrollment process for those providers who only order or refer, that is, who do not bill for services, similar to the CMS–855–O process in the Medicare program. Additionally, State Medicaid agencies may delegate to State or local governmental agencies, such as public school districts, the responsibility to screen public school based providers and to assign unique provider identification numbers for claims identification.

Comment: Several commenters noted that the regulations at § 455.410 do not address whether CMS will provide a reliable mechanism or national database in which screening results can be shared. Without a method to obtain results from these other entities, States will have to screen all Medicaid providers at considerable cost. One commenter noted that Medicare and CHIP do not define providers the same way which will lead to confusion over who has been screened through Medicare and the sister agencies.

Response: We are currently examining to what extent we can support a centralized information sharing solution for provider enrollment across programs and across States.

Comment: Several commenters responded that the proposed regulation would be burdensome on both States and providers, requiring providers who do not normally work with the Medicaid program and new groups of providers to enroll. One commenter suggested that rather than being required to enroll with the Medicaid program, providers be permitted to use the NPI as evidence of successful Medicare screening and enrollment.

Response: We are sensitive to the additional burden that obtaining an NPI will pose, however, inclusion of the NPI on all Medicaid claims is a statutory requirement. The commenter suggested that providers enroll with Medicare and use the NPI as evidence of successful screening and enrollment. Providers should be aware that the NPI is not evidence of successful Medicare screening and enrollment, but providers who are actually enrolled in Medicare will not have to be screened again by the States to be enrolled in the Medicaid programs. The States may implement a streamlined enrollment process for those providers who only order or refer, that is, who do not bill for services, similar to the CMS–855–O process in the Medicare program.

Comment: One commenter described a scenario of a salaried hospital physician who was not enrolled by the State Medicaid agency, but the hospital that employed the physician was an enrolled, participating Medicaid provider. The commenter questioned whether the referral rule applied to the physician.

Response: Yes, the salaried hospital physician must enroll with the State Medicaid agency to order or refer for Medicaid beneficiaries.

Comment: A commenter sought clarification whether the order or referral rule applied when an order or referral was made prior to the Medicaid beneficiary being eligible for Medicaid.

Response: No, if the order or referral was made before the beneficiary was Medicaid eligible, then the beneficiary may have the order filled or the referral fulfilled and the claim for the order or referral will be paid.

Comment: A commenter asked whether the ordering and referring rule applied to Medicare crossover claims.

Response: Yes, the beneficiary's claims would be Medicaid claims, therefore the provider who ordered or referred the Medicaid beneficiary's services would be required to be enrolled as a Medicaid participating provider.

Comment: One commenter requested clarification on whether CMS will be changing claims forms to accommodate the collection of information regarding ordering and referring providers.

Response: To the extent it is necessary for the State Medicaid agencies to make changes to their claim forms to accommodate the new requirement regarding ordering and referring providers, and then the States should make those changes.

Comment: Several commenters sought clarification on whether the terms "ordering and referring physicians or other professionals" included prescribing providers.

Response: We interpret the statutory terms "ordering" and "referring" to include prescribing (either drugs or other covered items) or sending a beneficiary's specimens to a laboratory for testing or referring a beneficiary to another provider or facility for covered services.

Comment: Some of the commenters sought clarification on the definition of the term "other professional." For example, does it include rendering providers, non-professional providers, or providers in waiver programs?

Response: Under § 455.410(b) and section 1902(kk) of the Act, the phrase "ordering and referring physicians and other professionals" does not include rendering providers, as these authorities impose a new enrollment requirement with respect to physicians and other professionals that order or refer items or services for Medicaid beneficiaries. Other professionals include any person or entity recognized to be enrolled by a State Medicaid agency, and that may order or refer. Of course, to be able to submit a claim to a State Medicaid agency, for services rendered or items supplied to a Medicaid beneficiary, a provider must be enrolled as a participating provider with that State Medicaid agency.

Comment: One commenter sought clarification whether the requirement for all ordering and referring physicians or other professionals to be enrolled with the Medicaid agency as participating providers applied to IHS providers.

Response: IHS providers are required to comply with § 455.410(b). However,

as a way to minimize the administrative burden of enrolling additional providers, State Medicaid agencies may implement a streamlined enrollment process for those providers who only order or refer, that is who do not bill for services, similar to the CMS–855–O process in the Medicare program.

Comment: A commenter questioned whether a provider that has enrolled as a participating provider to comply with § 455.410(b) must submit fee-for-service claims to the Medicaid agency, or is the provider's status as an enrolled provider sufficient for compliance.

Response: Under § 455.410(b), a physician or other professional need not submit fee-for-service claims to the State Medicaid agency to remain enrolled as a Medicaid provider.

Comment: With respect to § 455.440, one State asked whether the provider's NPI must be on each and every claim or whether it is sufficient for the provider's NPI to be on file with the State Medicaid agency, and whether the prescribing provider's NPI would be required on pharmacy claims.

Response: Under § 455.440, "all claims for payment for items and services that were ordered or referred" must contain the NPI. This is based upon the statutory requirement in section 1902(kk)(7)(B) of the Act that States require the NPI "of any ordering and referring physician or other professional to be specified on any claim for payment that is based upon an order or referral of the physician or other professional." Therefore, the provider's NPI must be on every claim, including pharmacy claims; it is not sufficient for the provider's NPI to be on file.

g. Other State Screening—Medicaid and CHIP

Section 1902(kk)(8) of the Act establishes that States are not limited in their abilities to engage in provider screening beyond those required by the Secretary. Accordingly, in § 455.452, we proposed that States may utilize additional screening methods, in accordance with their approved State plan.

As stated previously, pursuant to section 2107(e)(1) of the Act and specified in our regulations in Part 457, all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Because we proposed a new regulation under which all provider screening requirements that apply to Medicaid providers will apply to providers that participate in CHIP, this requirement for other State screening under § 455.452 applies in CHIP.

h. Final Screening Provisions—Medicaid and CHIP

We are adopting the Medicaid and CHIP provider screening requirements as proposed with the following modifications:

- We clarified § 455.104(b)(1) regarding the elements of corporate addresses.
- We clarified § 455.104(b)(2) with regard to whom the spouse, parent, child, or sibling is related.
- We clarified § 455.104(b)(4) to require managing employees to provide SSNs and DOBs.
- We clarified § 455.104(c)(1), and § 455.104(c)(1)(i) and (ii) to include submission of disclosures from disclosing entities as well as providers.
- We clarified § 455.104(c)(1)(iii) to require submission of disclosures upon the request of the Medicaid agency during the revalidation of enrollment process.
- We are adopting § 455.450 with modifications, having clarified that the State agency must screen applications both in re-enrollment and re-validation of enrollment in the introductory paragraph; deleted the reference to publicly traded companies in § 455.450(a); deleted reference to persons with controlling interests, agents and managing employees who are required to provide fingerprints in § 455.450(d); and clarified the basis for adjusting a screening level related to moratoria § 455.450(e)(2).
- At § 455.414 we clarified that States must revalidate the enrollment information of all providers at least every 5 years.
- We are adopting § 455.416 with modifications clarifying terminations of persons with 5 percent of more direct or indirect ownership interests in the provider; and deleting reference to persons with controlling interests, agents and managing employees under bases for termination for failure to provide fingerprints.
- We clarified § 455.434 to require criminal background checks from providers or persons with a five percent or more direct or indirect ownership interest in the provider who meet the State Medicaid agency's criteria as a high risk to the Medicaid program; and to require fingerprints from providers and person with a five percent or more direct or indirect ownership interest in the provider, upon the State Medicaid agency's or CMS' request.
- We are not finalizing the proposed provision that States deactivate the enrollment of any provider that has not billed for 12 months.
- And finally, we are not finalizing the proposed requirement at § 438.6(c)(5)(vi) that required all ordering and referring Medicaid Managed Care network providers to be enrolled as participating providers based on commenters' concerns regarding access to services for beneficiaries.

5. Solicitation of Additional Comments Regarding the Implementation of the Fingerprinting Requirements

While this final rule with comment period is effective on the date indicated herein, we strongly believe that certain issues warrant further discussion. Accordingly, we will continue to seek comment limited to our implementation of the fingerprinting provisions contained in § 424.518 and § 455.434 of this rule.

Specifically, we seek comment on methods that we can use to ensure the privacy and confidentiality of the records that will be generated pursuant to adopting the criminal history records check provisions specified herein. As described, we will adopt all protocols issued by the FBI. However, we are interested in any other privacy concerns that interested parties may have in addition to thoughts on how best to address these concerns.

In addition, we seek comment on the means by which we can measure the effectiveness of our adoption of criminal history records checks. That is, we are seeking comments on tangible, measureable methods we should use to demonstrate the effectiveness of these provisions.

In addition, we seek comment on whether we should adopt additional technology to identify providers and suppliers that are enrolling in the program. In the proposed rule, we solicited specific comments on this topic. However, we are interested in receiving additional input from providers, suppliers, and other interested parties in light of the provisions set forth in this final rule with comment period.

As noted, we are only seeking comment on the limited areas previously described. We will accept public comment for 60 days following publication of this final rule with comment period. To reiterate, we are finalizing the requirement that providers and suppliers will be subject to criminal history records checks in the event they are considered within the "high" level of risk as described in this rule. Providers and suppliers, and all other commenters, are encouraged to submit comments within the 60-day window to assist us in best implementing the requirements that we are finalizing surrounding this

technology. We are interested in hearing input from all stakeholders, including the beneficiary advocacy community, law enforcement, providers, and suppliers that are subject to the requirements set forth in this final rule with comment period, and any other interested parties.

B. Application Fee—Medicare, Medicaid, and CHIP

1. Statutory Changes

Section 6401(a) of the ACA, as amended by section 10603 of the ACA, amended section 1866(j) of the Act and requires the Secretary of DHHS to impose a fee on each "institutional provider of medical or other items or services or supplier." The fee would be used by the Secretary to cover the cost of screening and to carry out screening and other program integrity efforts, including those under section 1866(j) and section 1128J of the Act. Since section 10603 of the ACA excludes eligible professionals, such as physicians and nurse practitioners, from paying an enrollment application fee, we maintain that an "institutional provider" would be any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

Section 1866(j)(2)(D)(i) of the Act states that the new screening procedures implemented pursuant to section 6401 of the ACA would be applicable to newly enrolling providers, suppliers, and eligible professionals who are not enrolled in Medicare, Medicaid, or CHIP by March 25, 2011. Accordingly, the enrollment application fees for newly enrolling institutional providers and suppliers would be applicable on that date as well.

Section 1866(j)(2)(D)(ii) of the Act states that the new screening procedures will apply to currently enrolled Medicare, Medicaid, and CHIP providers, suppliers, and eligible professionals beginning on March 23, 2012. However, because the new procedures are applicable beginning on March 25, 2011 for those providers, suppliers, (and eligible professionals) currently enrolled in Medicare, Medicaid, and CHIP that revalidate their enrollment information, we will begin collecting the application fee for those revalidating entities for all revalidation activities beginning after March 25, 2011.

Section 1866(j)(2)(C)(ii) of the Act permits the Secretary, acting through CMS, to, on a case-by-case basis, exempt a provider or supplier from the imposition of an application fee if CMS determines that the imposition of the enrollment application fee would result in a hardship. It also permits the Secretary to waive the enrollment application fee for Medicaid providers for whom the State demonstrates that imposition of the fee would impede Medicaid beneficiaries' access to care.

Section 1866(j)(2)(C)(i)(I) of the Act establishes a $500 application fee for providers and suppliers in 2010. For 2011 and each subsequent year, the amount of the fee would be the amount for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average), (CPI–U) for the 12-month period ending with June of the previous year. To ease the administration of the fee, if the adjustment sets the fee at an uneven dollar amount, we will round the fee to the nearest whole dollar amount.

2. Proposed Application Fee Provisions

In § 424.502, we also proposed to establish a definition for an "institutional provider" as it relates to the submission of an application fee. We proposed that an "institutional provider" means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (but not physician and nonphysician practitioner organizations), or CMS–855S or associated Internet-based PECOS enrollment application.

For purposes of Medicare, Medicaid, and CHIP, we interpret the statutory reference to "institutional provider[s] of medical or other items or services or supplier" to include, but not be limited to: The range of ambulance service suppliers; ASCs; CMHCs; CORFs; DMEPOS suppliers; ESRD facilities; FQHCs; histocompatibility laboratories; HHAs; hospices; hospitals, including but not limited to acute inpatient facilities, inpatient psychiatric facilities (IPFs), inpatient rehabilitation facilities (IRFs), and physician-owned specialty hospitals; CAHs; independent clinical laboratories; IDTFs; mammography centers; mass immunizers (roster billers); OPOs; outpatient physical therapy/occupational therapy/speech pathology services, portable x-ray suppliers; SNFs; radiation therapy centers; RNHCIs; and RHCs.

In addition to the providers and suppliers listed previously, for purposes of Medicaid and CHIP, we proposed that a State may impose the application fee on any institutional entity that bills the State Medicaid program or CHIP on a fee-for-service basis, such as: Personal care agencies, non-emergency transportation providers, and residential treatment centers, in accordance with the approved Medicaid or CHIP State plan.

We proposed that an application fee will not be required from an eligible professional who reassigns Medicare benefits to another individual or organization, since it would not create a new enrollment of an institutional provider or supplier that would result in an application fee. In addition, we proposed that in no case would the application fee be required from any individual physician or Part B medical group/clinic.

We proposed that an application fee will be required with the submission of an initial enrollment application, the application to establish a new practice location, as a part of revalidation, or in response to a CMS revalidation request.

We proposed that prospective institutional providers and suppliers as well as currently enrolled providers who are revalidating their enrollment in Medicare must submit the applicable application fee or submit a request for a hardship exception to the application fee at the time of filing a Medicare enrollment application on or after March 25, 2011 in the case of prospective providers or suppliers, and in the case of revalidations. We believe that it is essential that we are able to receive and deposit the application fee or consider the institutional provider's request for a hardship exception prior to initiating an application review. Therefore, we would not begin processing an application for either a new provider or supplier, or for a provider or supplier that is currently enrolled, until the enrollment application fee is received and is credited to the United States Treasury.

The fee would accompany the certification statement that the provider or supplier signs, dates, and mails to CMS via the appropriate Medicare contractor if the provider or supplier uses Internet-based PECOS to enroll or revalidate. The fee would accompany the paper CMS–855 provider enrollment application if the provider or supplier enrolls or revalidates by paper. Because the statutory provisions are effective for newly enrolling providers and suppliers effective March 25, 2011 institutional providers and suppliers will not be required to furnish the application fee with applications submitted before that date. However, because the ACA provides that the new procedures will be applicable beginning on March 25, 2011 for those providers and suppliers, (and eligible professionals) currently

enrolled in Medicare, Medicaid, and CHIP that revalidate their enrollment information, we will begin collecting the application fee for those revalidating entities for all revalidation activities beginning after March 25, 2011. We will not collect the fee from individual physicians and eligible professionals.

We proposed that CMS reject and return to the provider or supplier an initial enrollment application submitted by a provider or supplier, without further review as to whether the provider or supplier qualifies to enroll in the Medicare program, when the Medicare enrollment application or the Certification Statement is received by the Medicare contractor and the provider or supplier did not include a request for hardship exception to the application fee, did not include the application fee or the appropriate number of application fees, if applicable. We do not believe that it is appropriate for CMS to begin the application review process without first having received the application fee.

We proposed that the CMS reject any initial enrollment applications submitted after March 23, 2011, if a provider or a supplier did not furnish the application fee at the time of filing, using § 424.525(a)(3) as the legal basis for the rejection.

In § 424.525(a)(3), we proposed adding a new reason why CMS could reject an initial enrollment application or an application to establish a new practice location. Specifically, we proposed a new § 424.525(a)(3) to state, "The prospective institutional provider or supplier does not submit an application fee in the appropriate amount or a hardship exception request with the Medicare enrollment application at the time of filing."

We also believe CMS should be allowed to reject an initial enrollment application received from a provider or supplier on or after March 25, 2011, using § 424.525(a)(1) as the legal basis, if, for any reason, CMS is not able to deposit the full application amount into a government-ownad account or the funds are not able to be credited to the U.S. Treasury. In the case where a provider or supplier did not submit the application fee because they requested a hardship exception that is not granted, a provider or supplier has 30 days from the date on which the contractor sends notice of the rejection of the hardship exception request to send in the required application fee and application forms.

In § 424.535, we proposed adding a new reason why a CMS can revoke Medicare billing privileges. Specifically, we proposed a new § 424.535(a)(6)(i) to state that billing privileges may be revoked if "An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with the Medicare revalidation application or the hardship exception is not granted."

In addition, in § 424.535, we proposed a new § 424.535(a)(6)(ii) to state that billing privileges shall be revoked if "CMS is not able to: deposit the full application amount into a government-owned account or the funds are not able to be credited to the U.S. Treasury."

In § 424.514(b), we proposed that currently enrolled institutional providers and suppliers that are subject to CMS revalidation efforts must submit the applicable application fee or submit a request for a hardship exception to the application fee at the time of filing a Medicare enrollment application on or after March 23, 2011.

In § 424.514(d)(2)(iii), we proposed that institutional providers submit the application fee with each initial application, application to establish a new practice location, or with the submission of an application in response to a CMS revalidation request.

In § 424.514(d)(2), we proposed that the application fee be based on the amount calculated by CMS using the CPI–U for the 12-month period ending June 30 of the previous year and adjusted annually to be effective January 1st of the following year. In § 424.514(d)(2)(v), we proposed that the application fee be non-refundable. Neither the Federal government, its Medicare contractors, State Medicaid agencies or CHIP should be liable for reimbursement of the application fee to the provider or supplier if the application fee has been received by the Medicare contractor and deposited into a government-owned account and, later, during the course of verifying, validating, and processing the information in the enrollment application, CMS appropriately denies the enrollment application. Appropriate denial requires a substantive reason and applications will not be denied over inconsequential errors or omissions or over errors or omissions corrected timely.

In § 424.514(d)(4)(vi), we proposed that a provider or supplier must submit a new application fee if the provider or supplier resubmits a Medicare enrollment application because a previously submitted enrollment application was appropriately denied or rejected. In some cases, a rejected application would be returned to the provider or supplier along with the application fee; in other cases, the application would be denied and the application fee retained by the Federal government because the processing of the application would have already begun. In those latter cases, CMS funds would have been expended for some or all of the required screening involved in processing the application. For example, if a home health agency enrollment application is rejected because the enrollment application, or the certification statement generated by Internet-based PECOS, was not signed, the enrollment application would be rejected and it and the check for the application fee would both be returned to the home health agency. If a home health agency enrollment application is denied based on non-compliance with a provider enrollment requirement or because the HHA did not meet the conditions of participation for its provider type, the enrollment would be denied and the application fee would be retained by the Federal government. If the HHA wishes to send a new enrollment application, it would have to include another application fee with that new enrollment application. Similarly, we propose that a provider or supplier would be required to submit to the Medicare contractor a new application fee with a subsequent enrollment application if, among other things, the previous enrollment application was rejected because the provider or supplier did not timely furnish the Medicare contractor with the applicable supporting documentation or information necessary to complete its review and verification of the previous enrollment application.

In § 424.514(d)(6)(vii), we proposed that the application fee must be able to be deposited into a government-owned account before an enrollment application will be approved.

Because we proposed that a State may rely on the results of the screening conducted by the Medicare contractor to meet the screening requirements for participation in a State Medicaid program or CHIP, we proposed that, for dually participating providers, the application fee would be imposed at the time of the Medicare enrollment application, consistent with the procedures described previously. Additionally, because the purpose of the application fee is to, in part, cover the costs of conducting the provider and supplier screening activities, we proposed that a provider or supplier enrolled in more than one program (that is, Medicare and Medicaid or CHIP, or all three programs) would only he subject to the application fee under Medicare and that the fee would cover

screening activities for enrollment in all programs.

Section 1866(j)(2)(C)(iii) of the Act also permits the Secretary to grant, on a case-by-case basis, exceptions to the application fee for institutional providers and suppliers enrolled in the Medicare and Medicaid programs and CHIP if the Secretary determines that imposition of the fee would result in a hardship. One instance that might support a request for hardship exception is in the event of a national public health emergency where a provider or supplier is enrolling for purposes of furnishing services required as a result of the national public health emergency situation. Such requests will be considered on a case-by-case basis, as required by the statute. In addition, we solicited comments on the appropriate objective criteria that should be used in making a hardship determination and if thera are any other circumstances in which such exemptions should be allowed. We also solicited comment on the kinds of documents to be submitted to CMS or its contractor to exhibit hardship, including any comments on the financial or legal records that might be needed to make a determination of hardship. Section 1866(j)(2)(C)(iii) of the Act also permits the Secretary to waive the application fee for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care. We solicited comments on how waivers from the application fee should be implemented for Medicaid-only or dually-participating Medicare and Medicaid providers and suppliers specifically those seeking to furnish services where beneficiary access issues are prevalent, either geographically or in the provision of the services.

We are committed to assuring access to care for program beneficiaries. We are in the process of developing promising practices related to ensuring access in the Medicaid program and CHIP. We also solicited comments on the appropriate criteria that we should consider for purposes of the proposed fee. We were particularly interested in hearing from States, providers, advocates, and other stakeholders relating to concrete examples based on experiences in using specific access criteria.

Based on the statutory requirements for calculating the application fee, we offer the following example for purely illustrative purposes. The initial application fee beginning in 2010 is established by law at $500. However, for the following year, when the annual Consumer Price Index (CPI–U) is calculated for the period ending June 2010, we would recalculate the application fee using the CPI–U. Thus, if the CPI increased by 2.34 percent for the 12 month period ending June 2010, the application fee would be calculated by multiplying the fee for the year by the CPI–U. The $500 application fee established by law on in 2010 would be multiplied by 1.0234 to give $511.70. We would then round to the nearest dollar amount of $512.00. This would be the amount of the fee in effect for 2011, and would apply to applications received after the effective date of the statute—March 25, 2011 for newly enrolling providers and suppliers and for revalidating providers and suppliers. A similar process, based on the CPI–U for the period of July 1, 2010 through June 30, 2011 would be used to calculate the fee that would become effective on January 1, 2012, and that would apply to new and currently enrolled providers or suppliers that submit applications on or after March 23, 2012. In § 424.514(d)(2), we proposed that the annually recalculated application fee amount would be effective for the calendar year during which the application for enrollment is being submitted.

The amount of the application fee that is required of enrolling providers or suppliers, would be the amount that is in effect on the day the provider or supplier mails an enrollment application or Certification Statement, postmarked by the USPS, or if mailed though a private mail service the date of receipt by the Medicare contractor. Because the application fee will become an integral part of the enrollment process, we believe that it is essential that we notify State Medicaid Agencies and the public about any changes in the application fee prior to implementing a change in the fee. Accordingly, we would afford States and the public with at least 30 days' notice of any impending change in the application fee. We will make such notification annually in the **Federal Register** and by issuing guidance to the State Medicaid and CHIP Directors, issuing CMS provider and supplier listserv messages, making announcements at CMS Open Door Forums, and placing information on the CMS Provider/Supplier Enrollment Web page (*http://www.cms.gov/MedicareProviderSupEnroll*).

We proposed that a provider or supplier that believes it is entitled to a hardship exception from the application fee enclose a letter with the enrollment application or, if using Internet-based PECOS, with the Certification Statement, explaining the nature of the hardship. Further, we proposed that we would not begin to process an enrollment application submitted with a letter requesting a hardship exception from the application fee until it makes a decision on whether to grant the exception. Further, we proposed that we a make hardship exception determination within 60 days from receipt of the request from an institutional provider and CMS contractor notify the applicant or enrolled institutional provider or supplier by letter approving or denying the request for a hardship exception. Moreover, if we deny the request for hardship exception, we would provide our reason(s) for denying the hardship exception.

In § 424.530(a)(9), we proposed adding a new reason why CMS can deny Medicare billing privileges. Specifically, we proposed a new § 424.530(a)(9) to state, "An institutional provider's or suppliers "hardship exception" request is not granted and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved."

In § 424.535(a)(6)(i), we proposed adding a new reason why CMS can revoke Medicare billing privileges. Specifically, we proposed a new § 424.535(a)(6)(i) to state, "An institutional provider does not submit an application fee or "hardship exception" request that meets the requirements set forth in § 424.514 with the Medicare revalidation application or the hardship exception request is not granted and the institutional provider does not submit the applicable application form or the application fee within 30 days of being notified that the hardship exception request was denied."

We also proposed that an institutional provider may appeal the determination not to grant a hardship exception from the application fee using the provider enrollment appeals process established in § 405.874 and found in 1866(j)(2) of the Act.

In § 455.460, we proposed that, for those providers who do not participate in Medicare, the State may collect the fee established by the Secretary as outlined previously as the State will be responsible for conducting the provider screening activities for these providers. Total fees collected will be used to offset the cost of the Medicaid and CHIP screening programs. The fees represent an applicable credit under OMB Circular A–87, entitled "Cost Principles for State, Local, and Indian Tribal Governments" (August 31, 2005 (70 FR 51910)), codified at 2 CFR part 225, and made applicable to States by 45 CFR

92.22(b). The cost principles require that the costs a State claims must be reduced by "applicable credits," or "those receipts or reduction of expenditure-type transactions that offset or reduce expense items allocable to Federal awards as direct or indirect costs", (Paragraphs C.1.i., C.4.a. and D.1. of Appendix A to 2 CFR part 225). If the fees collected by a State agency exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government. CMS will direct these fees to support program integrity efforts as permitted by the ACA.

3. Analysis of and Responses to Public Comments

Below is a summary of the comments we received regarding the proposed enrollment application fee.

Comment: Through section 6401 of the ACA, CMS is authorized to collect and retain an application fee. Some commenters stated that CMS did not explain or justify the purpose behind the enrollment application fee, for enrolled providers of service and suppliers, beyond stating that the Congress mandated it. The commenters urged CMS to explain whether the revalidation/enrollment fee is meant to ensure compliance with a provider's or supplier's reporting responsibilities or to collect monies for the Federal Government.

Response: The ACA authorizes the collection of an application fee to cover costs of screening, including screening required for providers and suppliers that are revalidating their enrollment. The ACA specifies that the fees are to be collected from institutional providers and are to be used for program integrity efforts, including the costs of screening.

Comment: Several commenters questioned whether CMS has the statutory authority to exempt medical clinics and group practices from the application fee. They contended that while section 10603 of the ACA strikes the provision found in section 6401 of the ACA relating to individual provider application fees, section 10603 of the ACA does not establish a waiver for organizational suppliers, such as groups or clinics. They also stated that CMS furnished only a limited discussion of why it decided to give medical groups and clinics an application fee waiver. They stated that CMS should explain why it is giving medical groups and clinics a significant financial benefit by excluding them from the application fee. Another commenter stated that if CMS retains its policy to exempt medical groups and clinics from the application fee, CMS should estimate the annual loss in revenue to the Federal government and explain what this will mean to CMS' efforts to fight fraud, waste and abuse. Another commenter stated that if CMS retains this provision, it should exclude the reference to physician and non-physician practitioner organizations in the proposed definition of institutional provider.

Response: Section 6401(a) of the ACA that adds section 1866(j)(2) of the Act specifically excluded physicians from paying the application fee. Physicians and non-physician practitioners in medical groups and clinics reassign their Medicare billing privileges to those medical group and clinics. As such they would be exempt from the fees.

Comment: One commenter asked if a small group practice would be considered institutional, and whether every practice location would need to submit a separate application fee.

Response: We will clarify that the application fee is not applicable to physicians and non-physician practitioners, regardless if the physician or non-physician practitioner is organized in a small group practice.

Comment: A commenter urged CMS to consider exceptions to the required application fee, which, the commenter stated, could impose a hardship on small home and community based service providers.

Response: We are committed to ensuring access to care and services for beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A commenter suggested that CMS develop and issue a standard enrollment fee "hardship exception form" that a provider can use when requesting an exception to the fee.

Response: Whereas a standard form might be useful, there could be many situations that justify exception from the fee. We do not want to limit the basis for fee exceptions for providers and suppliers to a pre-established list of circumstances. Accordingly we have not listed options for providers and suppliers to request hardship exceptions from application fees. As indicated in the preamble to the proposed rule, each request will be considered on its own merit on a case-by-case basis.

Comment: A commenter suggested that to avoid processing delays associated with depositing the application fee into a government-owned account, CMS should allow newly-enrolling Medicare, Medicaid and CHIP providers to submit the application fee in advance of submitting a new enrollment application.

Response: We disagree with the commenter's suggestion. We think payments should be clearly associated with the CMS–855 application form. We believe that payments submitted before the CMS–855 could have a greater likelihood of being disassociated with the appropriate CMS–855.

Comment: One commenter stated that since the application fee must be credited to the United States Treasury, CMS should explain how long it will take before the application fee is paid by a provider or supplier and when CMS will receive this money to fight fraud, waste and abuse.

Response: The Treasury Department has existing regulations in place governing the time frame in which received funds must be deposited and made available in the U.S. Treasury. We will be working with the Office of Management and Budget and Department of HHS budget officials to assure that the full amount collected from application fees will accrue to CMS for HHS's program integrity work as required by section 1866(j)(2)(C)(iii) of the Act.

Comment: A commenter requested that CMS explain why an application fee is required by a Competitive Acquisition Program (CAP) Part B Drug Vendor, since this entity does not bill the Medicare program.

Response: Only institutional providers, as defined in the proposed rule, are subject to the application fee. Providers and suppliers that do not bill Medicare on a fee-for-service basis are not subject to the application fee.

Comment: A commenter stated that in exempting medical groups/clinics from the application fee, CMS does not distinguish between clinics owned by physicians/practitioners and non-physicians/non-practitioners.

Response: We did not distinguish between medical groups/clinics on the basis of ownership. Medical groups and clinics are exempt from the fee because as noted previously, they are paid through reassignment of payments from physicians and non-physician practitioners. Physicians, non-physician practitioners and other individual practitioners are not subject to the fee by statute.

Comment: A commenter stated that FQHCs should be exempted from the application fees for two reasons. First, FQHCs, unlike other providers, are not permitted to submit one Medicare enrollment application for all sites, and that consequently, these low-risk entities would pay the majority of the

application fees. Second, a significant portion of an FQHC's budget includes section 330 grant funds. These funds are primarily intended for the care of uninsured and indigent patients. The application fees would take a significant portion of those funds away from the neediest individuals.

Response: While we understand the commenter's concerns, the statute did not exempt FQHCs from the application fee requirement. However, FQHCs can request a hardship exception to the fee.

Comment: A commenter recommended that CMS update the CMS–855A, CMS–855B, and CMS–855S forms to add information about the application fee, including the basis for this fee, the amount of the fee, and where the fee should be mailed.

Response: We agree that providers and suppliers need additional information about the process for submitting the application fee, its basis and intended use. We plan to have such materials available by the effective date of the final regulation. We will make these materials available through our Web site, listservs, open door forums, and other communication methods. We will also share these documents with professional and provider and supplier associations in an effort to provide additional information.

Comment: A commenter noted that section 1866(j)(2)(D)(ii) of the Act states that the application fee would not apply to current providers or suppliers until two years after enactment. However, the commenter argued, CMS was silent on this statutory provision in the proposed rule. The commenter recommended that CMS explain why section 1866(j)(2)(D)(ii) of the Act does not apply to current providers and suppliers and why CMS has decided to apply the provisions in section 1866(j)(2)(D)(iii) of the Act instead.

Response: Section 1866(j)(2)(D) of the Act contains conflicting effective dates for currently enrolled providers and suppliers. In 1866(j)(2)(D)(iii), providers and suppliers that are revalidating are subject to the fee and the other provisions of the proposed rule 180 days after enactment, or September 19, 2010. In section 1866(j)(2)(D)(ii) of the Act the new screening provisions including the fee are effective for currently enrolled providers and suppliers on March 23, 2012. For newly enrolling providers and suppliers the provisions are effective on March 25, 2011. We recognize the conflicting effective dates for the same group of currently enrolled providers and suppliers. As a result, in an effort to promote consistency in the application of the rule, we proposed two effective dates for the provisions of the rule for currently enrolled providers and suppliers. On March 25, 2011, the fees and other requirements of the regulation are applicable for currently enrolled providers that are revalidating their enrollment in the period between March 25, 2011 and March 23, 2012. For all other currently enrolled providers and suppliers, the fees and other provisions of the proposed rule are effective on March 23, 2012, as specified in the statute. The statute authorizes us to begin collecting fees from providers and suppliers that are revalidating as early as September 23, 2010.

Comment: A commenter recommended that—consistent with section 10603 of the ACA–CMS establish an application fee exemption for physicians who are sole proprietorships or sole owners and who provide DMEPOS "incident to" their medical service.

Response: Physicians who are enrolled in Medicare as physicians are exempt from the fee. DMEPOS suppliers, whether owned by physicians or otherwise, are institutional suppliers and as such, are subject to the application fee.

Comment: Several commenters urged an exception from the enrollment fee for: (1) Existing providers, or (2) new providers in under-served areas. A commenter added, however, that such exceptions should be limited to nonprofit and governmental entities with low overall margins. The commenter also stated that CMS should allow enrollment fee exceptions: (1) For existing providers when it is clearly equitable and in the public's interest—since to do otherwise simply transfers limited resources needed for patient care to the enrollment process and constitutes a tax on an otherwise nontaxable entity—and (2) for any new nonprofit or public provider that is proposing to establish services in an underserved area. The commenter did not believe that for-profit providers should qualify for fee waivers because their business model is based on their capacity to generate sufficient capital to start a business and operate profitably.

Response: We recognize that the application fees are a new financial obligation on nonprofit and public providers and suppliers; however, the statute provides no blanket exception for providers and suppliers by financial status. However, the law and rule contain provisions that would allow institutional providers and suppliers to apply for hardship exception to the fees for circumstances that are appropriate to their respective situations. We encourage any provider or supplier that cannot pay the fee to notify us and provide us with justification for the exception.

Comment: A commenter stated that the application fee should be waived for providers that routinely update their Medicare enrollment information more than once in a five-year period (3 years for DMEPOS).

Response: While we do not discourage providers and suppliers from submitting revalidation applications more frequently than the regulatory-prescribed timeframes, we do not believe that the fee should be waived for providers that do so. As stated in the preamble, the application fee is to be used by the Secretary to cover the cost of screening. If the provider or supplier submits a revalidation application on its own volition, we believe it is appropriate to require a fee that would cover the cost of processing that application.

Comment: A commenter, expressing concern about the time it can take for Medicare contractors to process applications, recommended that payment of the enrollment fee be tied to a corresponding obligation of the Medicare contractor to complete the enrollment process within a specified period of time. Specifically, the commenter requested that CMS create a hardship category that would permit an enrollment fee to be refunded to the provider or supplier if the Medicare contractor fails to process the application within a specified period of time (for example, 30 days from the date a completed enrollment is received by the Medicare contractor). The commenter stated that such a policy would create the proper incentive for Medicare contractors to process these applications in a timely fashion. Other commenters, too, stated that the fee should be refunded if the Medicare contractor does not process the application in a timely manner.

Response: We are concerned about any delay in processing enrollment applications. Our enrollment contractors have clear standards in their contracts regarding processing enrollment applications. In fact, we are currently in the process of strengthening such performance standards for all of our contractors. However, the ACA provides that a provider may be exempted from the fee only when the imposition of the fee itself would result in a hardship. We do not interpret the ACA as linking the application fee to contractor performance standards.

Comment: One commenter stated that it appears that physicians who also enroll as DMEPOS suppliers so they can furnish DMEPOS to their own patients

would be expected to pay an enrollment fee. The commenter believes that this would be inconsistent with the congressional decision to exempt physicians and other health professionals from the enrollment fee. It might also cause some physicians and other health professionals to decide against enrolling as DMEPOS suppliers, thus they would no longer be in a position to provide their patients with Medicare-covered DMEPOS. The commenter also stated that CMS should modify its enrollment procedures so that physicians who also wish to provide DMEPOS to their own patients would only need to enroll once, not twice. This approach would simplify the enrollment process for both physicians and CMS.

Response: Physicians that supply DMEPOS services to patients are currently required to enroll as both a physician (for medical services) and as a DMEPOS supplier. The screening required of any DMEPOS supplier, even one that is incident to a physician's practice, is more resource intensive than screening for physicians. Accordingly, we think applying the fee to all DMEPOS suppliers is justified. Moreover, we think it is a necessary component of our efforts to assure overall benefit integrity in Medicare to have all DMEPOS suppliers meet the supplier standards for DMEPOS suppliers. Accordingly, we have no plans to change the requirements as suggested by the commenter. We note in addition that a decision to make any such changes would be outside the scope of this rule.

Comment: A commenter asked why CMS is proposing to exempt a physician or non-physician practitioner organizations from the application fee when they submit a CMS–855B application, but the same physician or non-physician practitioner organization would be required to pay an application fee if they enrolled using the CMS–855S.

Response: The ACA specifically excluded physicians and nonphysician practitioners from paying the application fee. Physicians or non-physician practitioner organizations that elect to apply to enroll in Medicare as an institution or other entity, for example, submitting an CMS–855S to enroll as a DMEPOS supplier, are applying to enroll as an institutional provider not a physician or non-physician practitioner. Accordingly, applications to enroll as institutional providers are subject to submitting the application fee.

Comment: Several commenters stated that a $500 application fee for DMEPOS suppliers who are orthotists and prosthetists is not reasonable, especially on top of the required annual payment for a surety bond, accreditation and to maintain licensure. One of these commenters opposed the proposed rule because it seems redundant in light of other requirements such as accreditation, licensure, non-mandatory OIG compliance plans, and HIPAA. The commenter stated that with reimbursements being cut, expenses increasing, and the government constantly imposing new, unnecessary fees, it is becoming difficult for small businesses to survive in this economy. Several other commenters stated that the fee should be waived for the smallest providers. For community pharmacies, another commenter urged CMS to either: (1) Impose a $500 fee upon initial enrollment and in the case of the addition of new practice locations without imposing any fees for revalidation, or (2) impose a lower fee of $200 if the fee will apply to revalidation, as well as initial enrollment and adding new locations.

Response: The ACA sets the initial fee at $500.00 for all types of institutional providers or suppliers and for revalidating providers. Because the ACA specifies that the money be used for program integrity activities, including screening, we believe it is reasonable and appropriate to impose a fee on new practice location applications which require us to expend resources to screen for example onsite visits or background checks may be required. Also, the ACA specifies the formula for updating the fee. Affected providers and suppliers can request an exception from the fee if they can demonstrate that it poses a hardship.

Comment: A commenter requested clarification as to whether a returned, rejected, or denied application would trigger the need for a provider to resend another fee when it resubmits its application. The commeuter also asked whether a provider going from one state to another within Medicare would only be required to submit the fee once.

Response: The proposed rule itemized circumstances when additional fees would be required. The answer to the commenter's question about returned, rejected, or denied applications and whether these actions would trigger a requirement for a new fee will vary depending upon the circumstances. Providers and suppliers that submitted applications that were denied because the provider or supplier did not meet the requirements to enroll would be subject to an additional fee for any new application they submit. Providers and suppliers that submitted an application that could not be processed because of a temporary moratorium would not be required to submit an additional fee. Applications that were accompanied by a request for hardship exception waiver to the fee and for which the hardship waiver request was denied would be required to submit a fee in order for the application to be processed. If, in this latter circumstance, the provider or supplier submitted the fee with the application and the hardship exception waiver request, and the fee was not returned, the provider or supplier would not be required to submit a new fee payment. Providers establishing a new practice location in a different enrollment jurisdiction or as a new provider type would be required to submit a fee for each new practice location or provider type.

Comment: A commenter stated that CMS should allow application fees to be held in escrow when an application is denied.

Response: We think it is important for the fee to be associated clearly and specifically with the application for new enrollment or revalidation at the time the application for enrollment or revalidation is being processed. In this way we avoid any administrative errors involved in associating a fee held in escrow with an instant application. There are a number of reasons it might be complicated to associate an escrowed fee with an application, particularly if the provider or supplier has a different name or identifier, or a large amount of time has elapsed between applying for enrollment or revalidation.

Comment: A commenter believes it was inequitable that institutional providers in the limited level of screening are still subject to the same $500 application fee as providers in the high level of screening. The commenter recognized that this is a matter of statute, but stated that a more equitable policy would be to link the application fee amount to the assigned level of screening, with a zero or minimal fee applicable for facilities in the limited screening level and higher scaled fees applied to the moderate and high screening levels. The commenter also recommended that CMS use the application fee collected from "limited risk" providers to develop prioritized and expedited processes and timeframes for contractor review and approval of initial enrollment applications and revalidations for "limited risk" providers.

Response: The ACA established a flat rate of $500 for application fees to be imposed upon institutional providers and suppliers. In addition, the ACA does not include provisions to link the

fee to assigned screening level. Accordingly, the proposed rule implementing the statute did not link the fee to assigned screening level.

Comment: A commenter stated that for DMEPOS suppliers, requiring a $500 application fee at the time of submission of an enrollment application for each Medicare PTAN is unsupported and improper. A simple $500 fee per company, or paying for up to four facility locations (but not more) per company, or $500 for the first location and $50 for the next 10 makes sense. A flat $500 per location does not make sense according to the commenter, since clearly larger companies with multiple locations pose lower risk.

Response: As mentioned previously, the fee amount is included in the ACA. In addition, the ACA requires each institutional provider to pay the fee. Providers and suppliers will be charged the fee for each form CMS–855 they submit for enrollment or revalidation.

Comment: A commenter stated that CMS should not allow contractors to revoke a provider's billing privileges if an application fee or hardship waiver does not accompany a revalidation application.

Response: We disagree. We believe that the failure to submit an application fee or hardship waiver with a reenrollment or revalidation application should be treated as the equivalent of the non-submission of the application, which is grounds for revocation under regulation § 424.535(a)(6). However, we understand the concern expressed and will instruct our enrollment contractors to contact any enrolling or revalidating provider or supplier that does not submit the fee with the enrollment application and afford an opportunity to submit the fee. Thirty days after the date of the notification, the enrollment contractor would reject the application and revoke the billing privileges of the enrolled provider or supplier that has not submitted the fee. We have modified the regulation provisions in § 424.514(g) to include the 30 day period.

Comment: Several commenters requested clarification that changes of information, reactivations, and contractor-solicited, off-cycle revalidations do not require an application fee.

Response: The ACA authorizes fees for new enrollment and revalidation of enrollment. Simple changes in the CMS–855, for example, new phone numbers, new bank account information, new billing address(es), change in name of provider or supplier, or other such updates, do not constitute a new enrollment or a revalidation of an enrollment and therefore would not be subject to an additional fee.

Comment: A commenter stated that there is no justification to assess new fees to providers to support CMS enforcement activities that should be ongoing in any event. Moreover, CMS' proposed actions, the commenter contended, ignore the much more practical and effective measures to stem fraud and abuse outlined in H.R. 2479, and instead of stopping the fraud at the outset (as seems to be the stated objective) rely unduly on straightforward delays in delivering payments to all providers. This punishes all legitimate providers, and without any assurance that delays will solve the fraud problem.

Response: Section 1866(j)(2)(C) of the Act authorizes the the Secretary to collect application fees from institutional providers and suppliers. This section also specifies that "the amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J of the Act." We are implementing the provisions of the statute. The application fees collected will be used for program integrity efforts as specified in the statute.

Comment: A commenter stated that imposition of the fee on physicians who are enrolled as DMEPOS suppliers is unambiguously beyond the scope of CMS's statutory authority, would frustrate congressional intent, and is not warranted, since the vast majority of physicians would not be subject to additional screening.

Response: The fees are only paid by institutional providers and suppliers. If a physician is enrolled as a physician and also as a DMEPOS supplier, the fee is required only for the DMEPOS supplier enrollment.

Comment: A commenter supported CMS's proposal to exempt physicians and non-physician practitioners from the application fee. The commenter stated that with a potential Medicare provider shortage on the horizon, introducing an application fee to these suppliers would only serve to drive more providers out of the Medicare system.

Response: The ACA exempts physicians and non-physician practitioners from paying the application fee.

Comment: A commenter stated that an appropriate course would be to process the application and require that if the application is accepted but the hardship waiver is denied, the application fee will be deducted from future payments. This certainly creates the risk that some applications would be considered for which no application fee payment was ultimately available, but that outcome is offset by the need to avoid draconian requirements with illusory protections.

Response: The ACA requires institutional providers and suppliers that submit an application to enroll in or revalidate their enrollment in Medicare to pay the fee. Contractors should not process applications for new enrollment or revalidation of enrollment without a fee accompanying the application. In the case of an application that is accompanied by a request for a hardship waiver that is denied, the contractor will notify the provider or supplier that a fee is required for further processing. The provider or supplier has the option to submit the fee with the application and waiver request as a contingency to expedite processing should the hardship waiver be denied and the provider or supplier is concerned about delays associated with the time required to provide the fee.

Comment: A commenter expressed concern that there was no exception for governmental providers, including those that are funded by Federal agencies. To permit Medicare and Medicaid, for instance, to impose enrollment fees on Indian and tribal providers merely transfers funds from one health system to Medicare and Medicaid.

Response: Neither the ACA nor the proposed rule provide a blanket exemption from the fee for Federal institutional providers. Accordingly, we are unable to grant such an exception. However, Federal health care providers have the option to seek a hardship exception to the fee, and could request such an exception with any applications submitted to enroll in Medicare as an institutional provider.

Comment: A commenter stated that if an application fee or hardship waiver request is missing from an application, the contractor should—consistent with § 424.520—treat this as a request for additional information and give the provider 30 days to furnish the missing items.

Response: We agree. Consistent with § 424.514(g)(3)(ii), contractors will be instructed to give providers and suppliers 30 days after the provider or supplier receives notification that the request for a hardship waiver is denied to submit the enrollment fee.

Comment: A commenter stated that requiring two enrollment fees for a provider enrolling as two different

Medicare provider types—such as DMEPOS suppliers and mass immunizers—would be inconsistent with CMS' proposed one-fee policy for dually enrolled providers, that is those enrolled in Medicare and Medicaid. Similarly, a commenter stated that if physicians functioning as DMEPOS suppliers for their patients are subjected to the additional screening mechanisms in the "Moderate" and "High" screening levels, many physicians will simply relinquish the services they provide as DMEPOS suppliers with minimal to no benefit to CMS's anti-fraud efforts.

Response: The ACA specifically excludes physicians and nonphysician practitioners from paying the application fee. Physicians or non-physician practitioner organizations that elect to apply to enroll in Medicare as something other than a physician or nonphysician practitioner, for example, submitting an CMS–855S to enroll as a DMEPOS supplier, are applying to enroll as an institutional provider not as a physician or nonphysician practitioner. Accordingly, applications to enroll as institutional providers are subject to submitting the application fee. Individual institutional providers that enroll in Medicare and Medicaid will be required to pay only one application fee per enrollment. Entities or individuals that enroll only in Medicare or only in Medicaid as more than one kind of institutional provider, for example, a DMEPOS supplier and a home health agency, will be required to submit the fee for each enrollment.

Comment: A commenter suggested that providers submit one application for all commonly-owned entities, with addenda to address each specific entity as needed. A single fee for each provider would be paid by the parent. The commenter added that if multiple application fees are required for providers and suppliers wholly owned by the parent entity, a cap of $5,000.00 per year in application fees should be instituted.

Response: The ACA requires each institutional provider to pay the fee, in the amount specified in the statute. In general, most providers and suppliers must report each practice location on the enrollment Form CMS–855; however, the provider or supplier may list multiple practice locations on one Form CMS–855. The rules for DMEPOS suppliers, FQHCs and IDTFs are different; these entities must enroll each practice site separately—with separate for CMS–855. Because of these differences among the different categories of providers and suppliers, we believe it is most prudent to rely upon the requirement that a provider or supplier will simply pay the application fee whenever a Form CMS–855 is submitted.

Comment: A commenter suggests that CMS specifically exempt physical therapists in private practice from paying an enrollment fee when enrolling as a DMEPOS supplier with NSC. The commenter acknowledges that physical therapists in private practice are listed under "eligible professionals."

Response: As with physicians, physical therapists that enroll as individual practitioners will be exempt from the fee. DMEPOS suppliers that are owned by a physical therapist are institutional providers and as a result are subject to the fee.

Comment: A commenter stated that CMS should exempt recertification, re-enrollment, or other actions not related to a change in ownership from the application fee.

Response: The ACA specifically provides for the fee to be paid for revalidating institutional providers, section 1866(j)(2)(C) of the Act.

Comment: A commenter suggested that a provider or supplier enrolled in more than one program (that is, Medicare, Medicaid or CHIP) be subject to only one application fee.

Response: We agree. Dually-participating providers and suppliers will only be subject to the application fee at the time of Medicare enrollment or revalidation.

Comment: A commenter requested clarification on whether a fee is charged: (1) For each individual provider associated with a facility or institution, or (2) per facility. The commenter recommended a sliding fee based on the size and number of employees the facility has.

Response: Under the ACA, a fee is required only from institutional providers. Therefore, if the commenter is referring to individual physicians or non-physician practitioners who are associated with an institutional provider or supplier, the individual physician or non-physician practitioner would not be required to submit an application fee. Only the facility or institutional provider with which they are associated would be required to submit the fee. If the commenter was referring to affiliated entities that would be considered institutional providers, then each of those institutional providers would be required to submit the fee as would the institutional provider with which they are associated.

Comment: The same commenter also recommended a sliding scale for the fee that would be based on the size of the provider or facility and the number of employees.

Response: The application fee is derived from a statutorily-mandated formula. Neither CMS nor the States have the discretion to change the amount of the fee.

Comment: A number of commenters requested clarification regarding whether a State is required to collect the application fee for Medicaid-only or CHIP-only providers, or if the collection of this fee is at a State's discretion. One commenter stated that it should continue to be at a State's discretion.

Response: Section 1866(j)(2)(C)(ii) of the Act requires that the fee be imposed for institutional providers, and the State will be required to collect the fee in the case of Medicaid-only and CHIP-only institutional providers. In addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), psychiatric residential treatment facilities, and may include other institutional provider types designated by a State in accordance with their approved State plan. Under section 1866(j)(2)(C)(iii) of the Act, we may grant case-by-case exceptions to the application fee, based upon a demonstration of hardship, and in those instances, the State would not be required to collect the fee from Medicaid-only and CHIP-only institutional providers. Additionally, section 1866(j)(2)(C)(iii) of the Act permits the Secretary to waive the application fee for providers enrolled in a State Medicaid program for whom the State demonstrates the imposition of the fee would impede beneficiary access to care. If a State is concerned that the imposition of the application fee may adversely impact beneficiary access to care, we encourage them to seek a waiver of the fee in those circumstances.

Comment: One commenter asked whether a State could choose to lower the fee from $500 to a different amount, for example, $250.

Response: The amount of the application fee is derived from a statutorily-mandated formula. States do not have discretion to change the amount of the fee that is collected from Medicaid-only or CHIP-only institutional providers.

Comment: One commenter asked that if a State elects not to collect the application fee, would the cost of screening be eligible for FFP.

Response: As stated previously, Section 1866(j)(2)(C)(ii) of the Act requires that the fee be imposed for institutional providers, and the State will be required to collect the fee in the

case of Medicaid—only and CHIP—only institutional providers. However, to the extent that the costs associated with performing the screening exceed the amounts collected as a result of the application fees, these costs would be eligible for FFP.

Comment: One commenter requested that CMS describe the process for determining whether the Medicaid and CHIP application fee exceeds the cost of provider screening.

Response: States will be required to account for the costs of the provider screening program and measure it against total fees collected. If the cost of the program exceeds fees collected, then the State can claim FFP for excess cost. Note, that this requires that principles of OMB Circular A–87 be properly applied and that total fees collected serve as an applicable credit to the Medicaid program.

Comment: One commenter requested that CMS confirm whether the application fee is intended to cover both State and Federal share of the costs.

Response: The application fees collected by the State must be used to offset the total cost, both State and Federal share, of the screening program. As stated in the proposad rule, if the fees collected by a State agency exceed the cost of the State's screening program, the State agency must return that portion of the fees to the Federal Government.

Comment: One commenter asked if States would be eligible for enhanced Federal match for changes to provider enrollment and claims processing systems that implement reporting and screening requirements.

Response: If the changes are to the MMIS for purposes of Medicaid provider enrollment and Medicaid claims processing, then States may be eligible for the enhanced match rate (either 90 percent for enhancements/new functionality or 75 percent for ongoing maintenance and operations). States must contact their CMS Regional Office to determine whether an advance planning document (APD) is required.

Comment: One commenter requested clarification on how the state should record expenditures on necessary MMIS changes to implement the rule, prior to collecting the application fee.

Response: All State share costs including those involving the enhancement and operation of the MMIS in addition to administrative costs related to provider screening and reporting as specified in the proposed regulation (§ 455.460) are to be included in the screening program costs and offset by the application fees collected by the State. We understand that the MMIS costs may be matched at higher rates (90 percent for development and 75 percent for operation). States will be required to report the 10 percent and 25 percent State share of the MMIS costs associated with the screening program and offset the application fee against such costs. In the event that the application fees are greater than the costs for the screening program for any reporting period, the State will refund the difference to CMS. Please refer to OMB Circular A–87, "Cost Principles for State, Local, and Indian Tribal Governments" for guidance in the reporting of the application fees as an applicable credit.

Comment: One commenter asked if the application fee is an allowable cost report expense for Medicaid and CHIP providers.

Response: If a Medicaid-only or CHIP-only institutional provider is subject to the application fee, this could be considered an allowable cost report expense. This determination would be governed by the State's approved reimbursement methodology within its State plan.

Comment: One commenter asked if the amount of the fee could be included in determining a government provider's cost based rates.

Response: Yes, if the application fee is imposed on a government institutional provider, then the amount of the fee could be included in determining the government provider's cost-based rates.

Comment: A few commenters asked if a State is permitted to have the applicant/provider pay the fees associated with fingerprinting and conducting criminal history checks.

Response: The application fee is intended to cover the costs associated with the State's Medicaid or CHIP provider screening program. It is permissible for the State to require the provider to pay the costs associated with capturing fingerprints. However, we expect that the amount of funds collected by imposition of the application fee should be used by the State to fund the costs incurred by the State associated with processing the fingerprints and conducting the criminal background checks.

Comment: A number of commenters stated that local education agencies (that is, public schools) should be exempt from having to pay the application fee.

Response: To the extent that a State determines, consistent with the approved State plan, that a local education agency is an institutional provider for purposes of this provision, then it would be subject to the application fee.

Comment: A few commenters requested that CMS clarify whether the application fee applies to institutional providers only under Medicaid and/or CHIP, and what types of Medicaid and CHIP providers are considered institutional.

Response: We will clarify in the regulation that the application fee does not apply to physicians or other individual non-physician practitioners such as nurse practitioners under Medicaid and/or CHIP. Medicaid-only and CHIP-only institutional providers that would be subject to the application fee include: Medicaid-only nursing facilities, intermediate care facilities for persons with mental retardation (ICF/MR), and psychiatric residential treatment facilities. Additionally, a State may impose the application fee on other types of Medicaid-only or CHIP-only institutional providers, consistent with their approved State plan.

Comment: One commenter asked if pharmacies are considered institutional providers for purposes of the application fee.

Response: In the Medicare program, pharmacies are generally enrolled as DMEPOS suppliers, and thus are considered institutional providers for the purposes of the application fee. Therefore, pharmacies would be subject to the application fee, and it would likely be imposed at the time of Medicare enrollment or revalidation.

Comment: One commenter suggested that the application fee requirement should provide an exception for providers that are required to pay a pre-existing State-level application or certification fee to enroll in the Medicaid program.

Response: The enrollment screening activities are distinct from State-licensing and certification activities that seek to address conditions of participation or structures, processes and outcomes to support quality of care for the beneficiaries. The application fee is intended to support provider screening activities as part of enrollment.

Comment: A number of commenters requested that CMS provide further guidance regarding the manner in which States will be expected to report the costs associated with screening. One commenter specifically requested whether CMS will want screening costs detailed per screening, per provider (for example, detailed travel expenses for site visits) or if a more generic reporting of screening cost is expected.

Response: We anticipate that a State will be required to report the costs associated with its provider screening program on a semi-annual or annual

basis. Although we do not anticipate requiring States to routinely report very detailed information such as detailed travel expenses for a site visit, this information should be maintained by the State and be made available upon request if necessary for conducting an audit or other oversight activities. Additional guidance for States will be forthcoming regarding the specific form and manner of reporting.

Comments: One commenter requested that CMS clarify whether the application fee be designed to include current program integrity activities, or whether the State will be expected to track the increased expenditures of PI activities resulting from this regulation separate from historic PI activities.

Response: The application fee may only be used by the State to offset the cost of the provider screening program. It is not permissible for a State to design the fee in any manner that would include current program integrity activities. If the fees collected by a State agency exceed the cost of the screening program, the State agency must return that portion of fees to the Federal Government.

Comment: One commenter recommended that CMS provide a comprehensive exception for out-of-State providers providing emergency services to managed care members, stating that such an exception would allow for timely access to critical services for managed care enrollees.

Response: After considering the comment, we are not inclined to provide a comprehensive exception to the application fee in this circumstance. We believe that the overwhelming majority of providers that provide emergency services to out-of-State MCO members are dually-participating providers, and would thus be subject to the application fee at the time of Medicare enrollment. Furthermore, there are additional Federal laws that exist to safeguard beneficiary well-being in emergency situations, such as, the Emergency Medical Treatment and Active Labor Act (EMTALA).

Comment: A few commenters stated that each State should have the flexibility to waive the application fee, for particular providers or a class of providers, if it determines that this would help assure access to services for beneficiaries.

Response: We agree and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: One commenter stated that providers who have already paid the fee to their own State's Medicaid or CHIP program should also be exempt, if the provider is already enrolled in one and applies to the other.

Response: We agree that providers enrolled in more than one program, be it Medicare, Medicaid, and CHIP, including Medicaid and CHIP in multiple States must only be required to pay the application fee once.

Comment: One commenter urged CMS to expand the exemption provisions to allow an exemption for providers in medically underserved areas as well as those whose patient population are overwhelmingly Medicaid beneficiaries.

Response: We are committed to assuring access to care and services for program beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A few commenters expressed concern that requiring providers to pay a non-refundable application fee to participate in the Medicaid program will decrease the likelihood that providers will choose to participate.

Response: We are committed to assuring access to care and services for program beneficiaries and will clarify that a State, in consultation with the Secretary, may waive the application fee for Medicaid-only or CHIP-only providers if the State demonstrates that imposition of such a fee will impede beneficiary access to care.

Comment: A number of commenters requested clarification as to the process that a Medicaid agency would use to determine if a provider has paid an application fee to Medicare or another State. One commenter specifically requested clarification on whether the Medicare revalidation fee is applicable to payments made in one calendar year only when considered for Medicaid program(s). Will waiver programs honor fees made to Medicare? How will Medicaid honor a Medicare fee when the revalidation is a different time period?

Response: The basic concept of the screening and enrollment provisions included in this regulation is that Medicaid will accept Medicare screening for providers that receive payments from both Medicare and Medicaid. For dually-participating providers, the application fee is imposed at the time of Medicare enrollment and no additional screening fee is imposed by the State regardless of the time period or revalidation cycle. For institutional providers that participate only in Medicaid, the State Agency is responsible for assuring that the provisions of the regulation are met. Institutional providers will be required to submit the application fee to only one program. We believe these operational logistics are more appropriately addressed in subregulatory guidance. We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future.

Comment: One commenter supported the proposal that for dually participating providers, the application fee would be imposed at the time of Medicare enrollment.

Response: We agree and are finalizing this provision accordingly.

Comment: One commenter encouraged CMS to consider establishing a lower price point or expedited review for providers in the lower risk group.

Response: The amount of the application fee is derived from a statutorily-mandated formula. Neither CMS nor the States have discretion to change the amount of the fee that is collected from Medicaid-only or CHIP-only institutional providers.

Comment: One commenter requested clarification that ongoing resubmissions do not trigger the application fee and that the fee will merely be levied through the actual recertification process.

Response: The ACA authorizes fees for new enrollment and revalidation of enrollment. Simple changes to the provider enrollment information, that is, new phone numbers, new bank account information, new billing address, change in name of provider or other such updates are not subject to the fee. They will apply to newly-enrolling providers, revalidating providers and creation of new practice locations.

Comment: A commenter noted that the application fee and other provisions are effective on March 23, 2011. The commenter stated, however, that CMS must first complete the notice and comment rulemaking process. The commenter recommended that CMS implement the application fee only after a final regulation has been issued and the public has been given at least 60 days notice.

Response: We agree with the commenter and we are finalizing the regulation in regard to the application fee. It will be displayed for 60 days prior to the effective date on March 25, 2011.

Comment: A commenter stated that some of the provider types listed under

the definition of "institutional provider" do not bill Medicare on a fee-for-service basis. For example, RHCs and FQHCs bill Medicare on a cost-based, all-inclusive rate basis. The commenter believes this distinction is significant because on past occasions when the Congress authorized certain incentive payments and linked those payments to the "fee-for-service" payment, RHCs and FQHCs were excluded from those incentive payment programs. The commenter believes it was unfair to deny certain providers from participating in programs because they are not "fee-for-service," but then mandate their inclusion in other initiatives reserved for "fee-for-service" providers. Moreover, the commenter stated that RHCs and FQHCs are by definition located in areas designated as underserved or serving populations with a demonstrated problem accessing the healthcare delivery system. Imposing an application fee on these providers will only serve as a further barrier to access to care. The commenter believes that the term "institutional providers" should exclude new entities seeking designation as RHCs and FQHCs and include only those providers that bill Medicare on a fee-for-service basis. Another commenter believes that the term "institutional provider" refers to providers whose beneficiaries are institutionalized; the proposed rule's envisioned use of the term is therefore inappropriate. The commenter suggested using the term "non-institutional provider."

Response: In the NPRM, we proposed a definition of institutional provider that does not distinguish among providers or suppliers based on which version of the form 855 they submit, or whether they submit the form electronically. We are finalizing this definition. The distinction on payment methods the commenter suggests is not related to the definition of institutional provider used in this rule. Physician and practitioner organizations are exempt from the application fee by statute; the exemption is not affected by how they are reimbursed. In addition, the inpatient status of patients has no bearing on whether a provider or supplier is considered an institutional provider in this rule. For example, hospitals are institutional providers as are home health agencies and DMEPOS suppliers.

If certain institutional providers and suppliers such as FQHCs and RHCs may face financial obstacles to paying the application fee, they can seek a waiver of the fee based upon a request for a hardship exception for Medicare or a request for a hardship waiver for Medicaid. Newly enrolling institutional providers and suppliers that are seeking such a waiver must submit a request for the hardship exception at the time of filing a Medicare enrollment application on or after March 25, 2011.

Comment: A commenter stated that the proposed rule indicates that the fee will be applied only to those providers that bill "Medicare, Medicaid, or CHIP on a fee-for-service basis." The commenter stated that most Indian and tribal providers are reimbursed either on the encounter rates established annually by CMS and IHS for Indian health programs or on FQHC encounter rates. The commenter requested clarification as to whether Indian and tribal providers will therefore be exempt from the application fee. The commenter added that the proposed rate of increase in the fee has often exceeded the increase in funding for Indian and tribal programs. Finally, the commenter stated that CMS failed to seek an exchange of views, information, or advice from the Tribal Technical Advisory Group (TTAG) or to consult directly with Tribes or confer with urban Indian organizations. Unless Indian and tribal health programs are exempt from these rules, the commenter believes that the effective date should be delayed, discussions with the TTAG and consultation with Tribes held, after which the proposed rules with any changes that result from the advice and consultation be published with a new comment period.

Response: We are statutorily unable to exempt IHS, Tribal, and Urban (I/T/U) Indian health programs from these rules or to delay the effective date. Moreover, we do understand Tribal concerns about not having the opportunity to provide advice on this regulation. All I/T/U's are eligible to apply for the hardship exception to the application fee and CMS is committed to working with Tribes, the TTAG and I/T/Us in implementing requests for hardship exceptions.

4. Final Application Fee Provisions—Medicare, Medicaid, and CHIP

This final rule with comment period finalizes the provision of the proposed rule in regards to the application fees with the following exceptions:

In § 424.514, we modified our proposal as follows:

- Added language to clarify that a provider or supplier may submit both an application fee and hardship exception waiver to avoid delays in the processing of the application if the hardship exception is not approved at § 424.514(a) and (b).
- Added language at § 424.514(d)(2) clarifying that the application fee is non-refundable except in the circumstance where the provider or supplier opts to submit both an application fee and a hardship waiver request and the waiver request is subsequently approved.
- Added language to clarify that if a provider submits a hardship exception request without an application fee, and CMS does not approve the hardship exception request, CMS will notify the provider or supplier and allow the provider or supplier thirty (30) days from the date of notification to submit the application fee at § 424.514(h).
- Added language that specifies that States must collect the applicable application fee from Medicaid-only and CHIP-only providers and suppliers at § 455.460.

C. Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Providers

1. Statutory Changes

Section 6401(a) of the ACA amended section 1866(j) of the Act by adding a new section 1866(j)(7) of the Act, which provides that the Secretary may impose temporary moratoria on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines such moratoria are necessary to prevent or combat fraud, waste, or abuse under the programs.

Section 6401(b)(1) of the Act adds specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any temporary moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries' access to care. Section 1902(kk)(4)(B) of the Act further permits States to impose temporary enrollment moratoria, numerical caps, or other limits, for providers identified by the Secretary as being at high risk for fraud, waste, or abuse, if the State determines that the imposition of such moratorium, cap, or other limits would not adversely impact Medicaid beneficiaries' access to care.

Section 1866(j)(7) of the Act uses the term "providers of services and suppliers." Although, as noted previously, the Medicaid program does not use the term "suppliers," section 1902(kk)(4) of the Act refers to "providers and suppliers." In this regulation, for uniformity with sections II A. and B. of this final rule with comment period, we are using the term

"providers and suppliers" in lieu of the term "provider of services and suppliers." We are using the term "provider" or "Medicaid provider" or "CHIP provider" in lieu of the term "provider or supplier" when referring to all Medicaid or CHIP health care providers, including, but not limited to, providers and suppliers of Medicaid items or services, individual practitioners, and institutional providers.

2. Proposed Temporary Moratoria Provisions

a. Medicare

We proposed at § 424.570(a) that we may impose a temporary moratorium on the enrollment of new Medicare providers and suppliers in 6 month increments in situations where—(1) CMS, based on its review of existing data, without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category suggests that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both; (2) a State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider of supplier type or both; or (3) CMS, in consultation with the HHS OIG or the Department of Justice (DOJ) or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

- A particular provider or supplier type.
- Any particular geographic area.

As part of the CMS decision making process, we will consider any recommendation from the DOJ, HHS OIG, or the GAO to impose a temporary moratorium for a specific provider or supplier type in a specific geographic area.

We believe that imposing moratoria will, among other things, allow us to review and consider additional programmatic initiatives, including the development of additional regulatory and sub regulatory provisions to ensure that Medicare providers and suppliers are meeting program requirements, beneficiaries receive quality care, and that an adequate number of providers of suppliers exists to furnish services to Medicare beneficiaries.

We also proposed that enrollment moratoria be limited to: (1) Newly enrolling providers and suppliers (that is, initial enrollment applications); and (2) the establishment of new practice locations, not to a change of practice locations. The temporary moratoria will not apply to existing providers or suppliers of services unless they were attempting to expand operations to new practice locations where a temporary moratorium was imposed. Moreover, the temporary moratoria would not apply in situations involving changes in ownership of existing providers or suppliers, mergers, or consolidations.

We also proposed at § 424.570(b) that a temporary enrollment moratorium would be imposed for a period of 6 months, and such moratorium could be extended by CMS in 6 month increments if we continue to believe that a moratorium is needed to prevent or combat fraud, waste, or abuse. The Secretary will re-evaluate whether a moratorium should continue prior to each 6 month expiration date.

We also proposed at § 424.570(c) that we will deny enrollment applications received from providers or suppliers covered by an existing moratorium. We noted that denial of Medicare billing privileges is subject to the administrative review process established in § 405.874. Accordingly, we believe that a provider or supplier also is afforded the right to appeal a Medicare contractor determination to deny enrollment into the Medicare program.

In § 424.530(a)(10), we proposed adding a new reason why we can deny Medicare billing privileges. Specifically, we proposed a new § 424.530(a)(10) to state, "A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium." Further, in § 498.5(l)(4), we proposed that the scope of review for appeals of denials under § 424.530(a)(10) based upon a provider or supplier being subject to a temporary moratorium will be limited to whether the temporary moratoria applies to that particular provider or supplier.

We noted that section 1866(j)(7) of the Act provides that there shall be no judicial review of a temporary moratorium. Accordingly, we proposed that a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review.

Finally, we proposed at § 424.570(d) that we may lift a moratorium in the following circumstances: (1) In the case of a Presidentially declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act); (2) circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address any program vulnerability that was the basis for the moratorium; or (3) in the judgment of the Secretary, the moratorium is no longer needed.

We also recognized that in a limited number of circumstances a State Medicaid agency may enroll a provider or supplier into Medicaid during the temporary moratorium period established by Medicare. If this occurs and the prospective Medicare provider or supplier applies to enroll in the Medicare program after the temporary moratorium is lifted, we would use the screening tools described in section II.A. of this final rule with comment period.

We also solicited public comment on specific exemptions to the temporary moratoria criteria proposed previously. Prior to imposing a moratorium, we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply.

We would announce the implementation of a moratorium at any time when it is being imposed. The announcement would be made in the **Federal Register** and we would also address it in other methods or forums, such as Press Releases, at CMS Provider Open Door Forums, in CMS provider listservs, and on the CMS Provider/Supplier Enrollment web page (*http://www.cms.gov/MedicareProviderSupEnroll*). We would also require our Medicare contractors to post the moratorium announcement or note the expiration of a moratorium on their Web sites. Our **Federal Register** announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply.

b. Medicaid and CHIP

Pursuant to section 1902(kk)(4)(A) of the Act, we proposed at § 455.470(a)(2) and (3) that a State Medicaid agency will comply with a temporary moratorium imposed by the Secretary unless it determines that the imposition of such a moratorium would adversely affect beneficiaries' access to medical assistance.

Where the Secretary has imposed a temporary moratorium in accordance with § 424.570, and the State has determined that compliance with such a moratorium would adversely impact Medicaid beneficiaries', or CHIP participants', as the case may be, access

to medical assistance, section 1902(kk)(4)(A)(ii) of the Act creates an exception for the State from complying with the moratorium. We proposed that the State provide the Secretary with written details of the moratorium's adverse impact on Medicaid beneficiaries. Prior to the Secretary imposing such a moratorium in any State, we proposed at § 455.470(a)(1) that the Secretary consult with the State, so that the State may have an opportunity to seek an exception from the moratorium.

Pursuant to section 1902(kk)(4)(B) of the Act, States have authority to impose moratoria, numerical caps, or other limits for providers that are identified by the Secretary as being at "high" risk for fraud, waste, or abuse. We proposed, at § 455.470(b) that where the State identifies a category of providers as posing a significant risk of fraud, waste, or abuse, the State must seek our concurrence with that determination and provide us with written details of the proposed moratorium, including the anticipated duration, and with a substantial justification explaining why disallowing newly enrolling providers would reduce the risk of fraud. We proposed at § 455.470(c) that States' moratoria would be imposed for a period of 6 months and may be extended in 6 month increments.

Section 2107(e)(1) of the Act provides that all provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act apply to CHIP. Accordingly, we proposed in new regulation § 457.990 that all the provider screening, provider application, and moratorium regulations that apply to Medicaid providers also apply in providers that participate in CHIP.

3. Analysis of and Responses to Public Comment

Below is a summary of the comments we received regarding the temporary enrollment moratoria.

Comment: A commenter expressed support for our proposal to establish a moratorium on new providers or new practice locations only when it is believes through the agency's review that a risk of fraud and abuse is detected. The commenter, however, requested CMS to: (1) To review the proposed 6-month timeframe for the moratoria, (2) add more flexibility to the standard if it is determined that 6 months is too long, and (3) give the provider community an opportunity to comment prior to its effective date. Another commenter stated that a moratorium is a drastic remedy that should only be used when CMS can clearly articulate the basis for imposing such an extreme measure. CMS must, in such cases, publish: (1) The data it used to determine a moratorium was necessary, (2) the steps it will take to resolve the issues that gave rise to the need for the moratorium, and (3) when it expects to lift the suspension in new enrollments.

Response: We believe that the rule as proposed directly addressed the timeframe, standards, and process for imposing, explaining the rationale for, and lifting an enrollment moratorium; because we received multiple related comments, this response should be read in conjunction with the discussion of those comments. The ACA gives the Secretary broad authority to impose a temporary moratorium on the enrollment of new providers and suppliers if the Secretary determines that a moratorium is necessary to prevent fraud, waste or abuse in Medicare, Medicaid or CHIP. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in 6-month increments should the Secretary determine that the moratorium was still needed. The 6-month duration was proposed in the NPRM because it was sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address. The proposed rule also included criteria for when the Secretary would consider imposition of a temporary enrollment moratorium, and the circumstances under which such a temporary enrollment moratorium would be lifted. The proposed rule also indicated that we would announce the implementation of a moratorium at any time, that the announcement would be made in the **Federal Register**, and that the announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply.

Comment: A commenter stated that advance public notice in the **Federal Register** of a moratorium should be given. The commenter recognized that this may lead to a rush to apply prior to the effective date, but stated that this could be fixed by limiting the length of time for the advance notice to 30–60 days.

Response: A temporary moratorium on enrollment is an action that will only be used if necessary to fight fraud, waste or abuse in Medicare, Medicaid, or CHIP. Moratoria will be imposed only if based on detailed information indicating a problem that can be addressed through a temporary enrollment moratorium. Although not required by the ACA to do so, we will announce the imposition of a moratorium in the **Federal Register**. The announcement would explain in detail the rationale for the moratorium and the rationale for the geographic area(s) in which it would apply. We will not be providing advance notice of any planned moratorium as such a notice would likely cause a rush of enrollments of the type posing the problem that would be addressed by the moratorium.

Comment: Several commenters stated that applying a moratorium to providers whose enrollment applications are pending would be unfair and could—in light of the efforts and cost the provider incurred in attempting to enroll—prove financially harmful. They requested that CMS limit moratoria to new applications, not those already submitted. Another commenter requested that the moratorium not apply to applications submitted prior to public notice of the moratorium being given in the **Federal Register**. Another commenter recommended that CMS explain: (1) What will happen to an application submitted by a new provider when CMS imposes a temporary moratorium, and (2) whether pending applications will be processed when a temporary moratorium is imposed or whether the application will be automatically denied using § 424.530(a)(10).

Response: In the NPRM, we indicated both in the preamble and the proposed regulations that an application to enroll in Medicare from a provider or supplier that is subject to a temporary enrollment moratorium would be denied. With regard to pending applications, we interpret the ACA as applying to pending applications. If a temporary enrollment moratorium is deemed necessary for any provider or supplier type, or for any geographic area, then all enrollment applications from unenrolled providers and suppliers of the type subject to the temporary enrollment moratorium or in the geographic area subject to the moratorium would be denied. However, we will not deny any enrollment for which the Medicare enrollment contractor has completed review of the application and has determined that the provider or supplier meets all the requirements for enrollment and all that remains is to assign appropriate billing number(s) and enter the provider or supplier into PECOS.

Comment: A commenter stated that in CMS's manual instructions, it describes

a provider enrollment fraud detection program for high-risk areas, but that this process is not discussed in the proposed rule. The commenter requested that CMS explain the nexus, if any, between this fraud detection program and the policy described in the temporary moratorium provisions contained in this proposed rule. The commenter also requested that CMS explain whether it will use data submitted or obtained from its contractors in determining whether to impose a temporary moratorium.

Response: We plan to revise our manuals to be consistent with the provisions of the final rule with comment period. We plan to use data from many sources in making a decision about imposing a temporary moratorium—including data from our contractors.

Comment: One commenter recommended that CMS: (1) Explain why it is not using section 1866(j)(3) of the Act, related to a provisional period of enhanced oversight for new providers and suppliers, in the process of establishing a temporary moratorium, and (2) publish a **Federal Register** Notice explaining its reasons and rationale for establishing a temporary moratorium for a provider or supplier.

Response: Section 1866(j)(3) of the Act is not a part of this final rule with comment period. Moreover, its provisions can be implemented by subregulatory instructions. We plan to implement the provisions in that fashion and in concert with the provisions of this rule and other CMS regulations governing program integrity. As stated in a response to a previous comment, we will publish a notice of imposition of a temporary enrollment moratorium in the **Federal Register**.

Comment: One commenter expressed concern that the language associated with the temporary moratoria provision: (1) Is vague, (2) does not provide sufficient information on the specific triggers that would cause CMS to suspect that a provider or group of providers is committing fraud, and (3) does not identify the situations in which the moratoria would be applied. The commenter feared that certain providers or suppliers could be prevented from providing services in a particular area without sufficient grounds and that patient access to care could be hindered in the process. The commenter recommended that CMS specifically define the parameters and triggers that CMS intends to use in imposing or enforcing a moratorium on the enrollment of new Medicare providers or suppliers. Another commenter expressed concern with the general nature of the proposed temporary moratoria provisions because it could lead to an abuse of discretion or arbitrary and capricious decision-making with little recourse beyond the internal review process. The commenter was also concerned with the proposed length of the moratorium, stating that a 6 month period: (1) Cannot be reasonably inferred from the Congress having authorized "temporary" moratoria, (2) cannot be considered "temporary," (3) would have significant consequences for new physicians interested in enrolling in the Medicare program, and (4) should not be extended because there is no congressional authority to do so.

Response: As stated previously, the Affordable Care Act gives the Secretary broad authority to impose a temporary moratorium. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in six month increments should the Secretary determine that the moratorium was still needed. The 6 month duration was proposed in the NPRM because it was sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address, and would afford us the opportunity to determine whether the circumstances warranting the imposition of a temporary enrollment moratorium have abated or we have implemented program safeguards to address program vulnerabilities. With regard to the temporary nature of a moratorium, we would note that the NPRM explicitly indicated that an initial moratorium would be for a 6 month period, not an indefinite period. Regarding the impact a temporary enrollment moratorium would have on beneficiary access to care, we stated in the NPRM that we will assess Medicare and Medicaid beneficiaries' and CHIP participants access' to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. With regard to extending moratoria, we would note that, as stated previously, the Secretary has broad authority to impose a moratorium. The statute confers on the Secretary the responsibility and authority to make the judgment about the need for moratoria—whether initial or an extension—if the circumstances requiring the moratorium are still present.

Comment: A commenter stated that CMS failed to outline the criteria it will use to make the determination that a moratorium is to be extended.

Response: We would not impose a temporary enrollment moratorium without an adequate rationale. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will discuss the issues associated with the decision to impose a temporary enrollment moratorium in a public notice in the **Federal Register**.

In the NPRM, we listed some examples of circumstances that could lead to the imposition of a temporary enrollment moratorium in situations where: (1) CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse. We also included in the NPRM the reasons a temporary enrollment moratorium could be lifted. The decision to extend a moratorium would be based on the proposals in the NPRM and would take into account the extent to which the conditions necessitating the moratorium were still present.

Comment: A commenter requested clarification regarding the term "geographic area" as it is used in proposed § 424.530(a)(10).

Response: The geographic area referred to in § 424.530(a)(10) is the region that is under a temporary enrollment moratorium. For example, this may constitute a county, a number of counties, state, a number of states, regions, or MSAs.

Comment: A commenter expressed support for CMS's proposal to impose a temporary moratorium on the enrollment of new providers or provider types in a geographic location to prevent fraud and abuse. However, the commenter urged CMS to ensure that such moratoria do not prevent health care providers in the geographic

location from enrolling as an ordering/referring provider, as a moratorium may impair these practitioners from providing Medicare beneficiaries with needed care.

Response: We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. As a part of this assurance, we would consider the implications of a temporary enrollment moratorium for physicians and other eligible professionals who order and refer services for Medicare. However, enrollment moratoria imposed on provider types will not distinguish between the enrollment purpose, that is, enrollment for the right to bill Medicare versus enrollment solely to order and refer, unless otherwise specified in the **Federal Register**. As stated previously, the notice in the **Federal Register** will both discuss the issues associated such the decision, and identify the provider types subject to the temporary enrollment moratoria. We believe the rationale that supports a decision to put a temporary enrollment moratorium in place for those who bill Medicare should extend to those same types of providers who seek to enroll to order and refer. In addition, the enrollment process solely to order and refer was established by us for those provider types that do not typically enroll in Medicare, such as dentists, other government agency employees (such as the Department of Veterans Affairs), and pediatricians. Therefore, it will be highly unlikely that those who were seeking to enroll in order to bill Medicare will similarly seek to enroll solely to order and refer. Regarding the impact a temporary enrollment moratorium may have on beneficiary access to needed care, we stated in the NPRM that we will assess Medicare beneficiary access to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply.

Comment: A commenter supported CMS's statement in the preamble to the proposed rule that a moratorium shall not apply to a change of practice location or to changes of ownership of existing providers or suppliers.

Response: We agree and plan to finalize these provisions.

Comment: A commenter recommended that CMS establish a temporary moratorium on the enrollment of slide preparation Facilities, since these organizations are not authorized by the Congress to enroll in or bill the Medicare program.

Response: It would be premature to identify in this rule any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**.

Comment: A commenter recommended that CMS develop and implement a regulatory-defined process to utilize when determining whether or not to mandate a moratorium. The process should effectively prevent any negative impact in quality of and access to care for Medicare beneficiaries or Medicaid program enrollees.

Response: We would consider a number of factors in deciding whether to impose a temporary enrollment moratorium. These are spelled out in the proposed rule and include: situations where: (1) CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse.

As mentioned elsewhere, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter requested clarification as to the mechanism—for instance, via the **Federal Register**—by which it will announce the lifting of a temporary moratorium.

Response: We will announce the imposition of any temporary enrollment moratorium via a notice published in the **Federal Register**. We would also provide notice on our Web sites, listservs, and through open door forums. Similarly, we would provide notice of the lifting of a moratorium in the **Federal Register**. We would also provide notice on our Web sites, listservs, and through open door forums.

Comment: A commenter mentioned that while the preamble of the proposed rule states that CMS will announce a moratorium in the **Federal Register**, the regulation text does not include a reference to **Federal Register**. The commenter recommended that the regulation text match the preamble language.

Response: We agree. We will ensure that the regulation text matches the preamble and other portions of this document.

Comments: A commenter urged CMS to immediately impose the proposed 6 month moratorium on the new certification of HHAs and hospices in its final rule with comment period, stating that there is a clear relationship between rapid development of new home health and hospice providers and the growth in fraud, abuse and waste. The commenter added that this will allow some time for other initiatives and proposals in the proposed rule to reduce fraud and abuse before hundreds of more providers enter the already saturated home health and hospice programs. For home health, the commenter stated that the moratorium should be maintained until new home health conditions of participation (CoPs) are implemented by CMS and other protections against referral abuse can be implemented by the OIG. For hospices, the commenter recommended that the moratorium be maintained until standardized hospice quality measures and payment system reforms are implemented by CMS.

Response: It would be premature to identify any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium, or the circumstances necessitating such an action. Should it be necessary to impose a temporary enrollment moratorium on any provider or supplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**. We specified in the NPRM examples of why a moratorium would be imposed. "Revisions to the HHA Conditions of Participation" is not among the examples we cited for the reason that moratoria are focused on specific kinds of problems or areas, and are to be temporary.

Comments: A commenter requested that CMS clarify the process for timely notifying the State Medicaid agency of a moratorium imposition, and whether the process will include advance notice.

Response: We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future.

Comments: A commenter stated that while a temporary moratorium might be reasonable in some limited situations, CMS should make such decisions based on specialty, not on provider type; for instance, it would be inappropriate for all DMEPOS suppliers to be put under such a moratorium when fraud concerns do not include orthotists and prosthetists.

Response: The ACA gives the Secretary broad authority to impose a temporary enrollment moratorium. We believe that circumstances could justify imposing a temporary enrollment moratorium on a category of providers or suppliers and not a subset within a provider or supplier type. As stated previously, the Secretary would explain the reasons for the moratorium in a **Federal Register** notice.

Comment: A commenter stated that the proposed policies need to be modified to accommodate newly enrolling physicians (and physicians establishing new practice locations) in cases where a moratorium relates to DMEPOS suppliers. In other words, if CMS or a State imposes a moratorium on DMEPOS suppliers, the moratorium should not apply to newly enrolling physicians (or physicians establishing a new practice location) who are now also required to enroll as DMEPOS suppliers if they wish to furnish DMEPOS to their own patients.

Response: In the example cited by the commenter, physicians enrolled as physicians to provide medical care would not be subject to a moratorium on DMEPOS suppliers. Only the new DMEPOS suppliers would be subject to the temporary enrollment moratorium. Physicians would be able to enroll in Medicare as physicians for the purpose of providing medical care (or ordering or referring medical care or services). The moratorium would only apply to the physician if he or she were newly applying to be a DMEPOS supplier in the geographic area covered by the moratorium.

Comment: A commenter suggested that CMS specify that a moratorium will not be imposed unless: (1) There is significant risk of widespread fraud, waste, or abuse in a specified and discrete geographic region, and (2) clear and documented agency analysis showing that the moratorium will not exacerbate health disparities or create additional barriers for underserved communities. Also, CMS should include greater specificity as to what conditions would warrant the imposition of a moratorium and what factors would be considered to ensure that the harm does not outweigh the benefit and will not have a disparate adverse impact on racially and ethnically diverse beneficiaries and physicians.

Response: We appreciate the concerns expressed by the commenter and we are also concerned about the issues of access and disparities. As mentioned previously, we indicated in the proposed rule that prior to imposing a temporary enrollment moratorium we will assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which a moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. CMS and the States take the assurance of adequate access seriously. We do not intend to impose a moratorium that would impede access to needed services.

Comment: A commenter expressed concern that CMS's proposed standards for implementing a temporary moratorium on new enrollment of potentially high risk providers and suppliers is too broad, and that CMS could impose a moratorium on new enrollment of all DMEPOS suppliers, even though only a subset of suppliers or a particular region or State poses a high risk of fraud. CMS should specify that it will narrowly limit the moratoria to those provider types or those narrow geographic regions that generate the fraud concerns. In particular, the commenter stated that community pharmacies face the danger that, in the midst of preparing to open up, CMS will impose a moratorium. The commenter urged that the expansion of an existing community pharmacy DMEPOS supplier does not pose a fraud risk and such an expansion should not be subject to a possible moratorium. Another commenter stated that CMS should adopt a more targeted approach to moratoria that takes other relevant factors into consideration, such as the history or trend in proven fraud and/or abusive practices for specific types or categories of providers or suppliers. The commenter believes that painting all providers and suppliers in a particular geographic area with the same broad brush is too extreme a measure, and that CMS should not use geography, by itself, as a determining factor in imposing a temporary enrollment moratorium on all providers and suppliers.

Response: As stated elsewhere in this document, we will publish a notice in the **Federal Register** announcing imposition of a temporary enrollment moratorium. This notice would contain a discussion of the factors associated with the moratorium. Although there are clear differences in the levels of fraud in different geographic areas of the United States, geography by itself without any indication of a risk of fraud, waste or abuse would not be a cause for a moratorium. Community pharmacies generally enroll in Medicare as roster billers for purposes of immunizations, and as such are listed in the limited risk level. DMEPOS suppliers that are owned by a community pharmacy are enrolled in Medicare as DMEPOS suppliers and are subject to the supplier standards for DMEPOS suppliers (except accreditation under certain circumstances). If we, on behalf of the Secretary, determine that a moratorium is needed for any particular provider or supplier type or geographic area or both, we would publish our rationale for the moratorium in our **Federal Register** notice. Decisions to impose a temporary enrollment moratorium would be made based on presenting circumstances. It would not be appropriate to exclude any provider or supplier category, for example, DMEPOS suppliers owned by community pharmacies, from being subject to a moratorium if the circumstances warrant the imposition of a temporary enrollment moratorium.

Comment: Several commenters recommended that CMS also be permitted to lift a moratorium if the Secretary of HHS declares a public health emergency in an area.

Response: The ACA gives the Secretary broad authority to impose temporary enrollment moratoria as a means to combat fraud, waste or abuse. The Secretary has considerable discretion to consider all aspects of the impact of a possible temporary moratorium. In the NPRM we proposed that the Secretary may lift a moratorium in the following three circumstances: (1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, (2) circumstances warranting imposition of moratorium have abated or we have implemented safeguards to address the issue that was the cause of such moratorium, or (3) in the judgment of the Secretary, the moratorium is no

longer needed. Based on the comments received in response to the NPRM, and consistent with the broad authority provided to the Secretary in the Affordable Care Act, we have decided to add a public health emergency declared by the Secretary under section 319 of the Public Health Service Act to the list of circumstances the Secretary could cite in lifting a moratorium. We would closely evaluate these circumstances in the decision to continue a temporary enrollment moratorium.

Comment: A commenter suggested that CMS include the restrictions listed in the preamble regarding temporary moratoria in the regulation text at § 424.570.

Response: It is unclear which provisions included in the preamble of the NPRM are of concern to the commenter. However, we will include any provisions dealing with imposition of temporary enrollment moratoria at § 424.570.

Comment: A commenter asserted that new § 424.570 is inconsistent with the DMEPOS competitive bidding program. Under competitive bidding, a company might win a contract in a competitive bidding area (CBA) where a moratorium exists. If so, the company could not alter its geographic locations to best serve the CBA. The commenter requested that CMS in the final rule with comment period carefully delineate how the competitive bidding program and the proposed temporary moratoria requirements will intersect.

Response: All winners of DMEPOS competitive bidding contracts are required to be enrolled in Medicare as a condition of their contract. As a result, these suppliers would not likely be subject to a moratorium on enrollment after they were awarded a contract, as they would already be enrolled. However, in a situation where a competitive bid winner applied to expand to a new practice location, the new location would need to be enrolled in Medicare. If a moratorium were imposed on DMEPOS suppliers in the area where the competitive bid winner was attempting to enroll a new practice location, the application would in all likelihood be denied based on the existence of a moratorium.

Comment: The same commenter also suggested that: (1) Suppliers with 10 or more provider transaction account numbers (PTANs) be exempt from § 424.570 and (2) CMS allow exceptions for bona fide acquisitions of assets belonging to an existing provider in the area for the protection of the beneficiaries served by the selling provider.

Response: We will be applying the provisions of this rule to all enrolled physicians, individual practitioners, providers and suppliers regardless of the number of PTANs. In addition, as stated in the NPRM, changes in ownership are not subject to moratoria. Moreover, the provisions of this rule do not address the conditions under which a provider or supplier can complete a bona fide acquisition of assets.

Comment: Several commenters stated that new locations of enrolled suppliers should not be subject to a moratorium. Existing suppliers with no history of fraud should not be constrained in their ability to adjust their businesses to best meet the needs of beneficiaries; indeed, beneficiary access could be impaired if new locations were affected by a moratorium. Another commenter stated that applying a moratorium to a new location should only occur when the supplier has an objectively demonstrated history of fraud or for whom CMS has credible evidence of fraud.

Response: As mentioned elsewhere in this document, a temporary enrollment moratorium would not be imposed without adequate rationale. The decision to impose a temporary enrollment moratorium would not be made lightly and would only be pursued should one or more of the conditions for imposing a temporary moratoria exist—as described in the proposed rule. One factor for imposing a moratorium could be that—as stated in the NPRM—there are a disproportionate number of providers or suppliers relative to the number of beneficiaries. For example, currently enrolled providers and suppliers that are trying to enroll in or establish new practice locations in areas subject to a moratorium that has been imposed because there is a disproportionate number of a particular provider category relative to beneficiaries, should not be exempt from the moratorium.

Comment: A commenter stated that given that the intensity of a Certificate of Need program is designed to limit the number of providers to match beneficiary need, an exception to a temporary moratorium should be granted in the presence of such a program. Another commenter agreed that an exemption to the moratorium should be given if the State has a Certificate of Need program and the State determines that there is a need for additional providers. Several commenters also recommended exceptions to a moratorium when a provider is establishing a branch location within its geographic service area. Branch locations are subject to the oversight of the established parent location and operate under the same Medicare provider number. Another commenter stated that the addition of a branch office to an HHA is not the equivalent of "establishing a new practice location."

Response: We have decided not to provide a link to State CON programs because these programs vary in effectiveness and are subject to different standards, coverage and regulations and are not focused on fraud, waste or abuse prevention as would be a temporary enrollment moratorium that is authorized in the ACA. To provide an exemption in States with CON programs would require considerable effort to assure that all provider types are afforded due process and equal treatment. Accordingly, we did not propose an exemption from temporary enrollment moratoria in States with CON programs. We plan to take into account the impact a CON has on provider supply and beneficiary access when deciding to impose a moratorium. Regarding the HHA branch offices, we note that the extent to which the branch office is subject to a moratorium depends on whether the branch office is to be enrolled separately.

Comment: A commenter stated that the proposal to allow unlimited 6 month extensions without thorough documentation of supporting data hardly makes the moratoria temporary and could pose a significant risk to access to quality care for Medicare beneficiaries.

Response: The ACA gives the Secretary broad authority to impose a temporary moratorium on the enrollment of new providers and suppliers if the Secretary determines that a moratorium is necessary to prevent fraud, waste or abuse in Medicare, Medicaid or CHIP. The statute did not provide a specific time period for the duration of a moratorium. After considerable discussion within CMS and HHS, the proposed rule was published proposing that an initial temporary enrollment moratorium would be imposed for a period of 6 months, with possible extensions in 6 month increments should the Secretary determine that the moratorium was still needed. We proposed the 6 month duration because it would be sufficiently long to enable an assessment of its impact on the circumstances that the moratorium was designed to address, and would afford us the opportunity to determine whether the circumstances warranting the imposition of a temporary enrollment moratorium have abated or whether we have implemented program

safeguards to address program vulnerabilities. The 6 month period would also afford the Secretary reasonable opportunity to determine whether the moratorium was no longer needed. With regard to the temporary nature of a moratorium, we would note that the NPRM explicitly indicated that an initial moratorium would be for a 6 month period, not an indefinite period. Regarding the impact a temporary enrollment moratorium would have on beneficiary access to needed care, we stated in the NPRM that we will assess Medicare beneficiary access to the types of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We take seriously our responsibility to assure that all Medicare beneficiaries have access to the services and supplies they need. With regard to extending moratoria, the statute confers on the Secretary the responsibility and authority to make the judgment about the need for moratoria—whether initial or an extension—if the circumstances requiring the moratorium are still present.

Comment: A commenter stated that as part of the implementation of a temporary moratorium and any extension thereof, CMS should publish data and research that support their decision to impose the moratorium. The data should be thorough and indicate the "actual increased" risk rather than perceived risk for fraud and abuse, in addition to supportive material data. Another commenter added that CMS should ensure that beneficiary access is not curtailed in an area where a moratorium is imposed.

Response: As stated earlier, the ACA gives the Secretary broad authority to impose temporary enrollment moratoria when necessary to prevent or combat fraud, waste or abuse. We will announce any temporary enrollment moratoria in the **Federal Register**, including a discussion of the issues associated with the decision to impose a temporary enrollment moratorium. We are concerned about the effect imposition of a temporary enrollment moratorium would have on beneficiary access, and would consider access to care as one possible factor related to imposition of a moratorium. The ACA specifically mentions access to Medicaid services as a reason that States should consider in making decisions to implement moratoria.

Comment: A commenter stated that the proposed rule should be amended to state that a moratorium does not apply to instances where the new provider is a result of a merger, change of ownership, or consolidation. Also, the fact that the moratorium would not apply where there is a change in practice location should be stated directly in the rule.

Response: We agree. All of these instances are addressed in the final rule with comment period.

Comment: A commenter requested that FQHCs be exempt from any geographical moratoria established by CMS. FQHCs are required to contract with State Medicaid and CHIP programs within certain specified locations. Inclusion in a moratorium would force these FQHCs to provide services without compensation.

Response: The ACA gives the Secretary authority to impose a moratorium when necessary to combat fraud waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on FQHCs, we would need to be able to do so. As mentioned previously, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: The commenter also stated that Indian and Tribal providers should be exempt from the temporary moratoria provisions, as their programs are not viable without third-party revenue (especially Medicare and Medicaid) and that a moratorium could impede the programs and harm access to care.

Response: The ACA gives the Secretary authority to impose a temporary enrollment moratorium when necessary to combat fraud, waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on Indian or Tribal providers, we would need to be able to do so. As mentioned previously, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed moratorium would adversely impact Medicaid beneficiaries' or CHIP participants' access to care, the State would not be required to comply with the moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter stated that the moratorium exceptions should be very limited. The commenter agreed with CMS's proposal for an exemption for health crisis situations related to, for example, a natural disaster. The commenter also recommended that exceptions should be granted in areas: (1) With active CON programs, (2) not being served by any provider or (3) where the provider(s) (other than the applicant for the exception) attest that they lack the capacity to meet current demand. Still, the commenter stated that exemptions should only be granted in such exceptional circumstances and not become a vehicle for routine circumvention of the moratorium.

Response: We agree with the intent of these comments. Temporary enrollment moratoria must be considered carefully and the reasons for their imposition must be clear. Prior to imposing a moratorium, we will consider a number of factors, such as, any potential effect on access to care for beneficiaries. CON programs are not factored in to CMS decisions regarding exceptions.

Comment: A commenter requested clarification as to whether the temporary moratoria provisions apply to managed care organizations.

Response: This provision does not apply to Medicaid managed care entities. Medicaid risk based managed care is subject to contracts between States and the managed care entities, and the States rely upon those contracts to ensure that Medicaid beneficiaries have access to providers and a choice of networks within the managed care programs the State maintains. We would not impose moratoria on managed care programs that could restrict the ability of States to ensure beneficiary access and choice.

Comment: A commenter stated that an enrollment moratorium should not apply to publicly traded companies, since CMS can look to the board of directors and similar organizational structures to provide appropriate oversight and accountability. Moreover, after a moratorium is lifted, publicly traded providers and suppliers that were subject to the moratorium should not be lifted to a high screening level; to do so would be inconsistent with CMS's own statements in the preamble that publicly traded providers and suppliers pose a limited risk.

Response: It would be inappropriate for us to identify any one provider or supplier characteristic, such as being publicly traded, as a basis for not being subject to a temporary enrollment moratorium. In addition, as noted below, in the screening portion of this final rule with comment period, we have decided not to draw a distinction between publicly traded and other providers and suppliers. Should there ever be a reason to impose a temporary enrollment moratorium in a geographic area or on a particular provider or supplier category; we would need to be able to do so. We cannot state that there will never be circumstances that warrant imposition of a temporary enrollment moratorium that will affect providers and suppliers that are publicly traded or that these providers and suppliers will never be subject to a temporary enrollment moratorium. We have in response to many comments on this issue, has decided to eliminate the distinction between publicly traded and non-publicly traded status as a determinant of assignment of provider or supplier types to risk levels. Temporary enrollment moratoria will not be imposed without adequate rationale for how the moratorium would address fraud, waste and abuse in Medicare, Medicaid and CHIP. Such moratoria would be imposed based on careful analysis and assessment of circumstances that are present.

Comment: CMS, according to one commenter, states repeatedly that the application of the temporary moratoria could be to either a particular provider or supplier type or a particular geographic area. The commenter urged CMS to reconsider whether it is appropriate to ever apply moratoria on particular geographic areas for all provider and supplier types—such as physicians, whom CMS assigns to the limited level of screening. The commenter believes that physicians should be exempt from geographic provider/supplier enrollment moratoria.

Response: We would not likely impose a temporary enrollment moratorium on all provider and supplier types in a particular geographic area particularly given the potential impact on beneficiary access. However, if circumstances were to be such that a temporary enrollment moratorium in a particular geographic area should apply to all provider and supplier types in that area, we would need to be able to impose such a moratorium. As stated elsewhere in this document, we would publish notice of any moratorium and would include in the notice the rationale for the imposition of a temporary enrollment moratorium. Also, as stated earlier, we would consider access issues as well.

Comment: A commenter urged that the final rule with comment period be revised to clarify that it is only to be used as an option of last resort, when less onerous enforcement efforts have failed to reduce program abuse by a significant number of providers or suppliers of the same type. The commenter also stated that it should be imposed only if there is irrefutable evidence of fraud, waste or program abuse by a significant portion of the population of providers that are targeted by the moratorium.

Response: The ACA gives the Secretary broad authority to impose temporary enrollment moratoria in instances where the Secretary has determined that the moratorium is necessary to combat fraud, waste or abuse in Medicare, Medicaid or CHIP. A moratorium would not be imposed without adequate justification. We would announce in the **Federal Register** the imposition of any temporary enrollment moratorium and would include a discussion of the issues associated with the decision to impose the temporary enrollment moratorium.

In the NPRM, we did list circumstances that could lead to the imposition of a temporary enrollment moratorium in situations where: (1) Based on our review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as when a highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries or a rapid increase in enrollment applications within a category is associated with a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both, (2) a State has imposed a temporary enrollment moratorium, or (3) CMS in consultation with the Department of HHS Office of Inspector General or the Department of Justice or both identifies either or both a particular provider or supplier type or a particular geographic area as having significant potential for fraud, waste, or abuse. We also included in the NPRM the reasons a temporary enrollment moratorium could be lifted. The decision to extend a moratorium would be based on the proposals in the NPRM and would take into account the extent to which the conditions necessitating the moratorium were still present.

Comment: A commenter stated that CMS and Medicaid should be permitted to extend a temporary moratorium by a maximum of one additional 6 month period. Twelve months is more than a sufficient amount of time for CMS to consider additional programmatic initiatives. The commenter added that CMS's statement in the preamble that it "would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the moratorium would apply" before imposing a moratorium, should be included in the regulatory text.

Response: We reserve the option to extend a temporary moratorium if circumstances warrant the continuation. We do not want to limit our ability to keep a temporary enrollment moratorium in place if necessary. Conversely, if the Secretary determines that a moratorium is no longer needed, consistent with the provisions of the proposed rule, the moratorium could be lifted at any time. We have modified the regulation text to make this clarification. We will consider safeguards for beneficiary access related to the imposition of an enrollment moratorium at § 424.570.

Comment: A commenter stated that CMS should exempt new practice locations from the moratoria and should limit the moratorium to newly-enrolling providers and suppliers.

Response: Currently enrolled providers and suppliers that are trying to establish additional new practice locations as a means to enroll in areas that are subject to a moratorium, and the provider is of the type for which the temporary enrollment moratorium is imposed, should not be exempt from the moratorium. However, if an enrolled provider or supplier is merely changing its practice location from a current location to a new location—not an additional new location—then that new location would not be subject to a temporary enrollment moratorium.

Comment: A commenter stated that CMS should establish an administrative appeals mechanism to address adverse determinations based on the imposition of a temporary moratorium that would also permit providers and suppliers to question whether CMS has an appropriate statutory or evidentiary basis for imposing a temporary moratorium.

Response: The ACA specifies that there is no judicial review under sections 1869 and 1878 of the Act, or otherwise of the decision to impose a temporary enrollment moratorium

However, as stated in the NPRM, we note that a provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium.

Comment: One commenter stated that CMS should allow exceptions to the moratorium, such as: (1) A low ratio of the provider or supplier type to the number of beneficiaries in the targeted area, (2) pandemics and other threats to beneficiary health that would be served by the provider or supplier type, and (3) other circumstances as the Secretary or the State Medicaid director determine are in the best interests of the program.

Response: As discussed previously, the ACA gives the Secretary hroad authority to impose temporary enrollment moratoria. We also stated earlier that we listed in the NPRM circumstances that could lead to the imposition of a temporary enrollment moratorium in situations. We also indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access issues. And we indicated that if a State has determined that compliance with a Medicare imposed temporary enrollment moratorium would adversely impact Medicaid beneficiaries', or CHIP participants' access to care, the State would not be required to comply with the temporary enrollment moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter believes that CMS moratoria authority was open-ended to the point where CMS could, towards the end of a fiscal year, announce the suspension of provider enrollment in a variety of categories not to stem fraud and abuse, but rather to achieve some budgetary goal of reducing Medicare expenditures. The commenter requested that CMS clarify: (1) Who will decide what constitutes a highly disproportionate number of providers relative to the number of beneficiaries, (2) the standards that will be used to determine the number of providers necessary relative to the number of beneficiaries, and (3) whether this is a de facto return of the certificate of need process.

Response: We proposed and sought comments on factors that would have to be in place to impose a temporary enrollment moratorium, including identifiable trends in CMS data, State imposition of a moratoria, or consultation with the Office of Inspector General or the Department of Justice. The ACA requires that any moratorium imposed be implemented to reduce fraud, waste and abuse in the Medicare, Medicaid and CHIP programs. Additionally, we will not deny any enrollment for which the Medicare enrollment contractor has completed review of the application and has determined that the provider or supplier meets all the requirements for enrollment and all that remains is to assign appropriate billing number(s) and enter the provider or supplier into PECOS. Actively enrolled providers and suppliers will still be reimbursed for claims for services that are provided, and reimbursement would be at levels preceding the moratoria. The process for imposing a moratorium in this rule provides no opportunity for us to use the temporary enrollment moratoria to stop payments to enrolled providers and suppliers, and there is no intention for us to use temporary moratoria for purposes other than the ones authorized under the ACA.

Additionally, as stated previously, we would provide notice in the **Federal Register** of the imposition of a temporary enrollment moratorium and would include a discussion of the issues associated with the decision to impose a temporary enrollment moratorium. We will decide what constitutes a disproportionate number of providers relative to beneficiaries. We indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the temporary enrollment moratorium would apply. As a part of this process, we would examine the levels of providers in a given area and make a judgment about whether any temporary enrollment moratorium would adversely affect the delivery of needed services to beneficiaries. Regarding Certificate of Need processes, we would note that a number of States use the CON process. We have stated elsewhere in this document that we have not linked this proposed rule to the CON process. The CON programs vary in effectiveness and coverage and are subject to different standards and regulations. If there were a need to impose a temporary enrollment moratorium in any part of a State that has a CON requirement, we would impose the temporary enrollment moratorium in that part of the State, as needed.

Comment: A commenter stated that CMS should exclude from any moratoria those providers and suppliers: (1) Assigned to the limited level of screening, and (2) that have completed and passed a State licensure process. Another commenter urged that a moratorium be applied only to providers included within the moderate or high screening levels, and then only after: (1) Appropriate appeals measures have been established, and (2) CMS has addressed any beneficiary access to care issues.

Response: The ACA provides that the Secretary can impose a moratorium if she decides that it is necessary to combat fraud, waste or abuse. Accordingly the decision to impose a temporary enrollment moratorium will be based on a variety of factors, including the potential risk of fraud in the Medicare program that could be posed by a particular category of provider or supplier in a specific geographic area. The ACA gives the Secretary authority to impose a moratorium when necessary to combat fraud waste and abuse in Medicare, Medicaid, or CHIP. Should there ever be a reason to impose a temporary enrollment moratorium on any category of providers or suppliers, we would need to be able to do so—regardless of the screening level to which they were assigned as part of the provider and supplier screening process described in this regulation. We cannot state that providers and suppliers in the "limited" screening level will never be subject to a temporary enrollment moratorium. Nor are we prepared to state that providers or suppliers that are licensed would never be subject to a temporary enrollment moratorium. With regard to access to care, we indicated in the NPRM that prior to imposing a temporary enrollment moratorium we would assess Medicare beneficiary access to the type(s) of services that are furnished by the provider or supplier type and/or within the geographic area to which the temporary enrollment moratorium would apply. We also indicated that if a State has determined that compliance with a Medicare imposed temporary enrollment moratorium would adversely impact Medicaid beneficiaries', or CHIP participants' access to care, the State would not be required to comply with the temporary enrollment moratorium. We and the States take the assurance of adequate access seriously.

Comment: A commenter stated that while the preamble mentions that advanced notice of a moratorium will be given, this is not specified in the regulation text. The commenter stated that the text should be amended to reflect the advanced notice requirement.

Response: The preamble to the proposed rule says that we will announce the imposition of a temporary enrollment moratorium in the **Federal Register**. The preamble does not say we will give advance notice. We have stated in response to other comments that we do not think we should provide advance notice as this may foster an increase in applications for enrollment in an

attempt to circumvent the intent of the temporary enrollment moratorium. Accordingly, we did not include any language about advance notice in the regulation text.

Comment: A commenter requested clarification as to what the term "significant potential for fraud" means in the context of the moratorium and the datasets that will be used to determine whether such a trend exists.

Response: We offered examples in the NPRM of the kinds of circumstances that might warrant imposition of a temporary enrollment moratorium. We plan to draw on data and information from many sources in coming to a decision about imposition of temporary enrollment moratoria—including existing CMS claims and enrollment data as well as other public data as well as data from our contractors or from law enforcement entities.

Comment: A commenter noted that CMS proposes to allow a Medicare enrollment moratorium where a State Medicaid program has imposed a moratorium on a group of providers who are also eligible to enroll in Medicare. The commenter stated that the proposal does not clarify whether CMS intends for such a moratorium to apply only to those providers within the affected State or whether that moratorium could apply nationwide in the event that the moratorium pertains to provider type. The commenter believes that for a State-imposed moratorium to have such a drastic effect across the country without evidence of a nationwide problem would be an overly broad and unnecessary imposition of CMS authority, and urged CMS to craft this provision more narrowly.

Response: We agree that imposing a moratorium on a national level based on one State's action in its State would be an unnecessarily broad action for us to take. The intent of that provision in the NPRM was to afford Medicare the option to adopt a State moratorium in a State or part of a State if appropriate.

Comment: A commenter stated that in the case of a moratorium, CMS and the States should explain their actions and provide an opportunity for notice and comment.

Response: We have said that we plan to provide notice of imposition of a temporary enrollment moratorium in the **Federal Register**, explaining the rationale for the imposition. We will not be providing an opportunity for comment prior to the imposition of a temporary enrollment moratorium, because it is not a rulemaking effort. Moreover, we think that providing advance notice of a temporary enrollment moratorium might foster a spike in enrollment applications from providers or suppliers that would be subject to the moratorium. If we determine that a temporary enrollment moratorium is needed, we would not want to provide opportunities for providers and suppliers to circumvent the moratorium's purpose.

Comment: A commenter recommended that CMS impose a temporary moratorium nationally on any Medicare-certified HHAs. As an alternative, the commenter suggested a moratorium in any State without either HHA licensure or a certificate of need, or in any State where the growth in new HHAs in the most recent 4 years has exceeded 15 percent.

Response: At this time, we are not contemplating the imposition of national moratoria. Moreover, it would be premature to identify any provider or supplier type that might be subject to imposition of a temporary enrollment moratorium. Should it be necessary to impose a temporary enrollment moratorium on any provider or snpplier type, we will explain the reasons for the temporary enrollment moratorium in a public notice in the **Federal Register**.

Comment: One commenter stated that while they are in agreement with the proposal that State Medicaid agencies should have the authority to impose temporary moratoria on the enrollment of new providers or impose numerical caps or other limits on the providers assigned to the high screening level by the Secretary, the State Medicaid agency should also be allowed the discretion to identify providers that are high risk by State standards.

Response: We agree that the State Medicaid agency has the discretion to identify providers that are high risk by State standards. However, section 1902(kk)(4)(B) of the Act explicitly states that the designation of "high risk" providers for purposes of this provision must be made by the Secretary. Thus, we are finalizing the requirement that when a State Medicaid agency identifies a category of providers that are high risk of fraud, waste or abuse by State standards, the State must seek our concurrence with that assignment prior to imposing any type of moratoria, numerical caps or other limits on the enrollment of these providers.

Comment: One commenter requested that the rule be clarified to allow a State to complete any provider enrollment initiated prior to a Federally imposed moratorium.

Response: If a moratorium is deemed necessary, then we believe that all unenrolled providers should be subject to the moratorium. However, we would not require the State to deny any enrollment for which the State has completed its review of the enrollment application and has made a determination that the provider meets all requirements for enrollment.

Comment: A few commenters requested additional information regarding the process that should be used by State Medicaid agencies to notify CMS that imposition of a temporary moratorium would adversely impact beneficiaries' access to medical assistance, including the documentation that will be required and the standards CMS will use for its review.

Response: We believe that additional information regarding the operational processes that should be used by States regarding temporary moratorium are more appropriately addressed in subregulatory guidance. We will be issuing subregulatory guidance to assist States with the operational impact of implementing this provision in the near future.

Comment: Regarding State "identification" of providers with a "significant potential for fraud, waste or abuse," one commenter asked that documentation of the significant risk be reqnired, as well as a description of the rationale used to arrive at numerical caps or other limits on enrollment of that provider type.

Response: Consistent with section 1902(kk)(4)(B) of the Act, when a State Medicaid agency identifies a category of providers that is high risk by State standards, the State must seek our concurrence with that designation prior to imposing any type of moratorium, numerical cap or other limit on the enrollment of these providers. We will expect the State to provide rationale and justification for assigning providers to the high screening level when seeking our concurrence. We will be issuing subregulatory guidance to assist States with the operational aspect of implementing this provision in the near future. We agree a temporary enrollment moratorium should be imposed only with adequate rationale. A temporary enrollment moratorium on any category of provider that a State identifies as posing a significant potential for fraud, waste, or abuse, should be supported by adequate rationale to justify the imposition of a temporary moratorium, nnmerical caps or other limits on enrollment of that provider type.

Comment: One commenter requested that CMS add an exception where the State has other measures in place that adequately control for the potential fraud, waste, and abuse that is the basis for the proposed moratorium.

Response: The ACA does not allow us to grant such an exception to States even when the State has other fraud controls in place. Additionally, we believe this additional program integrity safeguard is necessary to prevent loss to Medicare, Medicaid and CHIP programs when existing safeguards have not prevented an emergent trend in fraudulent, *wasteful*, or abusive practices. We believe the authority to impose temporary enrollment moratorium when appropriate will be a useful tool for both CMS and the States.

Comment: Several commenters requested clarification regarding whether this requirement applies to Medicaid managed care. These commenters specifically asked CMS to provide an explicit exception to temporary moratoria for Medicaid managed care entities so to ensure that the adequacy of these plans' provider networks is not compromised and in turn, impede beneficiary access to care.

Response: As stated previously, this provision does not apply to Medicaid managed care entities. Medicaid risk based managed care is subject to contracts between States and the managed care entities, and the States rely upon those contracts to ensure that Medicaid beneficiaries have access to providers and a choice of networks within the managed care programs the State maintains. We would not impose moratoria on managed care programs that could restrict the ability of States to ensure beneficiary access and choice.

Comment: One commenter requested the development of a process for an individual provider exemption from a moratorium or, in the alternative, the establishment of a more focused process for imposing any necessary moratoria.

Response: As mentioned previously, we will take action to impose a temporary moratorium only if justified. Accordingly, the decision to impose a temporary enrollment moratorium will be based on the potential risk of fraud, waste or abuse in the Medicare or Medicaid programs.

Comment: A commenter stated that CMS, should it proceed with this proposed rule, must introduce much better controls to limit over-reaching and to assure providers due process rights. The commenter cited CMS's proposed ability to impose a temporary enrollment moratorium on potentially high risk providers and suppliers with no rights of judicial review of the agency's decision. The commenter stated that the absence of defined rights for orthotic and prosthetic suppliers in the proposed rule could, in some instances, appear to be a Federal "taking" without due process.

Response: As stated previously, we will provide a discussion of the factors for imposing a moratorium on a case by case basis when the notice of such a moratorium is published in the **Federal Register**. If a provider or supplier's billing privileges are denied due to the imposition of a temporary enrollment moratorium, the denial of billing privileges can be challenged administratively through the existing enrollment appeal procedures at 42 CFR part 498. Further, we disagree with the commenter's characterization of a temporary moratoria of newly-enrolling providers and suppliers as a Federal "taking."

4. Final Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Provisions

This final rule with comment period finalizes the provision of the proposed rule in regards to the temporary enrollment moratoria with the following exceptions:

In § 424.570, we modified our proposal as follows:

- Added language to clarify that we will fully assess the impact of a temporary enrollment moratorium would have on beneficiary access to services that will be subject to the temporary enrollment moratorium at § 424.570(a).
- Added language that specifies we will announce any temporary enrollment moratorium in a notice in the **Federal Register** that will include the rational for the imposition of the moratorium, the particular provider or supplier type or the establishment of new practice locations of a particular type in a particular geographic area at § 424.570(a).
- Added language to clarify that Medicare contractor will deny enrollment applications from a provider or supplier subject to a moratorium specified in paragraph (a) including providers and suppliers with pending enrollment applications, EXCEPT such applications that have been approved by the enrollment contractor before the imposition of a moratorium at § 424.530(a)(10).
- Added language that adopts a public commenter's proposal that the Secretary may lift a temporary enrollment moratorium in the event of a public health emergency in the affected geographic area at § 424.570(d).
- Added language that specifies we will publish notice of lifting the moratorium in the **Federal Register** at § 424.570(d).

D. Suspension of Payments

1. Medicare

a. Background

In section 6402(h) of the ACA, the Congress amended section 1862 of the Act by adding a new paragraph (o), under which the Secretary may suspend payments to a provider or supplier pending an investigation of a credible allegation of fraud unless the Secretary determines that there is good cause not to suspend payments. This section requires that the Secretary consult with the HHS OIG in determining whether there is a credible allegation of fraud against a provider or supplier. For purposes of this Medicare payment suspension regulation, we will refer to providers and suppliers collectively as "providers".

b. Previous Medicare Regulations

We have long been authorized to suspend payments in cases of suspected fraudulent activity. On December 2, 1996, we finalized regulations § 405.370 through § 405.379 that provides for suspension of payments to providers for several scenarios, including when we possess reliable information that fraud or willful misrepresentation exists. The rule provides that we may suspend payments to a provider in whole or in part based upon possession of reliable information that an overpayment or fraud or willful misrepresentation exists or that the payments to be made may not be correct, although additional evidence may be needed for a determination.

The existing rule provides that a suspension of payments is limited to 180 days, unless it meets one of several exceptions. A Medicare contractor may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information that serves as the basis for the suspension. Also, OIG or a law enforcement agency may request a one-time only extension for up to 180 additional days to complete its investigation in cases of fraud and willful misrepresentation. The rule provides that these time limits do not apply if the case has been referred to and is being considered by the OIG for administrative action, such as civil monetary penalties. We may also grant an extension beyond the 180 additional days if DOJ requests that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil actions. The DOJ extension is limited to the amount

of time needed to implement the criminal or civil proceedings.

c. Proposed Medicare Suspension of Payments Requirements

Section 6402(h) of the ACA requires that the Secretary consult with the OIG in determining whether there is a credible allegation of fraud against a provider. If a credible allegation of fraud exists, the Secretary may impose a suspension of payments pending an investigation of the allegations, unless the Secretary determines that there is good cause not to suspend payments. We proposed to revise § 405.370 to add a definition of what constitutes a "credible allegation of fraud," to include an allegation from any source, including but not limited to fraud hotline complaints, claims data mining, patterns identified through provider audits, civil False Claims Act, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. Many issues related to this definition will need to be determined on a case-by-case basis by looking at all the factors, circumstances and issues at hand. We continue to believe that CMS or its contractors must review all allegations, facts, and information carefully and act judiciously on a case-by-case basis when contemplating a payment suspension, mindful of the impact that payment suspension may have upon a provider.

We received the following comments:

Comment: We received numerous comments suggesting that the proposed definition of "credible allegation of fraud" was ambiguous and fails to detail a precise evidentiary standard that CMS and OIG will employ in determining if a payment suspension is warranted. Commenters were also concerned that including fraud hotline complaints as a source of allegations would inevitably lead to disingenuous allegations from competitors and/or disgruntled former employees that would lead to unjustified payment suspensions.

Response: We did not intend to detail a precise evidentiary standard in this definition; rather we intended to give examples of the typical sources of allegations of fraud and explain that assessing the reliability of an allegation is a process that will occur on a case-by-case basis. CMS and OIG fully understand the need to act judiciously when corroborating information and investigating allegations of fraud, especially when the source of the allegation is an anonymous fraud hotline complaint. The statutorily required consultation between CMS and the OIG prior to implementing a payment suspension will provide ample opportunity for the credibility of an allegation to be assessed and for a preliminary investigation into the allegation of fraud to occur sufficient to meet a reasonable evidentiary standard.

We additionally proposed modifying the existing § 405.370 to add a definition for "resolution of an investigation." The ACA provides for the suspension of payments pending the investigation of a credible allegation of fraud, and we believe that this provision necessitates defining when an investigation has concluded and the basis for the suspension of payments no longer exists. The definition proposed in the proposed rule and finalized here is that a resolution of an investigation occurs when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence. We solicited comments on an alternative definition of the term "resolution of an investigation" which is that it occurs when a legal action is initiated or the case is closed or dropped because of insufficient evidence to support the allegations of fraud. We did not receive any comments that specifically addressed a preference for either of these definitions.

We proposed modifying the existing § 405.371(a) to differentiate between suspensions based on either reliable information that an overpayment exists or that payments to be made may not be correct, and suspensions based upon a credible allegation of fraud. As required by the ACA, we proposed in this section that CMS or its contractor must consult with the OIG, and as appropriate, the Department of Justice (DOJ) in determining whether a credible allegation of fraud exists prior to suspending payments on the basis of alleged fraud.

We also proposed in accordance with the ACA that we retain discretion regarding whether or not to impose a suspension or continue a suspension, as there may be good cause not to suspend payments or not to continue to suspend payments to providers or suppliers in certain circumstances. We proposed to add a new § 405.371(b) to describe circumstances that may qualify as good cause not to suspend payments or not to continue to suspend payments despite credible allegations of fraud.

In paragraph (b)(1), we proposed a good cause exception based upon specific requests by law enforcement that CMS not suspend payments. There are numerous reasons for which law enforcement personnel might make such a request, including that imposing a payment suspension might alert a potential perpetrator to an investigation at an inopportune or particularly sensitive time, jeopardize an undercover investigation, or potentially expose whistleblowers or confidential sources.

In paragraph (b)(2), we proposed a good cause exception not to suspend payments if we determine that beneficiary access to necessary items or services may be jeopardized. We envision there may be scenarios in which a payment suspension to a provider might jeopardize a provider's ability to continue rendering services to Medicare beneficiaries whose access to items or services would be so jeopardized as to cause a danger to life or health.

In paragraph (b)(3) of the proposed rule, we proposed a good cause exception not to suspend payments if CMS determines that other available remedies implemented by or on behalf of CMS more effectively or quickly protect Medicare funds than would implementing a payment suspension. For example, law enforcement personnel might request that a court immediately enjoin potentially unlawful conduct or prevent the withdrawal, removal, transfer, disposal, or dissipation of assets, either or both of which might protect Medicare funds more fully or quickly than would imposition of a payment suspension.

More generally, in paragraph (b)(4) of the proposed rule, we proposed a good cause exception based upon a determination by us that a payment suspension or continuation of a payment suspension is not in the best interests of the Medicare program. We further proposed that we will conduct an evaluation of whether there is good cause not to continue a suspension every 180 days after the initiation of a suspension based on credible allegations of fraud. We believe that circumstances surrounding a specific case may change as an investigation progresses, and it may become in the best of interests of the Medicare program to terminate a payment suspension prior to the resolution of an investigation. As part of this ongoing evaluation, we will request a certification from the OIG or other law enforcement agency as to whether that agency continues to investigate the matter.

We considered additional specific circumstances and scenarios that may qualify as good cause not to continue a payment suspension prior to the resolution of an investigation, and solicited comments on this approach. For example, one scenario that we considered as additional good cause not to continue a suspension is when a

suspension has been in place for a specific length of time, such as 2 years or 3 years, and the investigation has not been resolved. We anticipated that on a case by case basis, we would evaluate the status of a particular investigation and the nature of the alleged fraud in determining whether keeping a payment suspension in effect beyond a certain length of time may not be in the best interests of the Medicare program. We chose not to propose specific language on duration in the regulatory text. However, we solicited comment on this approach.

Comment: Numerous commenters supported an additional good cause exception not to continue a payment suspension when the accompanying investigation continued beyond a certain length of time. Several commenters supported this exception, however most believe that 2 years or 3 years was much too long for a suspension to be in effect and the length of time associated with this good cause exception should be much shorter.

Response: We agree with the commenters who support the additional good cause exception not to continue a payment suspension when an investigation has continued beyond a certain length of time, in certain cases. We believe that 18 months is the appropriate timeframe for a good cause-based exception beyond which a payment suspension ought not continue except under certain limited circumstances. Therefore, good cause not to continue a payment suspension beyond 18 months shall be deemed to exist unless one of two specific criteria is met. The first of these criteria is if the case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties) or such administrative action is pending. The second of these criteria is if the Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal and/or civil actions or based on a pending criminal and/or civil action. We are adopting these two law enforcement specific scenarios that will serve as the criteria for extending a payment suspension beyond 18 months and are based upon the longstanding criteria for extending suspensions found in the Medicare payment suspension regulations.

We proposed modifying the existing § 405.372 to reflect the changes made in § 405.371 which divides the payment suspension authority into situations involving overpayments and situations involving allegations of fraud. In § 405.372(c) we clarify the subsequent action requirements to distinguish between suspensions based on credible allegations of fraud and those that are based on other factors, such as overpayments. For suspensions that are not based on credible allegations of fraud, CMS and its contractors will continue to take timely action to obtain additional information needed to make an overpayment determination and make all reasonable efforts to expedite the determination. Once the determination is made, notice of the determination will be given to the provider or supplier and the payment suspension will be terminated. If the payment suspension is based on credible allegations of fraud, CMS and its contractors will take subsequent action to determine if an overpayment exists or if the payments may be made, however the termination of the suspension and the issuance of a final determination notice to the provider or supplier may be delayed until resolution of the investigation. At the end of the fraud investigation, it is possible that the Medicare contractor will not have completed its overpayment determination, but will have reliable evidence of an overpayment or will have evidence that the payments to be made may not be correct. This typically occurs when a law enforcement investigation results in civil or criminal resolution prior to the Medicare contractor having had sufficient time to complete its overpayment determination. In such a situation, we would allow the suspension to continue as an overpayment suspension.

We proposed modifying the existing § 405.372(d) concerning the duration of suspension of payment. In § 405.372(d)(3) we except suspensions based on credible allegations of fraud from the established time limits specified in paragraphs (d)(1) and (d)(2). We believe the strict time constraints found in paragraphs (d)(1) and (d)(2) should only be applied to suspensions based on reliable information of an overpayment or where payments to be made may not be correct, both of which require a speedy overpayment determination. When credible allegations of fraud are present, we believe we should have the flexibility to maintain a suspension beyond these established time limits in order for an investigation to be completed or the matter to be resolved. However, we noted that by excepting suspensions based on credible allegations of fraud from these previously established timeframes, we do not intend to suspend payments to providers and suppliers indefinitely. We will be actively evaluating the progress of any investigation to determine if good cause exists to no longer continue the suspension of payments, as suspensions are designed to be a temporary measure. As part of this recurring evaluation, we will request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation.

We also proposed eliminating the two other existing scenarios in paragraph (d)(3) for extending payment suspensions beyond the time limits in paragraphs (d)(1) and (d)(2), which are when the OIG is considering administrative action such as civil monetary penalties and also when the DOJ requests an extension based on an ongoing investigation and the anticipated filing of criminal and/or civil actions. We have removed these two scenarios from the existing duration provisions in § 405.372(d), however we have added similar criteria for extending suspensions to the good cause criteria at § 405.371 (b)(3), based on these law enforcement scenarios.

Comment: We received numerous comments raising concern over the perceived lack of due process afforded to the provider community in this proposed rule and numerous commeuts suggesting that more attention needs to be paid to establishing clear criteria for suspensions and basic due process rights before implementing this provision. Commenters also pointed out that the ACA does not mandate a deadline for implementing this policy and commenters recommend we withdraw the suspension provision from the final rule with comment period and work to develop defined standards with meaningful due process protections.

Response: We believe that the proposed rule affords providers who have had their payments suspended based on credible allegations of fraud ample opportunity to submit information to us in the established rebuttal statement process to demonstrate their case for why a suspension is unjustified. We believe that the criteria for suspension of payments are clear. We reiterate that this authority will be exercised judiciously by CMS, in consultation with the OIG, and that only in the most egregious cases will payment suspensions last longer than the previously established timeframes for payment suspensions. We will not withdraw the suspension provision from the final rule with comment period as we believe the due process

protections are more than adequate and the evidentiary standards for payment suspensions cannot be more precisely defined.

Comment: A commenter suggested that the proposed rule lacks specificity around the required consultation between CMS and the OIG and the DOJ and asked which entity ultimately decides whether an allegation is credible and whether a unanimous determination is required.

Response: We retain the ultimate authority regarding whether or not a payment suspension will be implemented in a given case. The mechanics of the consultation between CMS and our law enforcement partners to determine the credibility of allegations will be detailed in a Memorandum of Understanding between the respective agencies and we do not believe it is appropriate to detail this process in the final rule with comment period.

Comment: A commenter questions why there is no defined time requirement for CMS to provide written notice of a suspension that was imposed without prior notice, similar to the time limits required of States in the Medicaid payment suspension rule.

Response: The Medicare and Medicaid payment suspension rules need not mirror each other in every respect. We have long suspended payments without prior notice to providers in cases of suspected fraud and have an established track record for providing written notice to providers as soon as is practicable after implementing a suspension. We do not believe it is necessary to impose a strictly defined time period for providing notice to providers who were suspended without prior notice based on credible allegations of fraud, and we do not believe that a 30, 60, or 90 day limit is necessary as in nearly all historical cases we have provided notice to providers well within these suggested time limits.

Comment: One commenter expressed concern over CMS treatment of payment suspensions in the cases of overpayments without credible allegations of fraud and pointed out that there are a multitude of scenarios under which physicians might be overpaid due to inadvertent billing errors or Medicare contractor claims processing errors that are no fault of the provider.

Response: We believe that we must retain the ability to suspend payments in both cases of potential fraud and cases that do not involve potential fraud but are based solely on potential overpayments. We have long had the authority to suspend payments without evidence of fraud but historically have not often used the suspension tool in these cases. We will determine on a case-by-case basis whether a suspension of payments is appropriate in cases that do not involve fraud, and factors such as Medicare contractor claims processing errors and provider billing history are certainly considered.

Comment: One commenter requested that CMS provide clarification on whether the proposed rule's suspension provisions apply to the Medicare Part D program and suggested that the proposed rule seems to conflict with legislation and CMS promulgated rules regarding prompt payment of Medicare Part D claims.

Response: The Medicare payment suspension authority is applicable to providers under both the Part A and Part B programs. Separate authorities are available to address potential fraud by plans participating in the Part C and D programs.

Comment: One commenter believes that Federally Qualified Health Centers (FQHCs) should be exempted from the potential application of the suspension of payments because payment to FQHCs is premised on reimbursement of reasonable costs and FQHCs are subject to an annual reconciliation process under which surplus payments in excess of reasonable Medicare costs are returned to the CMS contractor.

Response: All providers in Medicare Part A and Part B are subject to the payment suspension provisions, regardless of the method of reimbursement. The annual reconciliation process under which surplus payments are returned does not necessarily account for credible allegations of fraud and we reserve the right to impose a payment suspension on any provider for whom there is a credible allegation of fraud.

We are adopting the provisions of the proposed rule, with one exception. In § 405.371(b)(3), we state that good cause shall be deemed to exist to not continue to suspend payments if a payment suspension has been in effect for a period of 18 months unless certain conditions are met.

2. Medicaid

a. Background

In section 6402(h) of the ACA, the Congress amended section 1903(i)(2) of the Act to provide that Federal Financial Participation (FFP) in the Medicaid program shall not be made with respect to any amount expended for items or services (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished by an individual or entity to whom a State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity as determined by the State in accordance with these regulations, unless the State determines in accordance with these regulations that good cause exists not to suspend such payments.

b. Previous Medicaid Regulations

State Medicaid agencies have long been authorized to withhold payments in cases of fraud or willful misrepresentation. On December 28, 1987, DHHS finalized regulations at § 455.23 that they described as specifically encouraging State Medicaid agencies to withhold program payments to providers without first granting administrative review where the State agency has reliable evidence of fraudulent activity by the provider. The regulations were issued by the HHS OIG based on a concern that State administrative hearings could interfere with investigations conducted by HHS OIG's Office of Investigations or by the State's Medicaid fraud control unit (MFCU). The requirements of an administrative hearing could jeopardize criminal cases and investigators were reluctant to agree to a State's withholding payment, thus risking additional overpayments. (*See* the December 28, 1987 final rule (52 FR 48814)). The December 28, 1987 final rule remains in effect and has remained unchanged since it was promulgated.

At the time the rule was proposed, the Department was in the process of reorganizing its fraud and abuse regulations to reflect authorities transferred to HHS OIG in 1983, as well as those retained by CMS. HHS OIG authorities were transferred to a new 42 CFR chapter V, while CMS' Medicaid program integrity authorities were retained at 42 CFR part 455. (*See* the September 30, 1986 final rule (51 FR 34764)).

This current rule provides that a State Medicaid agency may withhold payments to a provider in whole or in part based upon receipt of reliable evidence that the need for withholding payments involves fraud or willful misrepresentation under the Medicaid program. At the time this rule was published, commenters questioned what constituted "reliable evidence of fraud." The HHS OIG declined to provide a specific definition, noting that what constitutes "reliable evidence" is not easily and readily definable. The HHS OIG noted that while the existence of an

ongoing criminal or civil investigation against a provider may be a factor in determining whether reliable evidence exists, that reliable evidence should be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand, and acting judiciously on this information.

The 1987 regulations also permitted payments to be suspended in whole or in part. Commenters had suggested that "clean claims" continue to be processed without delay, and that any withholding ought to be targeted to only the type of Medicaid claims under investigation. The HHS OIG responded that it is usually difficult to determine which claims are "clean" until after an investigation has been completed, but noted that where an investigation is solely and definitively centered upon a specific type of claim that a State could, at its discretion, withhold payments on just those types of claims. The HHS OIG also agreed to commenters' requests to clarify that the withholding provisions apply only to alleged fraud or willful misrepresentation related to improperly received Medicaid payments and not to ancillary unrelated matters such as deceptive advertising.

c. Proposed Medicaid Suspension of Payments Requirements

The current regulation at § 455.23 formed the framework for these final regulations. State Medicaid agencies have long had the authority to withhold payments in cases of alleged fraud or willful misrepresentation. Section 6402(h)(2) of the ACA now mandates that States not receive FFP in cases where they fail to suspend Medicaid payments during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity as determined by the State in accordance with these proposed regulations unless the State determines that good cause exists for a State not to suspend such payments. To conform the existing regulation to the terminology of the ACA, we proposed to change the phrase "withhold payments" to "suspend payments," a change we believe is merely semantic.

We proposed to implement section 6402(h)(2) of the ACA by modifying the existing § 455.23(a) to make payment suspensions mandatory where an investigation of a credible allegation of fraud under the Medicaid program exists. Based on the ACA's use of just the term "fraud," we did not propose to retain the existing term "willful misrepresentation." We believe that fraud encompasses willful misrepresentation as well as other acts that may constitute civil or criminal fraud; thus we do not believe this proposal represents a substantive change nor do we intend it to have a substantive effect insofar as reducing or limiting a State's authority to suspend Medicaid payments. We solicited comments on this approach.

To conform the proposed regulation to the requirements of the ACA, we proposed to modify terminology in the existing § 455.23(a) that now refers to "receipt of reliable evidence" to instead refer to a "pending investigation of a credible allegation of fraud." In contrast to the semantic change from "withhold payments" to "suspend payments," in this case we believe that there is a substantive difference between the threshold level of certainty or proof necessary to identify a "credible allegation" versus the heightened requirement of "reliable evidence" in the current regulation.

We do not believe that the phrase "when there is pending an investigation of a credible allegation of fraud" necessarily demands that an investigation originate in or with a law enforcement agency. Rather, State Medicaid agencies have program integrity units that, in the normal course of business, receive, and conduct investigations based upon, tips alleging fraud, and which also conduct proactive investigations based upon internal data analyses and other fraud detection techniques. We believe that State agency investigations, though they may be preliminary in the sense that they lead to a referral to a law enforcement agency for continued investigation, are adequate vehicles by which it may be determined that a credible allegation of fraud exists sufficient to trigger a payment suspension to protect Medicaid funds.

This threshold by which a State agency investigation may give rise to a payment suspension is a somewhat lesser threshold than that in the current regulation. The preamble to the current regulation specified that it was anticipated the State agency would confer with, and receive the concurrence of, investigative or prosecuting authorities prior to imposing a withholding action. However, that preamble also stated that it was establishing mere minimum requirements, and that States could exercise broader power where State law or regulation so provided. Most States have availed themselves of the existing Federal authority (or broader state authority) to withhold payments, and we believe that experience over the past 20 years offers no indication this authority has been misused against providers. Moreover, we believe this proposed threshold is consistent with the phrase "pending investigation of a credible allegation of fraud" of the ACA. We do anticipate that payment suspension authority will be used more frequently because the ACA dictates that where there is a pending investigation of credible allegations of fraud against a provider, a State that fails to suspend payments to that provider will not receive FFP with respect to such payments unless good cause exists not to suspend them.

We proposed to adopt at § 455.2 the same broad definition of "credible allegation" proposed previously in the context of the Medicare program. In many cases, what constitutes a "credible allegation" must be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand. Guided by the experience of more than 20 years, we are aware that States have been able to identify "reliable evidence" through a variety of means including, but not limited to, fraud hotline complaints, Medicaid claims data mining, and patterns identified through provider audits, along with the appropriate level of additional investigation that accompanies each of these. Moreover, States have received referrals from State MFCUs, other law enforcement agencies, and other State benefits program investigative units. We continue to believe that State agencies must review all allegations, facts, and evidence carefully and act judiciously on a case-by-case basis when contemplating a payment suspension, mindful of the impact that payment suspension may have upon a provider.

We proposed at § 455.23(b) that the State agency notify a provider of a payment suspension in a way very similar to the mechanism currently specified in regulation, by which the State agency is required to notify a provider, specifying certain details, within 5 days of taking such action. However, we did propose to provide for a 30-day period, renewable in writing up to twice for a total not to exceed 90 days, by which law enforcement may, in writing, request the State agency to delay notification to a provider. We proposed this because we believe that occasionally an investigation may be at a sensitive stage, perhaps involving undercover personnel or a confidential informant, where required notification to the provider at a particular time might jeopardize the investigation. We do not believe we should extend the delay notification beyond 90 days out of fairness to a provider and, in any event, a provider deriving any significant

revenue stream from Medicaid is likely to itself discern the fact of a payment suspension well in advance of 90 days.

We proposed only minor changes to the current provisions in § 455.23(c) on the duration of a suspension. To comport with the ACA, we change the term "withholding" to "suspension"; this is a semantic change that, as noted previously, has been made throughout. In the new § 455.23(c)(2), we propose to require a State to notify a provider of the termination of a payment suspension and, where applicable, to specify the availability to a provider of any appeal rights under State law and regulation.

Substantively, we did not propose significant change to the existing duration provisions, which specify that withholding (now, suspension) will be temporary and will not continue after: (1) Authorities discern that there is insufficient evidence of fraud upon which to base a legal action; or (2) legal proceedings related to the alleged fraud are completed.

We believe that maintaining the existing duration provisions is consistent with the ACA that requires that FFP not be made when a State fails to suspend payments "during any period when there is pending an investigation of a credible allegation of fraud against an individual or entity." We further recognized that the Act applies a very similar standard to the Medicare program. We solicited comments on our proposal to maintain the existing duration provisions.

In § 455.23(d) of the proposed rule, we proposed to require a State to make a formal, written suspected fraud referral to its MFCU or, where a State does not have a MFCU to an appropriate law enforcement agency, for each instance of payment suspension as the result of a State agency's preliminary investigation of a credible allegation of fraud. This will ensure that an appropriate full investigation by a law enforcement agency timely ensues. If the MFCU or other law enforcement agency declines to accept the referral, we proposed to require the State to immediately release the payment suspension unless the State refers the matter to another law enforcement entity or unless the State has alternative Federal or State authority by which it may impose a suspension. In the latter case, the requirements of that alternative authority, including any notice and due process or other safeguards, will be applicable.

We proposed to require that a State's formal, written suspected fraud referral meets fraud referral performance standards issued by the Secretary. The currently applicable fraud referral performance standards were issued by CMS on September 30, 2008.

In § 455.23(d)(3), we proposed that on a quarterly basis a State must request a certification from the MFCU or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation or in the course of enforcement proceedings warranting continuation of the payment suspension. We recognized that due to various constraints, law enforcement agencies may not be able to provide specific updates on matters under investigation. In recognition of the fact that payment suspensions are only temporary, however, we proposed to require such quarterly certifications to ensure, for example, that a suspension will not be continued long after a law enforcement agency has closed an investigation but neglected to alert a State agency of that fact. To maximize State flexibility to implement this requirement, we are not prescribing the precise format such certifications must take.

Consistent with the new ACA provision, we also proposed to create several "good cause" exceptions by which States may determine good cause exists not to suspend payments or to suspend payments only in part. In new § 455.23(e) we included several circumstances that we believe constitute "good cause" for a State to determine not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity despite a pending investigation of a credible allegation of fraud. In § 455.23(e)(1), we proposed a good cause exception based upon specific requests by law enforcement that State officials not suspend (or continue to suspend) payment. There are numerous reasons for which law enforcement personnel might make such a request, including that imposing a payment suspension might alert a potential perpetrator to an investigation at an inopportune or particularly sensitive time, jeopardize an undercover investigation, or potentially expose whistleblowers or confidential sources.

In § 455.23(e)(2), we proposed a good cause exception if a State determines that other available remedies implemented by the State could more effectively or quickly protect Medicaid funds than would implementing (or continuing) a payment suspension. For example, law enforcement personnel might request that a court immediately enjoin potentially unlawful conduct or prevent the withdrawal, removal, transfer, disposal, or dissipation of assets, either or both of which might protect Medicaid funds more fully or quickly than would imposition of a payment suspension.

Paragraph (e)(3) proposed a good cause exception based upon a determination by the State agency that a payment suspension is not in the best interests of the Medicaid program. It is conceivable that a State may, in rare situations, face exigent circumstances with respect to a suspension situation not addressed by the other good cause exceptions specified here but where it otherwise determines suspension would not be in the State Medicaid program's best interests. This broad standard is intended to reflect that payment suspension is a very serious action that can potentially lead to dire consequences, but that it is impossible to specify detailed contingencies with respect to every possible scenario that might arise. We did not anticipate that States will frequently make use of this exception; however where this exception is utilized we do require that States document their use of this exception, and will closely monitor its implementation to determine whether further regulation is necessary. We solicited comments on this approach.

In paragraph (e)(4), we proposed a good cause exception based upon a determination by the State of an adverse effect of the suspension on beneficiary access to necessary items or services. We envision there may be scenarios in which a payment suspension to a provider might jeopardize a provider's ability to continue rendering services to Medicaid beneficiaries, thus threatening Medicaid beneficiaries' access to care. Utilizing a standard identical to that which CMS and the HHS OIG apply in assessing requests for waivers of exclusion at Parts 402 and 1001 of Title 42, for example, we posit one basis for a good cause exception from payment suspension is if a provider under investigation is a sole community physician or the sole source of specialized services available in a community. Likewise, in Federally-designated medically underserved areas the potential impact of a payment suspension upon a large provider might equally threaten recipient access, thus this underlies a second access exception. We welcomed comments on this approach, including comments with respect to other metrics by which to assess potential beneficiary jeopardy in terms of access to necessary items or services.

Finally, in paragraph (e)(5) we proposed a good cause exception that would permit (but not require) a State to discontinue an existing suspension to the extent law enforcement declines to cooperate in certifying under the

requirements of paragraph (d)(3) that a matter continues to be under investigation and therefore warrants continuing the suspension.

We do not interpret the new provision in the ACA as mandating that a State must always suspend all payments to a provider in cases of an investigation of a credible allegation of fraud. In general, we continue to believe a payment suspension should apply to all of a provider's claims consistent with the HHS OIG's responses to comments in the 1987 regulations that it is usually difficult to determine which claims are clean claims until after an investigation is completed, and one purpose of payment suspension is to build a type of escrow account out of which any overpayments can be deducted when an investigation is concluded.

With certain new constraints, however, we have chosen to continue to allow States the flexibility to suspend payments in part. For example, as stated in the preamble to the current regulation, there may be times where an investigation is solely and definitively centered on only a specific type of claim in which case a State may determine it is appropriate to impose a payment suspension on only that type of claim. Likewise, a State might determine that an investigation of a credible allegation of fraud is limited to a particular business unit or component of a provider such that a suspension need not apply to certain business units or components of a provider.

Balancing these approaches, we proposed to allow States to implement a partial payment suspension, or, where appropriate, to convert a previously imposed full payment suspension to a partial payment suspension, if justified via a good cause exception. The good cause exceptions for partial suspension at paragraphs (f)(1) and (2) mirror those at paragraphs (e)(4) and (3), respectively, and allow the State to adopt a partial payment suspension where suspension in whole would so jeopardize a recipient's access to items or services as to endanger the recipient's life or health, or where the State deems it in the best interests of the Medicaid program. At paragraph (f)(3), we proposed that a State may avail itself of the good cause exception to suspend payments only in part if the nature of the credible allegation is focused solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider, and the State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid. Many such cases will still demand suspension in full, but this provision, which we anticipate States would exercise sparingly, gives States flexibility to act otherwise in those limited circumstances where appropriate. Finally, at paragraph (f)(4), we proposed that a State may avail itself of the good cause exception to convert a payment suspension in whole to one only in part to the extent law enforcement declines to cooperate in certifying under the requirements of paragraph (d)(3) that a matter continues to be under investigation. We solicited comment on these proposed approaches.

We proposed in new paragraph (g) to add several reporting and document retention guidelines to § 455.23. Payment suspension authority is critically important to protect Medicaid funds, but payment suspension can have dire consequences to a provider. Payment suspension authority, including a State's exercise of a good cause exception to otherwise address a suspension situation, must be exercised responsibly by a State at all stages, from the inception to the termination of the suspension. Through, among other things, our State Program Integrity Reviews, we expect to maintain close oversight of State utilization of suspension authority. However, to be clear, we expressly and explicitly do not expect State compliance (or noncompliance) with these documentation or retention provisions to give rise to any enforceable right of a provider aggrieved by any real or perceived failures with respect to these requirements to seek any form of redress (administratively, judicially, or otherwise).

Under these final reporting and retention guidelines, States are required to maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that is imposed, including: (1) All notices of suspension of payment in whole or part; (2) all fraud referrals to MFCUs or other law enforcement agencies; (3) all quarterly certifications by law enforcement that a matter continues to be under investigation; and (4) all notices documenting the termination of a suspension. Likewise, we proposed to require States to maintain for the same period all documentation justifying the exercise of the good cause exceptions. Finally, we proposed to require States to annually report to the Secretary information regarding the life cycle of each payment suspension imposed and any determinations to exercise the good cause exceptions not to suspend payment, to suspend payment only in part, or to discontinue a payment suspension.

To effectuate section 6402(h)(2) of the ACA's prohibition on expenditure of FFP where a State fails to suspend payments that should, by virtue of the ACA standard and this proposed rule, have been suspended, we proposed to add a new § 447.90. Paragraph (a) of proposed § 447.90 specifies the basis and purpose for the new provision, while paragraph (b) specifies the general rule that FFP would not be available with respect to items or services furnished by an individual or entity to whom the State has failed to suspend Medicaid payments during any period where there is pending an investigation of a credible allegation of fraud against the individual or entity except in specified circumstances that include certain emergency circumstances, or if good cause exists as specified at § 455.23(e) or (f).

As mentioned, we anticipate that CMS' enforcement and monitoring of these provisions will largely be accomplished through measures such as State Program Integrity reviews conducted by CMS. Such reviews will, among other things, evaluate States' complaint intake and investigation efforts, and assess whether States have an effective process to move matters where there are found to be credible allegations of fraud to the point where they are evaluated for payment suspension. However, we do not believe it is viable to require States to report and document to CMS every instance of where any allegation of fraud arises and further qualify which ones rise to the level of credible allegation. We want to foster effective and efficient State program integrity efforts with respect to which payment suspension is an integral component, but we do not want to create a system so procedurally onerous that it overwhelms a State's ability to substantively perform this critical work. Nevertheless, we will thoroughly investigate and act by, among other things, deferring and/or disallowing FFP in accordance with § 430.40 and § 430.42, if program integrity reviews or other methods of ensuring State compliance with Medicaid program requirements reveal a State is failing to suspend payments (or inappropriately applying a good cause exception) where pending investigations of credible allegations of fraud do exist. A State may not claim (on its Form CMS–64) FFP for payments that are suspended. Any State that does not suspend payments, or that suspends payments but continues to claim FFP with respect to what would have been paid had no suspension been in place,

puts that FFP at risk. In such cases, we would pursue a deferral and/or disallowance to reclaim the Federal portion of such payment. We solicited comments on CMS' proposed oversight approach.

Finally, three provisions were proposed to be added to the regulations at § 1007.9 that specify the State MFCU's relationship to, and agreement with, the State Medicaid agency. These proposed revisions were necessary to effectuate the proposed revisions under § 455.23. The regulations at 42 CFR part 1007 are enforced by HHS OIG as part of its delegated authority to certify and fund the State MFCUs. (*See* August 15, 1979 final rule (44 FR 47811). However, we are including amendments to part 1007 here to ensure a comprehensive regulatory package that sets forth in one location the Department's implementation of the suspension provisions of section 6402(h) of the ACA.

The first of these provisions proposes to add a new paragraph (e) to § 1007.9 that specifies that the MFCU may refer to the State agency any provider against which there is pending an investigation of a credible allegation of fraud for purposes of payment suspension in accord with § 455.23. Allegations of potential fraud may first be identified by the MFCU rather than by the State agency, so this provision merely formalizes a path from the MFCU to the State agency so a payment suspension may be implemented where appropriate. This provision also proposed that any referral to the State agency for consideration of a payment suspension be in writing. The written referral need not be extensive, but must include information adequate to enable the State agency to identify the provider and a brief explanation of the credible allegations forming the grounds for the payment suspension. The second proposed addition to § 1007.9 proposed to add a new paragraph (f) providing that any request by the unit to the State agency to delay notification of suspension to a provider pursuant to the provisions of the proposed § 455.23(b)(1)(ii) come in writing. Requiring that such requests be made in writing (which could take the form of an email) provides for an audit trail to ensure that proper procedures are followed. However, we expressly do not intend for this requirement to create any substantive right upon which a provider might lodge objection or other legal challenge to the extent the proper procedures were not followed. Last, a new paragraph (g) was proposed to require the unit to notify the State agency in writing when it has accepted or declined a case referred by the State agency. Aside from also creating an audit trail, this proposed provision is important in that it would alert the State agency as to the status of a referral, which would shape how the State agency would handle a suspension under the proposed revisions to § 455.23.

We received the following comments:

Comment: Several commenters expressed concern regarding the definition of "credible allegation of fraud." Specifically, several commenters requested that CMS provide an exact definition of "credible allegation of fraud" as well as specific standards and guidelines for providers to follow to make a determination regarding what is a credible allegation of fraud. One commenter suggested removing the word "fraud" from the term. Other commenters indicated that the definition of what is credible or reliable under the proposed rule is circular, that is, an allegation is credible if it has "indicia of reliability." In addition, several commenters have suggested that the new evidentiary threshold is too low.

Response: The term "credible allegation of fraud" is a statutory term as reflected in section 6402(h) of the ACA. Accordingly, we do not have the authority to change the term. We have considered these comments but decline to provide a more exact definition, recognizing that different States may have different considerations in determining what may be a "credible allegation of fraud." Accordingly, we believe that States should have the flexibility to determine what constitutes a "credible allegation of fraud" consistent with individual State law. We will neither seek to limit what States may determine qualifies as a "credible allegation of fraud" nor will we require States to consult with HHS in making such a determination.

Comment: One commenter suggested that CMS should update its policies and procedures and develop consistent and standard guidance to State Medicaid programs regarding the determination of credible allegations of fraud.

Response: We will review our current policies and procedures in light of the regulatory changes contained in this rule, and will provide updated guidance to States as necessary.

Comment: Several commenters expressed concern that the evidentiary standard is too low and urged CMS to retain the current standard, by which they suggested defining a "credible allegation of fraud" as "reliable information that fraud or willful misrepresentation exists" as a component of the basis for suspension of payments under § 455.23(a).

Response: In the proposed rule, we acknowledged that the proposed threshold for triggering a payment suspension is lower than what is contemplated in current regulations, but we also indicated that we believe this result is dictated by the ACA. However, in this final rule with comment period, we are amending the definition of "credible allegation of fraud" at § 455.2, which in the proposed rule read, in pertinent part, "[a]llegations are considered to be credible when they have indicia of reliability" to include the following: "and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis." Due to use of just the word "fraud" in section 6402(h)(2) of the ACA, we proposed to remove the term "willful misrepresentation" from existing regulation, though as we noted in the proposed rule, we take the position that "fraud" includes "willful misrepresentation."

Comment: A few commenters suggested that the final regulation should include a requirement and a discussion to provide technical guidance to State Medicaid programs that clarifies the term "fraud" as a legal term and one that carries evidence of a willful intent to deceive.

Response: The definition of fraud, for purposes of Medicaid program integrity, is reflected in existing regulations at § 455.2 and reads as follows: "an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law." Medicaid fraud is addressed through, for example, civil remedies imposed under Federal and State false claims acts, as well as through criminal prosecutions.

Comment: Numerous commenters expressed concerns regarding the list of potential sources of credible allegations of fraud. Specifically, several commenters expressed concern about false reports of fraud that may be generated by competitors or disgruntled employees. In addition, there were numerous comments that expressed concern over allegations received through a fraud hotline and whether such allegations could be considered to be reliable. Another commenter suggested that anonymous hotlines should refer to State-operated Medicaid fraud hotlines as well as specify to

whom or what entity the fraud hotline complaints are being made.

Response: First, we will not seek to limit the potential sources from which States may derive credible allegations of fraud. We provided examples of sources for States to consider and will clarify in the final regulation that we are not limiting such sources. We recognize that credible allegations may come from a variety of sources. Second, with respect to identifying fraud hotlines as a potential source of a credible allegation of fraud, we recognize that there may be irrelevant or false reports made through hotlines. Due to the potential for not just false allegations, but also the equal possibility of honest mistakes and the like, we encourage States to not solely rely on a singular allegation without considering the total facts and circumstances surrounding such allegations. In the proposed rule, we indicated that States "must review all allegations, facts, and evidence carefully and act judiciously on a case-by-case basis * * *". As noted previously, we are including this language in the final rule with comment period in the definition of "credible allegation of fraud" at § 455.2. We take the position that States should have the flexibility to determine what they deem to be reliable sources for credible allegations of fraud. Finally, we will not identify which specific fraud hotlines States may use. We are aware that there may be a variety of hotlines. For example, States may have different components within their respective agencies that utilize hotlines or State law enforcement agencies may also utilize hotlines from which credible allegations may be generated. Accordingly, we will not seek to limit the type of hotline States use as sources for credible allegations of fraud.

Comment: Commenters indicated that discussions of investigations and credible allegations of fraud need to defer to State and Federal legal definitions of "fraud." In addition, commenters suggested that existing Federal regulations indicate that investigating fraud is the responsibility of State Medicaid Fraud Control Units (MFCU). Accordingly, MFCUs should be the designated investigators of allegations of fraud.

Response: First, as noted previously, "fraud" is defined in existing regulations at § 455.2. Second, we disagree that only the MFCU may investigate allegations of fraud. While MFCUs clearly play a key role in investigating and prosecuting Medicaid fraud, most, if not all, States have program integrity units that, in the normal course of business, receive hotline and other tips about potential fraud, and conduct proactive investigations based upon internal data analyses and other fraud detection techniques. Program integrity units have the responsibility under existing Federal regulations at § 455.14 and § 455.15(a)(1) and the proposed regulation at § 455.23(d) of determining whether allegations constitute fraud, and if they do, referring the matter to the MFCU or an appropriate law enforcement agency for further investigations. Thus, we do not believe MFCUs are the sole investigators of fraud.

Comment: Several commenters requested that CMS clarify whether a finding of billing errors during an audit that are not related to allegations of fraud would trigger a payment suspension.

Response: Irrespective of the circumstances, absent pending investigations of credible allegations of fraud, payment suspensions would not be triggered under these regulations, although that does not preclude the possibility that a State may exercise its own broader suspension authority in other circumstances.

Comment: Several commenters requested clarification regarding whether States should determine the credibility of an allegation of fraud prior to initiating a suspension action.

Response: Due to the potential for not just false allegations, but also for good faith mistakes, misunderstandings, and misinterpretations regarding reports of alleged fraud as well as data analysis errors, we encourage States not to rely on any singular allegation or data run but rather States should review all allegations, facts, and data carefully and act judiciously on a case-by-case basis, mindful of the potential impact a payment suspension may have on a provider.

Comment: One commenter suggested that we include the term "abuse" as a basis for payment suspension and not limit such suspensions to investigations of "credible allegations of fraud."

Response: We decline to add the term "abuse" to Federal regulations in the context of payment suspensions, as the phrase we have adopted, "credible allegation of fraud" has a statutory basis reflected in section 6402(h) of the ACA. As a practical matter, however, conduct that constitutes abuse as opposed to fraud (we note that both terms are defined at § 455.2) may be indistinguishable not just at the outset of an investigation but even through the course of an investigation and enforcement proceedings and may hinge on fine factual distinctions or legal points including knowledge and intent, and this regulation would not preclude the imposition of a suspension in such a circumstance so long as there is a credible allegation of fraud. Moreover, this regulation presents a floor for protection of Medicaid funds and does not bar a State from setting a higher bar allowing for imposition of suspensions in other circumstances.

Comment: One commenter expressed concern regarding Federal oversight and whether such oversight will amount to second-guessing a State's determination of what constitutes a credible allegation of fraud.

Response: We do not intend to second-guess State determinations regarding credible allegations of fraud. We intend to work collaboratively with States to prevent critical Medicaid funds. The purpose of Federal oversight is to ensure that States have effective processes in place in order to make determinations regarding credible allegations of fraud.

Comment: Several commenters expressed concern regarding the lack of a definition for the phrase "indicia of reliability" and requested CMS to provide one.

Response: We have considered the concerns of commenters, but decline in this final rule with comment period to define "indicia of reliability." We recognize the possibility that there may be differing standards among States with respect to what may be considered "indicia of reliability," but also, as we have noted several times in these responses, we expect States to gauge the credibility of allegations through a lens after reviewing all allegations, facts, data, and evidence carefully and that State action will be exercised judiciously on a case-by-case basis.

Comment: Several commenters want CMS to define "investigation" of a credible allegation of fraud. One commenter inquired whether a State may rely on its MFCU to determine if an allegation of fraud is credible. Other commenters suggested that the State and its investigators are in the best position to determine when credible allegations of fraud should lead to a payment suspension, such that CMS should rely on the judgment of these individuals in deciding whether to withhold FFP. Certain commenters also wanted to know if the process of determining whether an allegation of fraud is credible is sufficient to trigger a payment suspension.

Response: We recognize that the process to determine whether an allegation of fraud is credible may vary among States, and we defer to States—applying the principles of careful review and judicious action to which we refer several times in these responses

and which we now include in the final rule with comment period—to determine whether an allegation or complaint rises to the level of a credible allegation of fraud. We do not want to limit a State's due diligence process or preliminary investigations with respect to its assessment of credibility. Nor do the proposed regulations specify or limit who, or what other agency, may assist the State agency with the investigation or validation of credible allegations of fraud. Nevertheless, if it is determined that an allegation is credible, a State must still submit a formal written referral to its MFCU irrespective of whether the MFCU assisted in validating an allegation's credibility. Finally, the mere fact of an investigation to assess the credibility of a fraud allegation is insufficient to trigger a payment suspension. Rather, a payment suspension is triggered when that there is, in fact, a pending investigation of a credible allegation of fraud. We will clarify this in the regulation.

Comment: One commenter suggested that the notice of suspension to providers should be sent by certified mail, set forth the specific (not general) allegations and inform the providers of the State's administrative review process and provide appropriate citation. Another commenter suggested revising the language in § 455.23(b)(2)(v) regarding notice of suspension to include information about any administrative appeal procedures that are available under State law. Other commenters suggested that notice be furnished to providers prior to the implementation of an adverse action such as payment suspensions. One commenter suggested giving States more discretion regarding when notices of suspension should be furnished to providers. One commenter in particular indicated that bi-weekly remittance advisories are issued to providers that would, in effect, disclose the State's actions.

Response: We believe that we should afford States the flexibility to determine the best method of delivery of notices of suspension so we decline to take an overly prescriptive approach in this regulation. However, we agree that a notice of suspension furnished to a provider should appropriately reference the general allegations upon which a suspension is based as well as any existing State appeals process. Accordingly, we will revise the proposed language to reflect the inclusion of State administrative appeal procedures in the notice of suspension to providers. We do not agree that providers should be given notice of a payment suspension prior to such action being taken. We recognize the sensitive nature of a fraud investigation which may be jeopardized by such notice, and expect that State agencies will act appropriately so as not to jeopardize any investigation.

Comment: Commenters suggested that if a provider or supplier who is subject to a payment suspension submits an acceptable written rebuttal statement as to why the suspension should be removed, then this should qualify as "good cause" as currently permitted under § 405.372(b). In other words, a rebuttal could establish a good cause exception to end a payment suspension. Several other commenters suggested that in cases of economic hardship, a provider should be able to submit evidence of this fact for consideration by the State in determining whether to terminate a payment suspension, and requested that CMS create an expedited review process. Commenters also suggested that the regulations should acknowledge the severe financial impact of a payment suspension and should limit the scope of the suspension to the services under review.

Response: We believe that the proposed regulation as written allows a State to account for a provider's rebuttal statement. Specifically, as proposed at § 455.23(e), States have the flexibility to make a determination that a payment suspension is not in the best interests of the Medicaid program. States also have the option to suspend payments only in part if there is good cause. Therefore, we do not believe that an additional good cause exception is necessary. Moreover, as the existing Medicaid suspension has for more than 20 years, we continue to defer to any State administrative (or judicial) review processes, and therefore decline to require States to adopt an expedited review process. Nevertheless, we are including new good cause exceptions in this final rule with comment period at § 455.23(e)(3) and (f)(2) to allow a State to terminate a whole payment suspension or impose a payment suspension only in part if a provider furnishes written evidence that persuades the State that a payment suspension should be terminated or imposed only in part. Furthermore, the preamble acknowledges and requests States to be mindful of the impact that suspensions may have upon providers.

Comment: One commenter inquired whether "good cause" is established if the items or services are furnished as an emergency.

Response: Section 1903(i)(2) of the Act provides for a limited exception for payment to be made with respect to emergency items or services, though not including items or services furnished in the emergency room of a hospital. We believe this statutory exception speaks for itself and we do not need to otherwise address or expand upon it in these regulations.

Comment: Commenters have suggested that the proposed "good cause" regulatory provisions should include the language contained in the preamble acknowledging that "reliable evidence should be determined on a case-by-case basis with the State agency looking at all the factors, circumstances, and issues at hand * * *" (75 FR 58224).

Response: We disagree that this language belongs in the "good cause" regulatory provisions. Instead, we have revised the definition of "credible allegation of fraud" to reflect that States must carefully review all allegations, facts and evidence on a case-by-case basis. Accordingly, we do not see the need to include this language in the "good cause" regulatory provisions.

Comment: One commenter suggested that CMS consider placing the catchall of "not in the best interests of the Medicaid program" reflected in § 455.23(e)(3) and similarly the catchall reflected at subparagraph (f)(2) of "* * * payment suspension in part is in the best interests of the Medicaid program" at the end of the respective subparagraphs.

Response: We agree and will make such changes in the final regulation.

Comment: One of the good cause exceptions not to suspend payments to Medicaid providers is when "an individual or entity is the sole community physician or the sole source of essential specialized services *in a community.*" (emphasis added) One commenter suggested replacing "in a community" with "for a particular beneficiary population."

Response: We disagree. We are concerned about negatively impacting beneficiary access to care so this exception does not turn on whether a provider serves a particular beneficiary population, but on whether a beneficiary's access to necessary care is impeded. Thus, the good cause exception may be applied when a beneficiary's access to care is jeopardized because he/she cannot obtain necessary services from a particular provider type.

Comment: Several commenters questioned whether the requirements of this section would apply to Medicaid managed care, including whether the term "provider" includes managed care entities, whether managed care capitation payments are included in suspensions when an individual network provider is under investigation;

and what would be the process for notifying a managed care entity of a credible allegation of fraud.

Response: The rules governing payment suspensions based upon pending investigations of credible allegations of fraud apply to Medicaid managed care entities. If there is a pending investigation of a credible allegation of fraud against a Medicaid managed care organization (MCO), prepaid inpatient health plan (PIHP), prepaid ambulatory health plan (PAHP), or health insuring organization (HIO) at the plan level, the State should address the issue either through imposing a payment suspension or through other authorities that may be available to them under State law or as part of the State's negotiated agreement with the Medicaid MCO, PIHP, PAHP, or HIO. The same would hold true for pending investigations of credible allegations of fraud regarding individual network providers. Managed care capitation payments may be included in a suspension when an individual network provider is under investigation based upon credible allegations of fraud, depending on the allegations at issue. We would expect the process regarding the notice of suspension to a Medicaid MCO, PIHP, PAHP, or HIO to follow the criteria as outlined in this final rule with comment period.

Comment: Some commenters requested clarification regarding whether FFP extends to managed care entities' capitation payment.

Response: FFP extends to Medicaid MCOs', PIHPs', PAHPs', and HIOs' capitation payments. Accordingly, if a State fails to suspend payments to such an entity for which there is a pending investigation of a credible allegation of fraud, without good cause, FFP may be disallowed with regard to such payments to the managed care entity.

Comment: Several commenters requested that CMS clarify whether interest accrued on suspended payments to providers is eligible for FFP.

Response: FFP is not available for interest accrued on suspended payments to providers.

Comment: Commenters asked how CMS will notify a State that FFP is to be suspended as a result of payment to an entity for items or services for which the State has received a credible allegation of fraud. Will the State receive advanced notice of the FFP suspension and be given the opportunity to correct or will the suspension be immediate?

Response: The process for deferring and disallowing FFP is governed by § 430.40 and § 430.42, respectively. Generally, we take action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with our instructions) that includes that claim. The notice of deferral to the State is provided by CMS within 15 days of such deferral. The notice should identify the type and amount of the deferred claim and specify the reason for deferral. The State is also requested to make available all the documents and materials that CMS believes are necessary to determine the allow-ability of the claim. However, prior to taking action to defer or disallow FFP, we may engage States to request that impermissible claims for FFP are removed from the Quarterly Medicaid Statement of Expenditures for the Medicaid Assistance Program (Form CMS–64).

Comment: One commenter asked, if CMS suspends a State's FFP, and the allegations of fraud are cleared after the fact, what the process will be to restore FFP.

Response: When we determine claims associated with deferred or disallowed FFP are permissible, we will release the deferred or disallowed funds to the State by providing FFP for the subject claims.

Comment: One commenter expressed concern regarding what the commenter saw as a "shift in evaluation of the appropriateness of suspensions away from the Medicaid agency and entities investigating the allegations of fraud to the exclusive and unilateral discretion of CMS" as well as a broad and sweeping increase in CMS's ability to impose a deferral of FFP.

Response: We have long had the authority to withhold FFP and the payment suspension rule is not an attempt to inappropriately withhold FFP from States. Instead, the rule is intended to protect precious Medicaid dollars from fraudulent providers, an effort in which we view the States as partners. Generally, we will withhold FFP only where a State has unreasonably or repeatedly failed to suspend payments or otherwise terminate a payment suspension where there are credible allegations of fraud.

Comment: One commenter suggested that the proposed rule regarding suspension of payments to Medicaid providers gives Medicaid agencies an improper incentive to aggressively deny payments to providers or risk losing FFP.

Response: We disagree. As we explained in the proposed rule, State Medicaid agencies have long had the authority to suspend payments to providers based upon suspected fraudulent conduct. Our goal is to ensure that State agencies appropriately suspend payments from potentially fraudulent providers, in order to protect critical Medicaid dollars from falling into the hands of such providers. In this rule we encourage State agencies to suspend payment based upon pending investigations of credible allegations of fraud only after reviewing all of the facts and circumstances surrounding a particular case and making a determination that such suspension is in fact warranted.

Comment: One commenter suggested that the suspension of payments could be interpreted to have retroactive application to providers who have already been referred to MFCUs or other law enforcement agencies:

Response: We will not require States to retroactively apply the law regarding suspension of payments based on pending investigations of credible allegations of fraud. However, upon the effective date of this final rule with comment period, we expect States; to the extent they have not already done so, to suspend payments to providers against whom there exist pending investigations of credible allegations of fraud.

Comment: Commenters have sought clarification regarding whether the proposed rule applies to individual providers who are employed or contracted by institutional providers.

Response: The payment suspension rule applies to institutional providers as well as enrolled providers who are employed or contracted by such institutional providers.

Comment: One commenter wanted CMS to clarify whether the "individual or entity" under investigation is the same "individual or entity" subject to the payment suspension.

Response: Yes, the "individual or entity" under investigation is the same "individual or entity" that is subject to the payment suspension.

Comment: Several commenters expressed concern with States' compliance dates with the Medicaid payment suspension rule because some States may require State law or regulatory changes in order to be able to implement the rule. Certain commenters also expressed similar concerns that the proposed document retention requirements exceed time frames currently required by their State laws.

Response: We encourage the State Medicaid or program integrity director of any State that faces State legislative, regulatory, or administrative implementation obstacles to contact us

in order to work out a plan of resolution.

Comment: One commenter suggested that the process for quarterly reporting and certification at § 455.23(d) is onerous to the State and the MFCU. The commenter further indicated that reporting is already addressed in Memoranda of Understanding between the States and the MFCUs, and therefore, additional reporting requirements would be burdensome on the State.

Response: We disagree, and in the proposed rule stated that we would not prescribe the format that such certifications must take to maximize State flexibility. The Memoranda of Understanding between the States and the MFCUs routinely do not address reporting and documentation to the degree that will be required by § 455.23(d). Moreover, in the proposed rule we emphasized that payment suspensions should be temporary and we noted the profound impact that a payment suspension can have upon a provider. We believe that the quarterly reporting and certification process is an important protection for providers to ensure that suspensions do not continue after law enforcement has concluded its investigation but did not report this information to the State Medicaid agency.

Comment: Some commenters suggested that documentation and record retention in instances regarding the decision to not suspend payments is expensive and unnecessary given the high volume of unfounded allegations. These commenters also suggested that the requirement to report summary information to the Secretary is duplicative given that CMS will be reviewing State actions on suspension of payment during periodic on-site program integrity reviews.

Response: We disagree. As we generally discuss in both these responses and in the proposed rule, we are balancing a number of interests including: (1) A statutory directive from the ACA that FFP not be paid in certain circumstances; (2) a payment suspension provision that, if not rigorously and carefully administered, can detrimentally impact honest providers; and (3) CMS' intent to maintain its appropriate oversight role but at the same time not to arbitrarily or unreasonably second-guess State decision-making. As such, we believe rigorous documentation requirements that go beyond what may be reviewed during on-site program integrity reviews actually serve to protect everyone's interests. Moreover, we believe it is particularly important that States carefully document those processes that require special judgment calls, such as with respect to exercising the various good cause exceptions, so that, upon CMS review, FFP is not inappropriately withheld.

Comment: One commenter recommended that Medicaid State agencies should be allowed to share potentially helpful information with their MFCUs without following the requirements in the proposed rule regarding documentation and timing of the referral of a credible allegation of fraud.

Response: We fully agree with the notion that States may share information or otherwise consult with their MFCUs, recognizing that States may need to consult and/or exchange information with their respective MFCUs prior to making a formal referral, and do not seek to limit or otherwise define the circumstances by which States make such communications. We disagree, however, with the proposition that States should not need to follow our proposed MFCU documentation/referral requirements, which we believe are important for reasons similar to those addressed in the previous response, thus we will not alter the proposed documentation and timing requirements.

Comment: Certain commenters have suggested that it will be cumbersome to require the State to obtain a written certification from the MFCU or other law enforcement agency that any matter that is accepted on the basis of a referral continues to be under investigation or in the course of enforcement proceedings warranting continuation of the payment suspension every 90 days. In addition, these commenters expressed concern that this requirement will result in a substantial increase in workload and could result in increased staffing levels. Commenters also suggested that existing methods of communication regarding caseload and referrals between the States and the MFCUs should be sufficient.

Response: We disagree with the proposition that the quarterly law enforcement certification requirement is overly cumbersome or that the documentation requirements finalized here will result in substantial increases in workload. As we have indicated previously in these responses and in the proposed rule, we believe rigorous documentation requirements are in everyone's interest. Moreover, to maintain State flexibility, we are not prescriptive with respect to the format of the quarterly certification. States have long had authority to implement payment suspensions and, though we formalize certain documentation and referral requirements here, we believe that most States that have used suspension authority likely have rigorous documentation requirements already in place to ensure they are able to adequately justify suspension actions and withstand any provider challenges.

Comment: With regard to formal fraud referrals issued by the State to the MFCU or other law enforcement agency, one commenter suggested combining the relevant NPIs of the affected providers into one referral instead of referring individual cases.

Response: This is outside the scope of the proposed rule and therefore we will not address this issue at this time.

Comment: One commenter suggested that the regulation at § 455.23(g) proposing to require States to annually report to the Secretary information regarding the life cycle of each payment suspension imposed and any determinations to exercise the good cause exceptions not to suspend payment, to suspend payment only in part, or to discontinue a payment suspension, be modified. Specifically, the commenter suggested that such annual report be filed only if such information is shared by law enforcement.

Response: We disagree with the commenter's proposition for two reasons. First, a number of the elements the commenter points out are not contingent on any response from law enforcement. Second, we certainly appreciate that States can only report on the information that is in their possession, but believe that annual reporting should not be contingent on whether law enforcement has shared such information. Importantly, to the extent that annual reporting reveals gaps where law enforcement has neglected or refused to share information it will illustrate where CMS may have to exercise additional oversight authority to attempt to close such gaps. Likewise, law enforcement's "failure to communicate" may be a significant factor in a State's decision to exercise certain of the rule's good cause exception authorities.

Comment: One commenter suggested that CMS include in the final regulation at § 455.23(d)(4), as reflected in the preamble to the proposed rule, a requirement for States to immediately release the payment suspension "unless the State has alternative Federal or State authority by which it may impose a suspension." (75 FR 58225). The proposed regulation does not reflect this additional language governing the immediate release of a payment suspension when MFCU or law

enforcement declines to accept the fraud referral.

Response: We agree, and are including this language in the final rule with comment period.

Comment: Certain commenters suggested revising the proposed language to include a 180 day time limit for the duration of a suspension of payment in the Medicaid program, similar to the proposed process under Medicare.

Response: Aside from the general constraints and protections built in to the rule around the notion that suspensions are intended to be temporary, we believe that States need the flexibility to decide the duration of payment suspensions in order to accommodate State laws and legal processes. Because Medicare is a national program there is more uniformity surrounding the disposition of Medicare program suspensions. So while a specific time limit may be adequate there, we believe a more flexible approach, nearly identical to the approach used with respect to Medicaid payment suspensions for more than 20 years, is necessary to address the needs of 50 plus States and territories.

Comment: One commenter suggested that the duration of a payment suspension by States should be permanent where the provider is later convicted of the offense.

Response: Payment suspensions are intended to stem the flow of Medicaid dollars to providers against whom there are credible allegations of fraud, during the pendency of the investigation, which includes any related proceedings. Separate authorities, some administered by other agencies, including possible exclusion from participation in Federal health care programs, may be implemented upon a provider's conviction.

Comment: One commenter indicated that while the proposed rule gives States authority to immediately release payment suspensions if a timely investigation by law enforcement does not ensue, that "timely," is not clearly defined.

Response: We believe that when a State learns that law enforcement has declined to investigate a fraud referral from the State in connection with a payment suspension or otherwise discontinues a pending investigation, the State should immediately take steps to terminate a payment suspension. As discussed several times in these responses, we proposed a requirement for States to obtain quarterly certifications from law enforcement to help address this type of scenario so that providers are not subject to a continuing payment suspension based upon a fraud referral that was declined by law enforcement or an investigation that has been concluded without the State's knowledge.

Comment: Certain commenters requested clarification regarding the resolution of an investigation for purposes of terminating a payment suspension.

Response: Generally, a payment suspension is temporary and will not continue after the State Medicaid agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider or legal proceedings related to the alleged fraud are completed.

Comment: One commenter suggested that the proposed rule be changed to defer to State law to dictate how long and under what circumstances a payment suspension can be imposed.

Response: As we noted in an earlier response, this rule presents a floor for protection of Medicaid funds and does not bar a State from setting a higher bar allowing for imposition of suspensions with other conditions or in other circumstances.

Comment: Several commenters suggested that the proposed rule does not provide adequate due process for providers facing suspension of payments. Certain commenters also suggested that the proposed rule could result in a de facto termination from the Medicaid program without any meaningful due process. Commenters expressed concern that non-fraudulent providers may effectively be terminated by lengthy suspensions. Commenters also suggested shortening the length of suspensions or in the alternative, maintaining the current permitted duration without extension. Another commenter indicated that the proposed rule does not create a right to challenge the ongoing validity of a payment suspension.

Response: Under the proposed rule, providers have an opportunity to submit written evidence for consideration by the Medicaid agency regarding payment suspensions. Based upon this written evidence, a State may determine whether there is good cause to terminate a suspension of payment. Accordingly, we believe there are adequate due process protections in place pursuant to which a provider may establish good cause to terminate a payment suspension. In addition, this process was already accounted for in existing Medicaid regulations and we did not change the process. We are not aware of any issues associated with this process which has been in existence for more than 20 years. Moreover, we expressed in the proposed rule that suspensions, because of their significant impact upon providers, are only temporary. We provided in the rule several protections (such as the quarterly law enforcement certification and State documentation requirements) and also various "good cause" exceptions. Moreover, the duration of suspension provisions of the proposed rule, finalized here, are essentially the same as have been in place for more than 20 years with the existing Medicaid payment suspension rule. We believe that the significant built-in protections, in conjunction with the fact that we are not aware that the current Medicaid suspension process has caused significant undue hardship with providers having payments wrongly suspended, lend adequate safeguards to the process. CMS will also monitor States' implementation of the Medicaid payment suspension rule through the various documentation requirements and State program integrity reviews, to ensure that there are no marked shortcomings with regard to States' processes.

Comment: One commenter suggested that the final regulation should require State Medicaid programs to establish and codify a Medicaid administrative review process with regard to the review of payment suspensions.

Response: We recognize that individual State laws vary with regard to their respective administrative review processes, and believe that most or all States have established such processes. As previously stated, we will revise the proposed language in the regulations to reflect the inclusion of State administrative appeal procedures in the notice of suspension furnished to providers. In addition, we believe the notice should also include relevant citations to State law, where applicable.

Comment: A couple of commenters suggested that CMS develop a system or process for exposing and penalizing those who make false fraud complaints.

Response: This is outside the scope of the proposed rule and therefore we will not consider this suggestion at this time.

Comment: One commenter requested clarification regarding the fraud referral standards established by CMS as a result of an OIG January 2007 report entitled "Suspected Medicaid Fraud Referrals" (OEI 07–04–00181).

Response: We issued fraud referral standards on September 30, 2008. The link to CMS' Web site where the fraud referral standards may be found is: *http://www.cms.gov/FraudAbuseforProfs/downloads/fraudreferralperformancestandardsstateagencytomfcu.pdf.*

Comment: One commenter suggested that the content of a fraud referral should be left to the discretion of each State. This commenter suggested that a continuing collaborative environment will fulfill the regulatory provisions regarding content of fraud referrals.

Response: We encourage States to collaborate with their MFCU. A fraud referral must contain, at a minimum, the elements as outlined in the proposed regulation and finalized here, but it is within a State's discretion to the extent it wishes to add additional information.

Comment: One commenter suggested that FQHCs should be exempted from the application of payment suspensions.

Response: We disagree. There is no statutory requirement to carve out an exception for any particular category of provider. We believe that payment suspensions apply to fraudulent conduct regardless of provider type.

Comment: One commenter suggested that payment suspensions should only apply to providers in the limited screening level, as that term is defined and used in connection with the provider screening rules, under only the most extraordinary circumstances.

Response: We decline to carve out an exception for providers in the limited screening level in the context of a payment suspension. This assignment to the limited level applies in the context of provider screening, not for suspension of payments. The determination regarding whether to impose a payment suspension is driven by credible allegations of fraudulent conduct and not whether a provider is assigned to a certain level for purposes of screening.

Comment: One commenter requested clarification regarding the application of payment suspensions to billing providers as opposed to prescribing providers. Another commenter requested a guarantee that payment suspensions will not be imposed against a billing provider.

Response: We understand that there are circumstances in which the prescribing provider may be different from the furnishing provider and/or billing provider. Generally, we believe that payment suspension is not the appropriate mechanism to recover Medicaid funds from one provider who inescapably, but innocently, happens to be associated with the fraudulent conduct of another provider. Because payment suspensions only apply based upon credible allegations of fraud, payment suspensions are generally not the appropriate vehicle by which to recover reimbursement for items and/or services furnished by a provider against whom there are no allegations of fraud. Nevertheless, there is no guarantee that a payment suspension will only be imposed against the billing provider as, particularly at the outset of an investigation of a credible allegation of fraud, it may be impossible to precisely determine the locus of the fraud or whether it involved collusion or conspiracy.

Comment: One commenter requested clarification regarding whether States with authority under existing State law may impose suspensions for reasons other than where there is a credible allegation of fraud. This commenter suggested that where such authority exists, the requirements proposed under § 455.23, including those concerning referrals to the MFCU and the duration of suspension should not apply.

Response: The requirements for payment suspensions under the proposed rule are based upon credible allegations of fraud. As we have noted several times in both these responses and in the proposed rule, nothing in these rules bar a State from exercising other broader authorities to suspend payments to providers.

We are adopting the provisions of the proposed rule with the exception of the following changes:

- In § 455.2, we have revised the definition of "credible allegation of fraud" to address the issue of the State's verification of the allegation.
- In § 455.23(a)(1), we have added the verbiage "after the agency determines there is a credible allegation of fraud for which" after the term "provider."
- In § 455.23(b)(2), we have added a new subsection (vi) that reads: "Set forth the applicable State administrative appeals process and corresponding citations to State law."
- In § 455.23(d), we have added the verbiage "has alternative Federal or State authority by which it may impose a suspension or" before "makes a fraud referral to another law enforcement agency."
- In § 455.23(e), we have revised subsection (3) to state: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed."
- In § 455.23(e), we have added a new subsection (6) that states: "The State determines that payment suspension is not in the best interests of the Medicaid program."
- In § 455.23(f), we have revised subsection (2) to read: "The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part."
- In § 455.23(f), we have added a new subsection (5) that states: "The State determines that payment suspension only in part is in the best interests of the Medicaid program."

E. Proposed Approach and Solicitation of Comments for Sections 6102 and 6401(a) of the Affordable Care Act —Ethics and Compliance Program

1. Statutory Changes

Under section 6102 of the ACA which established new section 1128I of the Act, a nursing facility (NF) or SNF shall have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care, consistent with regulations developed by the Secretary, working jointly with the HHS OIG. The regulations to establish the compliance and ethics program for operating organizations may include a model compliance program. The statute requires that in the case of an organization that has five or more facilities, the formality or specific elements of the program vary with the size of the organization. The statute also requires that not later than 3 years after the effective date of the regulations, the Secretary shall complete an evaluation of the programs to determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in the quality of resident care. The Secretary shall submit to the Congress a report on such evaluation with recommendations for changes in the requirements, as the Secretary deems appropriate.

Similarly, under section 6401(a) of the ACA, which established a new section 1866(j)(8) of the Act, a provider of medical or other items or services or a supplier shall, as a condition of enrollment in Medicare, Medicaid or CHIP, establish a compliance program that contains certain "core elements." The statute requires the Secretary, in consultation with the HHS OIG, to establish the core elements for providers or suppliers within a particular industry or category. The statute allows the Secretary to determine the date that providers and suppliers need to establish the required core elements as a condition of enrollment in Medicare, Medicaid, and CHIP. The statute requires the Secretary to consider the extent to which the adoption of compliance programs by providers or suppliers is widespread in a particular industry sector or particular provider or supplier category. Please note, NFs and

SNFs are subject to both compliance plan requirements under sections 6102 and 6401(a) since section 6401(a) of the ACA includes all providers and suppliers enrolling into Medicare, Medicaid and CHIP. We intend to establish compliance program core elements per section 6401(a) of the ACA for NFs and SNFs that closely match the required components of a compliance program per section 6102 of the ACA.

2. Proposed Ethics and Compliance Program Provisions

In order to consider the views of industry stakeholders, we solicited comments on compliance program requirements included in the ACA. We do not intend to finalize compliance plan requirements in this final rule with comment period; rather, we intend to do further rulemaking on compliance plan requirements and will advance specific proposals at some point in the future. We were most interested in receiving comments on the following:

The use of the seven elements of an effective compliance and ethics program as described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual (*http://www.ussc.gov/2010guid/20100503_Reader_Friendly_Proposed_Amendments.pdf,* pp. 31–35) as the basis for the core elements of the required compliance programs for Medicare, Medicaid and CHIP enrollment. These elements instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable laws, regulations and requirements, and include:

- The development and distribution of written policies, procedures and standards of conduct to prevent and detect inappropriate behavior;
- The designation of a chief compliance officer and other appropriate bodies (for example a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program and who report directly to high-level personnel and the governing body;
- The use of reasonable efforts not to include any individual in the substantial authority personnel whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance and ethics program;
- The development and implementation of regular, effective education and training programs for the governing body, all employees, including high-level personnel, and, as appropriate, the organization's agents;
- The maintenance of a process, such as a hotline, to receive complaints and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
- The development of a system to respond to allegations of improper conduct and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or Federal health care program requirements;
- The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
- The investigation and remediation of identified systemic problems including making any necessary modifications to the organization's compliance and ethics program.

In addition, we are particularly interested in comments about the following:

- The extent to which, and the manner in which, providers and suppliers already incorporate each of the seven U.S. Federal Sentencing Guidelines elements into their compliance programs or business operations. We are interested in how and to what degree each element has been incorporated effectively into the compliance programs of different types of providers and suppliers considering their risk areas, business model and industry sector or particular provider or supplier category.
- Any other suggestions for compliance program elements beyond, or related to, the seven elements referenced previously considering provider or supplier risk areas, business model and industry sector or particular provider or supplier category including whether external and/or internal quality monitoring should be a required for hospitals and long-term care facilities.
- The costs and benefits of compliance programs or operations including aggregate or component costs and benefits of implementing particular elements and how these costs and benefits were measured.
- The types of systems necessary for effective compliance, the costs associated with these systems and the degree to which providers and suppliers already have these systems including, but not limited to, tracking systems, data capturing systems and electronic claims submission systems. We anticipate having providers and suppliers evaluate the effectiveness of their compliance plans using electronic data.
- The existence of and experience with State or other compliance requirements for various providers and suppliers and foreseeable conflicts or duplication from multiple requirements.
- The criteria we should consider when determining whether, and if so, how to divide providers and suppliers into groupings that would be subject to similar compliance requirements including whether individuals should have different compliance obligations from corporations.
- Available research or individual experience regarding the current rate of adoption and level of sophistication of compliance programs for providers or suppliers based on their business model and industry sector or particular provider or supplier category.
- How effective compliance programs have been for varied providers and suppliers and how the level of effectiveness was measured.
- The extent to which providers and suppliers currently use third party resources, such as consultants, review organizations, and auditors, in their compliance efforts.
- The extent to which providers and suppliers have already identified staff responsible for compliance and, for those who already have staff responsible for compliance, the positions of these staff.
- A reasonable timeline for establishment of a required compliance program for various types and sizes of providers and suppliers, assuming the compliance program core elements were based on the aforementioned U.S. Federal Sentencing Guidelines' seven elements of an effective compliance and ethics program, considering business model and industry sector or particular provider or supplier category.

We welcomed any information concerning how the industry views compliance program elements and how we can establish required compliance program elements to protect Medicare, Medicaid, and CHIP from fraud and abuse.

3. Analysis of and Responses to Public Comment

We received numerous comments on compliance program elements in response to this request. Though we will not respond to those comments within this final rule with comment period, these will be considered for further rulemaking on compliance plan requirements.

4. Final Provisions—Ethics and Compliance Program

We are not finalizing these provisions in this final regulation. We are in the process of developing a new Notice of Proposed Rule Making incorporating the

compliance plan provisions and comments received that will be published at a later date. The proposed rule will also have an opportunity for further public comment.

F. Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

1. Statutory Change

Section 6501 of the ACA amends section 1902(a)(39) of the Act to require a State Medicaid program to terminate any provider, be it an individual or entity, participating in that program, subject to the limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act, if the provider's participation has been terminated under title XVIII of the Act or another State's Medicaid program. Effective provider screening prevents excluded providers from enrolling in government health care programs and being paid with Federal and State funds. Effective screening of providers barred from participation can reduce the risk of fraud, waste, and abuse in the Medicare and Medicaid programs and CHIP

When a State terminates a provider but does not share that information with any other State, all other States become vulnerable to potential fraud, waste, and abuse committed by that provider. Similarly, a provider, supplier, or eligible professional that has been terminated from Medicare or has had Medicare billing privileges revoked may enroll with a State Medicaid program or with CHIP when a State is not aware of the Medicare termination or revocation. We may terminate or revoke the billing privileges of a provider, supplier, or eligible professional under Medicare for a number of reasons, as set forth at § 424.535, including exclusion from health care programs, government-wide debarment, and conviction of certain violent felonies and financial crimes.

Section 6501 of the ACA requires a State's Medicaid program to terminate an individual or entity's participation in the program (subject to certain limitations on exclusions in sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act), if the individual or entity has been terminated under Medicare or another State's Medicaid program. Although the term "termination" only applies to providers under Medicare whose billing privileges have been revoked (and does not apply to Medicare suppliers or eligible professionals), we believe it was the intent of the Congress that this requirement also be applicable to suppliers and eligible professionals that have had their billing privileges under Medicare revoked as well. Therefore, we proposed that "termination" be inclusive of situations where an individual's or entity's billing privileges have been revoked. The requirement for States to terminate would only apply in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause. "For cause" may include fraud, integrity or quality, but not cases where the providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked based upon voluntary action taken by the provider to end its participation in the program, except where that voluntary action is taken to avoid a sanction, or where a State removes inactive providers from its enrollment files.

In addition, State Medicaid programs would terminate a provider only after the provider had exhausted all available appeal rights in the Medicare program or in the State that originally terminated the provider or the timeline for such appeal has expired.

Section 6501 of the ACA builds upon the requirements in section 6401(b)(2) of the ACA, which requires that we establish a process to make available Medicare provider, supplier, and eligible professional and CHIP provider termination information to State Medicaid programs. Section 1902(kk)(6) of the Act also requires States to report adverse provider actions to CMS, including criminal convictions, sanctions, and negative licensure actions.

When States are apprised of the terminations or revocations of billing privileges, as the case may be, of providers, suppliers, and eligible professionals that have occurred in other State Medicaid programs, CHIP, or in Medicare, States have the information they need to protect their programs.

2. Proposed Provisions for Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

We proposed at § 455.416(c) that a State Medicaid program must deny enrollment or terminate the enrollment of a provider that is terminated on or after January 1, 2011 under Medicare, or has had its billing privileges revoked, or is terminated on or after January 1, 2011 under any other State's Medicaid program or CHIP.

While section 6501 of the ACA does not expressly require that individuals or entities that have been terminated under Medicare or Medicaid also be terminated from CHIP, we also proposed, under our general rulemaking authority pursuant to section 1102 of the Act, to require in CHIP regulations that CHIP take similar action to terminate a provider terminated or revoked under Medicare, or terminated under any other State's Medicaid program or CHIP.

We also proposed to add a definition at § 455.101 for termination for purposes of this section. That definition distinguishes between Medicaid providers and Medicare providers, suppliers, and eligible professionals and specifies that termination means a State Medicaid program or the Medicare program has taken action to revoke the Medicaid provider's or Medicare provider, supplier or eligible professional's billing privileges and the provider, supplier or eligible professional has exhausted all applicable appeal rights. There is no expectation on the part of the provider, supplier, or eligible professional or the State or Medicare program that the termination or revocation is temporary. The provider, supplier or eligible professional would be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

3. Analysis of and Responses to Public Comment

We received the following comments:

Comment: One commenter stated that while there is value to the States to have additional autbority under which to deny or terminate Medicaid providers, it will be necessary to amend current statute and regulations to include new reasons for denials and terminations, and additional time will be required.

Response: In accordance with section 6508(b) of the ACA, a State may delay implementation of this provision if the Secretary determines that State legislation is required.

Comment: Commenters asked for clarification regarding ACA section 6401(b)(2) that requires CMS to establish a process to make available Medicare provider, supplier, and eligible professional and CHIP termination information to State Medicaid programs. Commenters asked if a mechanism was in place for States to check for terminated providers starting January 1, 2011. One commenter requested clarification as to how State Medicaid programs would communicate with Medicare contractors when the States had revoked or suspended a Medicaid enrollment. Another commenter asked if the Provider Enrollment, Chain, and Ownership System (PECOS) would be

used. Another commenter stated it would be "next to impossible" to carry out this provision without an effective way to obtain information from Medicare regarding terminated providers. One commenter urged CMS to establish a national database that contains Medicare, CHIP termination and exclusion information as well as information on terminations from all State Medicaid programs.

Response: We are in the process of establishing a secure web-based portal that will allow States to share information regarding terminated providers. Using this web-based portal, a State will be able to upload as well as download information regarding its terminated providers and download information regarding terminated providers in other States and Medicare. States will not be required to report those providers who were terminated prior to January 1, 2011. Access to the information-sharing portal is limited to users that we have approved.

Comment: Some commenters requested that CMS clarify the timeframes for State reporting of terminations.

Response: States should report terminations on a monthly basis in order to assist other States and the Medicare program in protecting themselves from providers who pose an increased risk to government health care programs.

Comment: One commenter requested that States be granted real time access to the exclusion database. Another commenter suggested that CMS consider leveraging existing Federal databases such as the NPI and NPPES.

Response: We are in the process of exploring potential opportunities to leverage existing databases and infrastructure that would enable timely access to provider enrollment data across programs. We are currently examining to what extent we can support such a centralized information sharing solution.

Comment: One commenter requested clarification that Medicaid termination should only last as long as the Medicare termination, especially in States where "terminate" means "permanent exclusion."

Response: When a State terminates a provider based on the fact that the provider was terminated by Medicare, the duration of the State's termination action should be consistent with State law, and not necessarily driven by the length of the Medicare termination. The same would hold true when a State terminates a provider based on a termination action in another State. We do not wish to dictate to States the duration of their terminations.

Comment: One commenter contended that the proposed rule did not detail the parameters of the termination process. Specifically, it did not state what would happen if a provider is wrongfully terminated from participation in Medicare or another public benefit, or the different termination scenarios—such as the effect on a group practice if a provider in that group is suspected of fraud. The commenter also requested further explanation and clarification regarding the timeline and parameters for termination of provider participation in Medicare, Medicaid, and CHIP.

Response: For purposes of the Medicaid program, the parameters of the termination process would be governed by the terminating State's administrative appeals processes. Accordingly, the timeline and parameters for termination will vary depending on the State in which the termination occurs. State Medicaid agencies and CHIP must deny enrollment or terminate the enrollment of any provider that is terminated by Medicare or another State's Medicaid program or CHIP on or after January 1, 2011. If a provider is wrongfully terminated from Medicare or another State's Medicaid program or CHIP, and a subsequent State has already terminated such provider from its Medicaid program or CHIP, the subsequent State should reinstate the provider once the subsequent State has evidence demonstrating that the provider was wrongfully terminated.

When an individual provider is terminated by a State Medicaid program or CHIP, the effect on a group practice would be that the individual provider who is terminated may not participate in the Medicaid or CHIP programs until that provider is eligible to, and does re-enroll. Therefore, neither the individual provider, nor the group practice would be able to bill Medicaid or CHIP for care and/or services provided by the individual provider that has been terminated.

Comment: One commenter stated that termination is defined to be inclusive of situations where an individual or entity's billing privileges have been revoked. The commenter requested clarification because not all providers have billing privileges. For example, a particular pharmacist may be denied participation in a State's Medicaid program; however, because the pharmacist does not have direct billing privileges, another State would not have to also terminate that provider.

Response: The requirement for termination is not limited to situations in which a provider is billing the Medicaid program. The requirement for termination applies to enrolled providers generally, not just billing providers. An enrolled provider that has had its billing privileges revoked by Medicare must be terminated by the States' Medicaid programs, regardless of whether the provider is submitting claims.

Comment: One commenter requested clarification for States regarding termination when a provider has more than one NPI or Medicare ID number. A commenter inquired if CMS will terminate a provider's NPI, Medicare legacy number or both. This commenter also asked if a provider has multiple NPIs and/or Medicare numbers, does Medicare terminate a provider under one number but allow them to continue to participate under other NPI/Medicare numbers. This commenter indicated that if the response is yes, would a State be expected to follow suit, that is, terminate only the NPI that Medicare has terminated. Finally, the commenter asked what States should do in cases where providers have multiple legacy Medicaid numbers that crosswalk to a single NPI.

Response: It is the provider, not the provider's identifiers, which are to be terminated under this provision. Thus, to the extent that Medicare terminated one or multiple NPIs/Medicare legacy numbers for cause that are tied to one provider we generally expect that State Medicaid agencies will follow suit. Accordingly, if one provider has multiple Medicaid identification numbers, then the State would be required to terminate such provider numbers if the State determines there is cause for such termination and the provider has exhausted its appeal rights.

Comment: Several commenters expressed concern over the potential for terminations of affiliated providers when one provider had been terminated in another State. One commenter asked if other State Medicaid agencies will be compelled to terminate affiliates that have a common corporate parent. A commenter asked if terminations for a corporation apply to any branches or franchises of that corporation.

Response: Section 6501 of the ACA does not require the termination of affiliates of terminated entities. Accordingly, we are not requiring States at this time to terminate affiliates of those individuals or entities that have been terminated by another Medicaid program or had their billing privileges revoked by the Medicare program.

Comment: One commenter stated that it is a common State statutory requirement or best practice for a provider to form a legal corporate entity

unique to the State. The commenter requested clarification for the legal basis for Federal enforceability of termination from or denied enrollment into a State's program based upon the termination or denial status in another State where the provider and its principals are the same individuals but the "provider" is a separate legally incorporated entity under State law.

Response: Section 1902(a)(39) of the Act requires State Medicaid agencies to terminate the participation of any individual or entity that has been terminated under Medicare or another State's Medicaid program. When a State is contemplating a termination as a result of a termination that was initiated by another State's Medicaid program, and there is a question regarding the identity of the provider who is the subject of the termination, it is generally up to the subsequent terminating State to determine whether a provider in their State is the same provider that was initially terminated by another State's Medicaid program. In order to determine whether a provider in one State is the same provider that was terminated in another State, a State could look at a variety of factors, including, but not limited to, NPI and correspondence address. The State could also communicate with the Medicaid agency that originally terminated the provider to help resolve the question of the provider's identity. If the State believes that background checks are required to verify the identity of a provider, then States should conduct such background checks. We believe the States should have flexibility to determine the best method for identity verification.

Comment: One commenter suggested that the regulatory definition of termination at § 455.101 should be revised to include the termination of persons or entities with an ownership or control interest or who is an agent or managing employee of a provider.

Response: The ACA does not contemplate termination based upon ownership or control. The statute requires termination of the same individual or entity that was terminated by Medicare or another State's Medicaid program.

Comment: A few commenters requested that CMS clarify in the final rule with comment period that termination from the Medicaid program must only occur when a provider has had billing privileges revoked or terminated by Medicare for cause.

Response: The requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to, fraud, integrity or quality issues. In addition, we have defined "termination" in the final rule with comment period as occurring when a State Medicaid program has taken action to terminate a provider and the provider has exhausted all applicable appeal rights that are available in the State or the Medicare program, or the timeline for appeal has expired, whichever is applicable.

Comment: One commenter requested information regarding how managed care organizations will be able to access provider termination information.

Response: We encourage States to share such information with their managed care entities.

Comment: One commenter requested that an appeals process be established for providers and suppliers that would permit a provider/supplier to continue to provide care under a program if they can demonstrate "good cause exemptions."

Response: While we appreciate the commenter's suggestion, section 6501 of the ACA requires States to terminate the participation of any provider that has been terminated under Medicare or another State's Medicaid program, and allows for exceptions only as permitted under sections 1128(c)(3)(B) and 1128(d)(3)(B) of the Act.

Comment: Commenters expressed concern that the proposed rule allows for the imposition of sanctions based upon findings made outside the agency. For example, if Medicare revokes a provider's billing privileges and a State initiates a termination action as a result of such revocation, then, in the commenter's view, the proposed rule gives the provider a right to use the State administrative appeal process to challenge anew the Medicare revocation.

Response: We disagree. The provider is not provided a new forum in which to litigate the Medicare termination action. The ACA does not give a State the authority to review a Medicare termination action. The statute requires a State to terminate a provider that was terminated by Medicare or another State's Medicaid program, with certain limited exceptions.

Comment: A few commenters indicated that the proposed regulation fails to state that termination from the Medicaid program must only occur in situations in which the provider or supplier had its billing privileges terminated or revoked for cause, that is, fraud, integrity or quality issnes.

Response: We agree. In the regulatory definition for "termination," we will state that the requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to, fraud, integrity or quality issues.

Comment: Certain commenters requested a specific timeline for due process in connection with the appeal of termination actions and the parameters of the termination process in Medicaid.

Response: As we have indicated previously in these responses, we believe that States should have the flexibility to decide termination actions consistent with their individual State administrative appeals process. In addition, since State law and regulations may vary with regard to this issue, we defer to the States regarding their existing termination processes.

Comment: One commenter suggested that reciprocal termination must be limited to revocations of privileges due to fraud and where the physician has exhausted all possible appeal rights.

Response: We agree. As stated in the proposed rule, the requirement for States to terminate would only apply in cases where providers, suppliers or eligible professionals were terminated or had their billing privileges revoked for cause. In addition, we defined "termination" as occurring when a State Medicaid program has taken action to revoke a Medicaid provider's billing privileges and the provider has exhausted all applicable appeal rights that are available in that State, or the timeline for appeal has expired, or when the Medicare program has revoked the provider or supplier's billing privileges and the provider or supplier has exhausted all applicable appeal rights, or the timeline for appeal has expired.

Comment: One commenter requested a definition of "eligible professional."

Response: In the context of terminations, "eligible professional" is a term that is specific to the Medicare program. For purposes of the Medicare program, an eligible professional may include a physician assistant, nurse practitioner, or clinical nurse specialist, certified nurse-midwife, clinical social worker, clinical psychologist, registered dietitian or nutrition professional. *See* section 1842(b)(18) of the Act.

Comment: Certain commenters requested clarification regarding when a termination is triggered under the statute.

Response: A termination in a subsequent State is triggered when Medicare or a State Medicaid program has taken action to revoke a provider's billing privileges for cause *and* the provider has exhausted all applicable appeal rights that are available in

Medicare or the originally-terminating State or the timeline for appeal has expired.

Comment: A commenter stated that section 6 of Executive Order 13132 requires that: (1) Each agency have an accountable process to ensure meaningful and timely input by State officials in the development of regulatory policies that have Federalism implications, and (2) no agency shall promulgate any regulation that has Federalism implications that imposes substantial direct compliance cost on State governments. The commenter recommended that CMS explain the process that was used to ensure that meaningful and timely input was received from the States prior to the development of this proposed rule.

Response: We have worked closely with State Medicaid agencies on the proposed rule and in the development of the final rule with comment period.

Comment: One commenter requested clarification regarding the process of how Medicare reinstatements will be communicated to States and whether States will be required to automatically reinstate a provider in the Medicaid program once a provider "finishes the Medicare termination/revocation period."

Response: Presumably, States will be notified by providers who are seeking re-enrollment or reinstatement in the Medicaid program. It is the responsibility of the States to validate the status of a provider's termination with Medicare. When a provider may seek re-enrollment is up to the discretion of the States and should be consistent with State law. Similarly, the duration of termination should be consistent with existing State law.

4. Final Provisions for Termination of Provider Participation Under the Medicaid Program and CHIP if Terminated Under the Medicare Program or Another State Medicaid Program or CHIP

We have retained the provisions of the proposed rule, with the exception of the following:

• In § 455.101, we have added the following subsection (3) to the definition of termination: "The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to: (i) Fraud; (ii) integrity; or (iii) quality."

G. Additional Medicare Provider Enrollment Provisions

1. Statutory Changes

Section 6501 of the ACA requires States to terminate a provider or supplier under the Medicaid program when the provider or supplier has been terminated by Medicare or by another State's Medicaid program. We believe that permitting CMS to revoke Medicare billing privileges when a State Medicaid agency terminates, revokes, or suspends a provider or supplier's Medicaid enrollment or billing privileges works in tandem with section 6501 of the ACA.

2. Proposed Provisions for Additional Medicare Provider Enrollment

In § 424.535(a)(11), we proposed allowing CMS, directly or through its contractor, to revoke Medicare billing privileges when a State Medicaid agency terminates, revokes, or suspends a provider or supplier's Medicaid enrollment or billing privileges. Moreover, we believe that providers and suppliers whose enrollment has been terminated by a State Medicaid program may pose an increased risk to the Medicare program.

3. Analysis of and Response to Public Comments

We received one comment on the proposed provision related to Medicare termination.

Comment: A commenter stated that proposed § 424.535(a)(11) contains an editorial error that makes the language of the proposed rule difficult to understand.

Response: Section 424.535(a) lists reasons for revocation of Medicare enrollment. § 424.535(a)(12) is one such reason—if a State has terminated a provider from Medicaid, Medicare can terminate the provider from Medicare. We will reword the language in § 424.535(a)(12) to clarify the circumstances being addressed.

4. Final Provisions for Additional Medicare Provider Enrollment

This final rule with comment period finalizes the provisions of the proposed rule in regards to our discretion to revoke a provider or supplier's Medicare billing privileges when terminated, revoked or suspended by a State Medicaid agency with no modifications.

H. Technical and General Comments

Comment: A commenter stated that the definition of "provider of services" in section 1861(u) of the Act and "supplier" in section 1861(d) of the Act differs from the meaning of "provider of services" and "supplier," respectively, in the proposed rule. The commenter also was unclear as to whether the proposed rule's references to "providers" refer to "provider of services." The commenter requested clarification on both issues.

Response: The proposed rule stated that in Medicare, the term provider of services under section 1861(u) of the Act means health care entities that furnish services primarily payable under Part A of Medicare, such as hospitals, home health agencies (including home health agencies providing services under Part B), hospices, and skilled nursing facilities. The term "suppliers" defined in section 1861(d) of the Act refers to health care entities that furnish services primarily payable under Part B of Medicare, such as independent diagnostic testing facilities (IDTFs), durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) suppliers, and eligible professionals, which refers to health care suppliers who are individuals, that is, physicians and the other professionals listed in section 1848(k)(3)(B) of the Act. For Medicaid and CHIP, we use the terms "providers" or "Medicaid providers" or "CHIP providers" when referring to all Medicaid or CHIP health care providers, including individual practitioners, institutional providers, and providers of medical equipment or goods related to care. The term "supplier" has no meaning in the Medicaid program or CHIP.

Comment: A commenter suggested that to avoid misinterpretation, non-physician practitioners should be clearly defined in the final rule with comment period.

Response: The proposed and final rule with comment period refer to non-physician practitioners to mean any non-physician practitioner who is eligible to enroll in Medicare, Medicaid or CHIP under existing regulations and statutes. In addition, this term is already defined at section 1848(b)(18)(C) of the Act.

Comment: A commenter stated that with the issuance of CMS–1510–F on November 2, 2010, CMS should renumber the denial and revocation reasons found in this proposed rule. In CMS–1510–F, CMS finalized a new denial reason in § 424.530(a)(8) and a new revocation reason in § 424.535(a)(12).

Response: We have revised these provisions in the regulatory text.

Comment: A commenter stated that CMS violated section 6(a) of Executive Order 12866 by not giving the public a 60 day review period for this rule and that CMS only allowed a 55 day review period. The commenter also could not

find a CMS Press Release or information on the CMS Web site indicating that CMS notified the public that it placed this rule on display and began the public comment period in advance of the publication of the proposed rule in the **Federal Register**. The commenter recommended that CMS reissue a new proposed rule or extend the comment period for this proposed rule by additional 60 days.

Response: The Department of Health and Human Services released a press release on September 20, 2010 accessible on its Web site that announced the display of the proposed rule at the **Federal Register**. The press release is accessible at: *http://www.hhs.gov/news/press/2010pres/09/20100920e.html.* Additional media outlets reported the proposed rule display on September 17th, 2010. We do not believe it is appropriate to extend the comment period for an additional 60 days, and we have taken into account all comments received during the comment period.

Comment: Several commenters stated that the proposed timeframe for implementation and compliance is extremely aggressive. First, smaller, rural providers and suppliers may not be organizationally able to fully comply without significant cost and effort, thus impacting access to care. Second, the DME MACs and the NSC will have to be able to identify suppliers and implement payment edits, both by specialty code.

Response: As stated previously, the timeline is a required under the ACA. We have been working closely with our contractors and with providers and suppliers to ensure that compliance with this final rule with comment period will not affect patients' access to health care.

Comment: Several commenters stated that the implementation timetables for this proposed rule were too ambitious, and that sufficient lead time is necessary for CMS to have operational computer programs in place to administer these requirements correctly and consistently.

Response: This final rule with comment period is implementing provisions of the ACA which sets forth deadlines for implementation of the screening provisions.

Comment: A commenter stated that in its manual instructions, CMS describes the verification of legalized status for physicians and non-physician practitioners. However, the commenter stated that the proposed rule is silent regarding the verification or screening process that will be used to determine legal status of an owner, authorized official, delegated official, managing employee, physician or non-physician. The commenter recommended that CMS explain this process in the proposed rule. Another commenter urged CMS to revise its existing CMS–855 enrollment applications to include questions on residency, legal status, and/or citizenship, arguing that this would help reduce fraud.

Response: Information collected on the CMS–855 enrollment applications are used to verify residency, including the Social Security Number and the Date of Birth. This process is a part of the general screening process, and is applied to all screening levels, including limited.

Comment: A commenter stated that since illegal immigrants are not legally authorized to work in the United States or own or operate a business in the United States, CMS should: (1) Coordinate and verify both the identity and work status of any individual practitioner or owner with the United States Citizenship and Immigration Services, and (2) establish new Medicare, Medicaid and CHIP denial and revocation reasons when an individual is not authorized to work in the United States legally and that CMS refer any individuals to the appropriate authorities for expulsion from the United States.

Response: As stated previously, we have existing procedures in place that verify an applicant's eligibility to work in the United States.

Comment: One commenter recommended that CMS furnish the number of providers and suppliers by specialty type that have or do not have an enrollment record in PECOS. This will, the commenter believes, help clarify the impact of this rule on providers and suppliers.

Response: This final rule with comment period does not impact the enrollment requirements related to PECOS for providers and suppliers. In May of 2010, we published CMS—6010–IFC which required all physicians and eligible professionals who order and refer home health services or Part B items and services (excluding Part B drugs) to Medicare to be enrolled in PECOS. Additional communications have been published with regard to that interim final rule with comment period, and do not impact the provisions finalized here. This final rule with comment period established the screening requirements for providers under Medicare, Medicaid and CHIP, and application fees for newly enrolling or revalidating providers. All newly enrolling or revalidating providers must establish records in PECOS as this is the only available enrollment option at this time.

Comment: A commenter stated that Medicare, Medicaid and CHIP must work in tandem to assnre compliance, so that bad actors cannot move from one program to another and shelter themselves through the lack of coordinated data, standards, information and enforcement.

Response: We concur with this comment. This final rule with comment period implements the ACA provision that requires State Medicaid Agencies, to terminate a provider when a provider has been terminated by Medicare added at § 455.416. This final rule with comment period also implements regulations at § 455.470 that authorizes State Medicaid agencies to impose a temporary moratoria when Medicare imposes such a moratoria, except when the State Medicaid agency determines an imposition would affect beneficiaries' access. These provisions are directly aimed at eliminating the type of program abuses addressed by the commenter.

Comment: A commenter stated that despite the additional burdens it will create, it supported the proposed rule because there is no alternative. The commenter stated that if fraud, abuse and waste are not eliminated and quality improvement is not made central to home health and hospice, it feared for the future of home-based care when it is needed most.

Response: We agree with the commenter. We believe that these provisions are intended to protect the integrity of these programs for future generations.

Comment: A commenter suggested that CMS should change its contractors' claims processing system to a system similar to that used by credit card companies. This will help ensure that fraud and abuse can be detected in real time, rather than later.

Response: We are continually exploring additional improvements to our data systems, but disagree with the commenter's suggestion that we must change all of our contractors systems to implement real time data analysis. We are committed to working with both private and public partners to evaluate technologies that can provide the scalability and safeguards to beneficiary access that are necessary to ensure accurate payments to legitimate providers for appropriate services supplied to enrolled beneficiaries.

Comment: A commenter stated that CMS should establish a new requirement that organized medical staffs and hospitals report the provision of (but not the results of) peer review as

a quality indicator, and that CMS should post the quality indicator for each hospital department on its Hospital Compare Web site, together with an explanation of the importance of peer review to assure patient safety, quality, and identification of medically unnecessary services.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address the reporting of quality indicators or the Hospital Compare Web site.

Comment: A commenter stated that MACs should no longer accept certain CPT codes for laboratory test payments.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address our coverage and payment decisions for CPT codes.

Comment: A commenter stated that CMS should consider bidding out laboratory coding to a contractor, similar to the manner in which the PDAC operates for DME coding.

Response: This comment is beyond the scope of this rule. This final rule with comment period does not address the bidding of laboratory coding to a contractor.

Comment: A commenter expressed support for many of the details and provisions contained within the proposed rule and requested that CMS continue to seek input from all stakeholders about matters related to hospitals and health systems.

Response: We concur with the commenter's request to continue to seek input from all stakeholders, and fully intend to do so in regard to the requirements of this final rule with comment, as well as annual payment regulations.

Comment: A commenter expressed concern that anti-fraud laws and regulations, adopted to root out unscrupulous activity resulting from criminal intent, are increasingly used to impose harsh penalties for inadvertent mistakes and contribute to the escalating costs of health care as providers attempt to comply with increasingly voluminous and sophisticated systems and requirements.

Response: We continually balance the necessity to eliminate fraud, waste, and abuse with reducing the burden on legitimate providers, suppliers, and beneficiaries. Section 6401 of the ACA requires that the Secretary determine the level of screening according to the risk of fraud, waste, and abuse. This final rule with comment period implements this provision by instituting levels of screening based on risk of fraud, waste, and abuse, and has the flexibility to adapt to future developments by adjusting the categories as appropriate. We will use this new authority to prevent just such situations as described by the commenter, and will reduce the burden on legitimate providers who may make mistakes, and target fraud prevention resources appropriately.

Comment: A commenter stated that serial number tracking should be considered for much of the equipment provided by DMEPOS suppliers, similar to the Vehicle Identifier Number (VIN) system used in the transportation manufacturing industry.

Response: While we appreciate this comment, it appears to be outside the scope of this rule. Also, this comment would require a thorough evaluation of the cost of such a requirement on DMEPOS suppliers, the access issues it could potentially cause to beneficiaries if we mandated that only serial numbered equipment must be provided to beneficiaries, the additional system requirements that we would need to enhance to track such equipment, and the estimated benefit from such a requirement.

Comment: A commenter stated that the fight against health care fraud would be bolstered if Medicare, Medicaid and private insurers would share information about providers' enrollment and billing patterns. The commenter therefore recommended that CMS: (1) Revise its regulations and the CMS–855 to collect information about all other health care payers, and (2) share the information it collects via the enrollment and payment process with private payers, Medicaid, and Medicare Advantage Organizations.

Response: We would have to carefully evaluate the commenter's proposal. We must go through notice of rulemaking and comment period before revising any regulation. Additionally, we would have to carefully consider the privacy issues that accompany increased data sharing, especially with private payers, and weigh the potential concerns of providers and suppliers with the expected benefit of such a measure. However, we have been working closely with private and public partners regarding strategies to effectively work together to have a broad view of the health care claim landscape, and will continue to evaluate opportunities to collaborate on the improved detection of health care fraud.

Comment: A commenter urged CMS to consider ways to enhance Medicare CoPs for home health and hospice providers to achieve more lasting changes. The commenter stated that CMS withdrew the proposed CoPs changes for home health in 1997 and has not taken further action. The commenter recommended that CMS consult with provider groups to revise and finalize the CoPs for home health as quickly as possible.

Response: This comment is outside of the scope of the final rule with comment period.

Comment: A commenter recommended that CMS: (1) Provide the direct savings that have resulted from provider screening activities between 2000 and 2010, (2) calculate the savings to the Medicare Trust Funds and the General Fund based on this proposed rule, and (3) explain whether the estimated savings will result in fewer actual dollars spent on health care or whether the changes proposed will only slow the expenditure growth.

Response: We believe that all of the agency's program integrity activities have resulted in savings to the Trust Fund and the General Fund. We are not required to report a return on investment regarding historical screening initiatives, or project savings regarding the statutory requirements. The fact that we have in the past denied any application means that we have prevented an unqualified provider or supplier from providing services and/or care to Medicare beneficiaries that could have resulted in physical harm or financial loss to such a beneficiary.

Comment: One commenter stated that this proposed rule will be ineffective in halting fraud because it is reactive, and it is impossible for any government entity to react in a timely manner.

Response: We disagree with the comment that the new authorities in this final rule with comment period are reactive. Particularly, the screening requirements for newly enrolling providers which will proactively prevent individuals from entering the Medicare, Medicaid and CHIP programs for the sole purpose of defrauding taxpayers. Temporary moratoria will also permit the agency to develop a strategy to mitigate the risk of fraud while stopping the pace of potentially fraudulent enrolling providers. We believe these new tools will enable us to become a more proactive gatekeeper of the Medicare Trust Fund.

Comment: A commenter recommended that all providers and suppliers be subject to the provisions associated with section 6401(a)(3) of the ACA.

Response: This comment is outside of the scope of this final rule with comment period.

Comment: A commenter contended that CMS's statement in the preamble that Medicare is the primary payer of health care for 45 million enrolled

beneficiaries is incorrect. The correct number should be more than 47 million. The commenter also recommended that CMS provide the number of Medicare beneficiaries that are enrolled in Medicare Advantage plans.

Response: We will address this correction in the preamble. The provisions of this final rule with comment period do not apply to Medicare Advantage plans, so the number of Medicare Advantage-enrolled beneficiaries would not be relevant to the preamble.

Comment: A commenter questioned whether CMS could implement the provisions of this proposed rule when information on its provider enrollment Web site is not regularly updated.

Response: We are implementing provisions of this proposed rule, and are working with the provider community in various outlets, including its provider Web site. The provider enrollment Web site will reflect the requirements of this final rule with comment period.

Comment: Several commenters stated that the Federal and State programs will be more efficient if they recognize another program's enrollment determinations, decisions to suspend payments, and imposition of moratoria. To handle the complexity and coordination of monitoring participation and appropriately suspending payments or terminating contracts with providers and suppliers, the commenter recommended CMS develop and maintain a central, consolidated database for housing participation status, suspension of payments and imposed moratoria for all three programs. The commenters stated that CMS should also strengthen and expand efforts to coordinate data sharing between government health programs across the various Federal agencies, as well sharing of information with MAOs, MCOs and CHIP sponsors.

Response: We agree with the previous comment that we should seek to become more efficient by sharing screening determinations, decisions to suspend payments and imposition of enrollment moratoria to the extent possible under applicable laws. We are continually evaluating and strengthening efforts to coordinate data sharing between health programs across various agencies.

Comment: A commenter stated that regulators and industry need to work together to minimize the impact of sham companies and other instances of fraud, and that this proposed regulation is a step in the right direction.

Response: We agree with this comment.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For this final rule with comment period, we will be retaining the Collection of Information estimates in the proposed rule, in accordance with the discussion below.

A. ICRs Regarding Medicare Application Fee Hardship Exception (§ 424.514)

Section 424.514(e) states that a provider or supplier that believes it has a hardship that justifies a waiver exception of the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies a waiver exception. The burden associated with this requirement is the time and effort necessary to submit a Medicare enrollment application, which is required currently of any individual or entity enrolling in Medicare. In addition to the enrollment application, a provider or supplier would have the new burden of drafting and submitting a letter to justify its hardship waiver request should it choose to submit one. The burden associated with submitting Medicare enrollment applications A, B, I, R and CMS–855S, are currently approved under Office of Management and Budget (OMB) control numbers 0938–0685 and 0938–1057, respectively). Although we have no way of knowing for certain how many entities will actually submit an application with a letter requesting a waiver, we know that there are likely to be more such requests in the early years of implementation than in later years. We estimated that in the first year, 12,000 providers or suppliers—or slightly over 50 percent of the total number of providers and suppliers that we believe will be subject to the application fee—will submit waiver request letters as part of their application packages. (As stated in the preamble, the application fee does not apply to individual eligible professionals nor to group practices of these individual professionals.) We also estimated that it will take each provider or supplier 1 hour to develop the letter. The total estimated annual burden associated with this requirement is therefore 12,000 hours at a cost of $600,000, or $50.00 per waiver request.

B. ICRs Regarding Medicare Fingerprinting Requirement (§ 424.518)

Consistent with § 424.518 we will require the submission of a set of fingerprints—either electronically collected by CMS' authorized channeler or using the FD–258 standard fingerprint card obtained from the local law enforcement agency that collected the fingerprints—from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in a prospective HHA or DMEPOS supplier that is enrolling in Medicare. We estimate that CMS or its designated contractors will make 7,000 such requests per year. This is predicated on our projection that—based on 2009 statistics—roughly 7,000 DMEPOS suppliers and HHAs will annually enroll in Medicare. For purposes of this ICR statement only, and to ensure that we do not underestimate the possible burden, we estimate that all of these providers and suppliers will be required to submit fingerprints. We further estimate that an average of five individuals per provider or supplier will be required to comply with this request. (It must be noted that for purposes of this ICR and the RIA below, we sought comments on whether the estimate of five individuals per applicant is accurate. No comments were received.) Additionally, we estimate that it will take each of the 35,000 respondents (7,000 provider requests × 5 respondents per provider request) an average of 2 hours to obtain and submit fingerprints. Consequently, the total estimated annual burden associated with this requirement is 70,000 hours (35,000 responses × 2 hours per response) at a cost of $3.5 million (70,000 hours × $50 per hour).

Sections 424.518(c)(3)(ii) and (iii) call for the submission of a set of fingerprints for a national background

check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in a provider or supplier that has moved into the "high" risk category based on an adverse action or the lifting of a moratorium. The burden associated with this requirement is the time and effort necessary for the individual to submit the required information upon request. We estimate that CMS or its designated contractors will make 2,000 requests per year. This is based on the number of providers and suppliers that we estimate will attempt to enroll in Medicare: (1) After the lifting of a moratorium for their respective provider or supplier type, or (2) that have had one of the adverse actions in § 424.518(c)(3)(ii) imposed against it. This estimate of course, cannot be conclusively quantified because it is impossible for us to say with certainty which provider and supplier types will be subject to a moratorium. To ensure that we do not underestimate the potential burden, we also calculated projections should 5,000 or 10,000 requests be made.

We estimate that an average of five individuals per provider or supplier will be required to comply with this request. We further project that it will take each of the 10,000 respondents (2,000 provider or suppliers requests × 5 respondents per provider or supplier request) an average of 2 hours to obtain and submit the fingerprints. The estimated annual burden associated with this requirement, based on 2,000 requests is 20,000 hours (10,000 respondents × 1 response per respondent × 2 hours per response) at a cost of $1 million (20,000 hours × $50 per hour). If 5,000 requests are made, the burden is 50,000 hours at a cost of $2.5 million (5,000 requests × 5 responses per request × 2 hours per response × $50 per hour.) If 10,000 requests are made, the burden is 100,000 hours at a cost of $5 million (10,000 requests × 5 responses per request × 2 hours per response × $50 per hour).[6]

In addition, there are some limited circumstances when CMS could ask a physician to submit fingerprints. For example, a provider or supplier that is being enrolled in Medicare after the lifting of a temporary moratorium could automatically be classified as "high" risk and, as such, would be subject to criminal background checks and fingerprinting of owners of the company. If a physician were to have a 5 percent or greater direct or indirect ownership interest in the provider or supplier, CMS would have the authority to request fingerprints from him or her. Other circumstances might include when a physician has had an adverse action imposed against him or her and, in accordance with § 424.518(c)(3)(ii), has been placed in the "high" risk category. We estimate that CMS or its designated contractors will make 500 such requests for fingerprints per year. We further estimate that it will take each of the 500 respondents a total of 2 hours to obtain and submit the fingerprints. The total estimated annual burden associated with this requirement is 1,000 hours (500 respondents × 1 response per respondent × 2 hours per response) at a cost of $50,000 (1,000 hours × $50 per hour).

Therefore, assuming that 2,000 post-moratorium requests for fingerprints are made, the total estimated annual burden associated with the Medicare requirements in this ICR is 103,000 hours at a cost of $5,150,000. If 5,000 post-moratorium requests are made, the estimated annual burden is 133,000 hours at a cost of $6,650,000. If 10,000 post-moratorium requests are made, the estimated annual burden is 183,000 hours at a cost of $9,150,000.

Comment: In the collection of iuformation requirements section of this proposed rule, CMS used 2009 statistics for estimating the number of individuals that will need to undergo fingerprinting. A commenter recommended that CMS update these estimates using 2010 data.

Response: We believe it is more appropriate to use the most recent full year's data.

Comment: A commenter contended that CMS's estimate that it will take 2 hours to obtain a set of fingerprints using the FD–258 standard fingerprint card seems low. The commenter recommended that CMS provide the analysis used, including literature review, to estimate the time it will take to obtain a set of fingerprints using the FD–258 fingerprint card. The commenter also asked that CMS explain whether there are any alternatives to the FD–258 standard fingerprint card and, if there are, the costs associated with these alternatives.

Response: We believe that the 2 hour figure, which was based on our analysis of a number of materials, is accurate. Since the FD–258 is the standard fingerprint card, we focused primarily on the use of this format in the proposed rule. However, as explained in the preamble to this final rule with comment period, electronic fingerprints will be an alternative—and one that we will encourage—to the FD–258.

C. ICRs Regarding Medicaid Fingerprinting Requirement (§ 455.434)

Section 455.434 states that when a State Medicaid agency determines that a provider is "high" risk, the State Medicaid agency will require that provider to submit fingerprints. We anticipate that States will be collecting fingerprints on a significantly smaller number of providers. However, as with our estimates of the potential burden for the Medicare requirements, we preferred to overestimate the potential burden rather than underestimate it. Therefore, we anticipate that States may require an additional 26,000 individuals to submit fingerprints prior to enrolling in a State's Medicaid program or CHIP. The total estimated annual burden associated with this requirement for Medicaid and CHIP is 52,000 hours (26,000 respondents × 1 response per respondent × 2 hours per response) at a cost of $2.6 million (52,000 hours × $50 per hour).

D. ICRs Regarding Suspension of Payments in Cases of Fraud or Willful Misrepresentation (§ 455.23)

As stated in § 455.23(a), a State Medicaid agency must suspend all Medicaid payments to a provider when there is pending an investigation of a credible allegation of fraud under the Medicaid program against an individual or entity unless it has good cause to not suspend payments or to suspend payment only in part. The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments. A provider may request, and must be granted, administrative review where State law so requires.

The burden associated with this requirement is the time and effort necessary for a provider to request administrative review where State law so requires. While this requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.4.

E. ICRs Regarding Collection of SSNs and DOBs for Medicaid and CHIP Providers (§ 455.104)

As stated in § 455.104(b)(1), the State Medicaid agency must require that all persons with an ownership or control interest in a provider submit their SSN and DOB. The burden associated with the Medicaid requirements in § 455.104(b)(1) is the time and effort necessary for a provider to report the SSN and DOB for all persons with an ownership or control interest in a provider.

Although our data on Medicaid provider enrollment at the national level

[6] Note that these figures pertain only to individuals who are not physicians. Physicians are addressed in the following paragraph.

is very limited, we do collect annual data on State Medicaid program integrity activities. This annual data collection, known as the State Program Integrity Assessment (SPIA) program, approved under OCN 0938–1033, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated.

According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2 year period of FFY 2007 and FFY 2008. We estimate that one-fifth or 371,014 (1,855,070 × 20 percent) of existing Medicaid providers would be required to re-enroll each year. Additionally, we estimate that there will be 56,250 newly enrolling Medicaid providers each year, for a total of 427,264 Medicaid providers that will be subject to the SSN and DOB reporting requirements each year. We further estimate that it will take each provider an average of 2 minutes to report the SSN and DOB for all persons with an ownership or control interest. Thus, the estimated annual burden associated with this requirement for Medicaid providers is 14,242 hours (427,264 × (2 minutes, divided by 60 minutes per hour)) at a cost of $712,100 (14,242 hours × $50 per hour).

F. ICRs Regarding Site Visits for Medicaid-Only or CHIP-Only Providers (§ 455.450)

As stated in § 455.450(b), a State Medicaid agency must conduct on-site visits for providers it determines to be "moderate" or "high" categorical risk. We anticipate that Medicare contractors will perform the screening activities for the overwhelming majority of providers that are dually enrolled in both Medicare and Medicaid and thus, we estimate that State Medicaid agencies will conduct approximately 5,000 site visits for Medicaid-only providers nationally per year. We further estimate that it will take one individual 8 hours to perform each on-site visit (including travel time). Thus, the total estimated annual burden associated with this requirement for Medicaid is 40,000 hours (5,000 site visits × 8 hours) at a cost of $2,000,000 (40,000 hours × $50 per hour).

G. ICRs Regarding the Rescreening of Medicaid Providers Every 5 Years (§ 455.414)

As stated in § 455.414, a State Medicaid agency must screen all providers at least every 5 years. This requirement is consistent with the Medicare requirement that providers, suppliers, and eligible professionals must re-enroll at least every 5 years (more often for certain types of suppliers). The burden associated with this requirement would be the time and effort necessary for Medicaid-only providers to re-enroll in Medicaid, and the time and effort necessary for a State to conduct the provider screening,

Although our data on Medicaid provider enrollment at the national level is very limited, we do collect annual data on State Medicaid program integrity activities. As previously explained, this annual data collection, known as the State Program Integrity Assessment (SPIA) program, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated.

According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2 year period of FFY 2007 and FFY 2008. We estimate that one fifth, or 371,014 (1,855,070 × 20 percent), of existing Medicaid providers would be required to re-enroll each year. Although provider enrollment requirements vary by State, we further estimate that it will take each provider an average of 2 hours to complete the Medicaid re-enrollment requirements. Thus, the estimated annual burden associated with this requirement for Medicaid providers is 742,028 hours (371,014 responses × 2 hours per response) at a cost of $37,101,400 (742,028 hours × $50 per hour).

In addition, we estimate that 80 percent of Medicaid providers also participate in Medicare, and thus would have provider screening activities performed by the Medicare contractors. Thus, we estimate that States would be required to conduct provider screening activities for 74,203 (371,014 × 20 percent) re-enrolling Medicaid-only providers each year. We further estimate that it will take States, on average, 4 hours to perform the required provider screening activities—noting that currently enrolled providers would generally be categorized as lower risk than newly-enrolling providers. The estimated burden associated with this requirement for State Medicaid agencies is 296,812 hours (74,203 responses × 4 hours per response) at a cost of $14,840,600 (296,812 hours × $50 per hour). We believe that the burden on States will be in large part offset by the application fees collected and by the Federal share for the amounts not covered by the application fee.

The total estimate annual burden associated with the Medicaid prescreening requirement is 1,038,840 hours at a cost of $51,942,000 ($37,101,400 + $14,840,600).

TABLE 10—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
§ 424.514(e)**	0938–0685; 0938–1057	12,000	12,000	1	12,000	50	600,000	0	600,000
§ 424.518(c)(2)(b) and (d)	0938–New	35,000	35,000	2	70,000	50	3,500,000	0	3,500,000
§ 424.518(c)(3)(iv) end (d)	0938–New	10,500	10,500	2	21,000	50	1,050,000	0	1,050,000
§ 455.434	0938–New	26,000	26,000	2	52,000	50	2,600,000	0	2,600,000
§ 455.104	0938–New	427,264	427,264	.033	14,242	50	712,100	0	712,100
§ 455.450	0938–New	5000	5000	8	40,000	50	2,000,000	0	2,000,000
§ 455.414 (Providers)	0938–New	371,014	371,014	2	742,028	50	37,101,400	0	37,101,400
§ 455.414 (State Medicaid Agencies)	0938–New	74,203	74,203	4	296,812	50	14,840,600		14,840,600

TABLE 10—ESTIMATED ANNUAL REPORTING/RECORDKEEPING BURDEN—Continued

Regulation section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/maintenance costs ($)	Total cost ($)
Total		960,981	960,981		1,248,082				62,404,100

** Denotes that we will be submitting revisions of the currently approved information collection requests for OMB review and approval.

Comment: A commenter requested clarification on whether the dollar figure of $62 million in Table 6 of the proposed rule (entitled "Estimated Annual Reporting/Recordkeeping Burden") is the cost shared by the Federal Medicare programs as well as all of the State Medicaid agencies collectively.

Response: It includes Medicare costs, and those of the State Medicaid agencies.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "**DATES**" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period is needed to implement the following provisions of the ACA: (1) Section 6401(a) and section 6401(b) of the ACA added section 1866(j)(2) to the Act and requires the establishment of screening procedures for providers and suppliers in the Medicare, Medicaid and CHIP programs; (2) section 6401(a) of the ACA added section 1866(j)(2)(C) to the Act and requires the establishment of application fees for institutional providers and suppliers; (3) section 6401(a) of the ACA added a new section 1866(j)(7) to the act establishing the use of temporary moratoria regarding the enrollment of providers and suppliers in Medicare, and section 6401(b)(1) of the ACA added a new section 1902(kk)(4) of the Act for a parallel requirement in the Medicaid and CHIP programs; (4) section 6501 of the ACA added section 1902(a)(39) to the Act establishing guidance for States regarding the termination of providers from Medicaid and CHIP if terminated by Medicare or another Medicaid State plan or CHIP; and permitting guidance regarding the termination of providers and suppliers from Medicare if terminated by a Medicaid State agency; and (5) Section 6402(h) of the ACA added 1862(o) to the Act establishing the requirements for the suspension of payments pending credible allegations of fraud in the Medicare and Medicaid programs. As previously explained, we believe these provisions are necessary to assist us in preventing fraud, waste and abuse in the Medicare, Medicaid and CHIP programs.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (U.S.C. 804(s)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). This final rule with comment period does reach the economic threshold and thus is considered an economically significant rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. Under the RFA, we must either prepare an Initial Regulatory Flexibility Analysis or certify that the final rule with comment period will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.0 to $34.5 million (depending on provider type) in any one year. Individuals and States are not included in the definition of a small entity. We do not believe that our application fees will have a significant impact on any small entities. Likewise, we do not believe that other screening provisions, such as the provision of fingerprints or accommodating unannounced visits, will have a significant impact on any small entities. We believe this final rule with comment period could have significant impact on a relatively small proportion of small businesses in terms of restrictions on federal health monies paid to small businesses participating in the Medicare or Medicaid programs or CHIP. Clearly, imposition of an enrollment moratorium would have an impact on a small business that is attempting to do business with any of the Federal health programs. Similarly, suspension of payments to any small entity could create a significant impact on that entity. However, we have no basis for estimating how many entities might be affected by these provisions. Finally, we believe that this final rule with comment period will reduce fraud and abuse among potential providers.

We believe there will be a significant impact on their ability to defraud the taxpayer in several ways. First, closer screening of certain high-risk providers and suppliers will better enable CMS to detect those individuals and entities that pose a risk to the Medicare program. We expect that the prevention of unqualified providers and suppliers from enrolling in Medicare will protect the Medicare Trust Fund and save the taxpayers millions of dollars. Second, the temporary moratoria provisions will enable CMS to restrict the entry of certain providers and suppliers into Medicare in order to prevent or combat fraud, waste, and abuse, thus, again, saving millions of Federal dollars. While we cannot quantify with exactitude the amount of money that the Medicare program will save as a result of these measures, we do believe that the figure will exceed the costs outlined in this RIA. We solicited comment on the overall proposed screening processes of the proposed rule, including how the risk of fraud is determined, the administrative

interventions proposed to address the risk, and the criteria for exceptions to the enrollment application fee and any temporary enrollment moratoria. We requested that small businesses comment on these provisions and offer suggestions about how to mitigate what they might see as adverse administrative or financial impacts. This RIA, taken together with the remainder of the preamble, constitutes an Initial Regulatory Flexibility Analysis under the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we have determined that this final rule with comment period will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $135 million. This rule does mandate expenditures by State and local governments, in order to enforce the Medicaid-related provisions, but we believe that those expenditures will be relatively minor. The mandated costs on providers—primarily for application fees—may approach or exceed the threshold for the private sector. Accordingly, this RIA constitutes the required assessment of costs and benefits under UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this final rule with comment period would not impose any substantial direct requirement costs on State or local governments, preempt State law, or otherwise have Federalism implication, the requirements of E.O. 13132 are not applicable.

We received several comments on the RIA. They are as follows:

Comment: A commenter noted that, under the proposed rule, Medicare contractors will not begin processing an enrollment application until the application fee is received and credited to the United States Treasury. The commenter recommended that CMS estimate the increase in enrollment application processing times due to the fee requirement and the impact this additional time will have on private sector.

Response: It is not possible to qualify the additional time, if any, that this requirement would have on processing times. Moreover, we do not believe that a minor delay in processing would result in any quantifiable and definable monetary cost to a particular provider.

Comment: Several commenters contended that CMS did not comply with section 6(a)(3)(C)(i) of Executive Order 12866. Specifically, CMS: (1) Did not include an assessment or quantification of benefits associated from this regulatory action; (2) the underlying analysis of the costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation; (3) explain why the planned regulatory action is preferable to the identified potential alternatives; (4) include any feasible alternatives to the planned screening process; (5) include alternatives to the payment suspension portions; (6) include the cost impact on health care providers due to increased processing times; (7) solicit comments on or consider the costs or benefits of reasonably feasible alternatives, such as assessing the application fee by NPI or TIN or assessing the risk based on as past experience with the Medicare program or other health plans; or (8) consider the Medicare error rate in determining the category of risk. The commenter stated that CMS should therefore not finalize the provisions of this proposed rule until a new proposed rule is published.

Response: The proposed rule and the final rule with comment period both contain a Regulatory Impact Analysis as required by Executive Order 12866. As explained in section IV.E. and throughout this final rule with comment period, we believe that this regulation will have a significant benefit by reducing the ability of potential providers to defraud taxpayers. The proposed rule solicited comments on the proposed screening categories, on the use of fingerprinting and other alternatives to identity verification, on the kind of documentation that must be submitted to assert a hardship exception to the application fee, an alternative definition of the term "resolution of an investigation," on criteria that would justify the reclassification of a provider from one risk category to another, on the applicability of geography in the determination of a risk category, and on additional triggers that would move a provider into a different risk category.

We did not believe the use of NPIs or TINs in the assessment of the application fee was appropriate because the requirement to submit an enrollment application is separate from the requirement to have an NPI or a TIN. We believe that basing the fee on the submission of an application is most consistent with the statute. With respect to the Medicare error rate, an erroneously paid claim does not necessarily mean that the claim was fraudulently submitted. For this reason, we believe it would be improper to use it in our placement of providers into risk categories when there were other factors—including comprehensive studies of fraudulent behavior, such as OIG and GAO reports—that were more conclusive. We have solicited comments on proposals and potential alternatives, and have considered such comments in the development of this final rule with comment period.

Comment: A commenter stated that the proposed rule contained a number of internal inconsistencies between the preamble and regulation impact statement, such as: (1) use of 2.34 percent as the CPI in preamble and 3.0 percent as the CPI in the regulation impact section; (2) the lack of an "Alternatives Considered" section in the regulation impact section, and (3) a failure to account for the cost or impact of the additional off-cycle revalidations in the regulation impact section. The commenter recommended that CMS publish a new proposed rule.

Response: The use of 2.34 percent in the preamble was simply for illustrative purposes. Having said that we have revised the 3 percent figure to more accurately reflect actual and projected CPI–U statistics we have received. Specifically, the rates we used for 2011, 2012, 2013, 2014 and 2015 are, respectively, 1.0 percent, 2.0 percent, 2.0 percent, 2.0 percent and 2.0 percent. The figure for 2011 is based on data obtained from the Bureau of Labor Statistics, while the data for years 2012 through 2015 represent the estimated CPI–U figures offered in the Budget of the U.S. Government, Fiscal Year 2011. The CPI–U figures reflect the percentage change in the consumer price index for all urban consumers (all items; United States city average), for the 12-month period ending with June of the previous year. Moreover, we have added an "Alternative Considered" section to the RIA.

As stated previously, we solicited comments on multiple issues in the

proposed rule. Additionally, we are implementing provisions of the ACA that had already outlined certain requirements for the regulations. The ACA, for example, required that we determine the level of screening to be conducted with respect to the category of provider or supplier, to require an application fee of $500 adjusted after 2010 for the consumer price index, and to suspend payments pending an investigation of credible allegations of fraud.

The RIA took into account the cost of revalidations beginning on March 25, 2011, prior to the date at which CMS conld begin off-cycle validations under § 424.515(e), but the same date at which the new screening requirements will go into effect. Any provider validated after March 25, 2011 but before March 23, 2012 will not be subject to off-cycle revalidation and any provider that is revalidated will begin a new cycle of revalidation requirements. Therefore, any off-cycle revalidations that occur after March 23, 2012 will restart the revalidation cycle, and only DMEPOS suppliers who are on 3 year validations will be revalidated, in cycle, prior to the end of CY 2015. We believe the RIA is valid.

Comment: A commenter noted that, under the proposed rule, Medicare contractors will not begin processing an enrollment application until the application fee is received and credited to the United States Treasury. The commenter recommended that CMS estimate the increase in enrollment application processing times due to the fee reqnirement and the impact this additional time will have on private sector.

Response: It is not possible to qualify the additional time, if any, that this requirement would have on processing times. Moreover, we do not believe that a minor delay in processing would result in any quantifiable and definable monetary cost to a particular provider.

Comment: One commenter stated that the preamble of this proposed regulation uses 2.34 percent as the Consumer Price Index (CPI) for the application fee, while the regulatory impact section uses 3 percent as the CPI for the application fee. The commenter recommended that CMS: (1) Use the official percentage by the Bureau of Labor Statistics in calculating the change in application fee year by year, (2) explain if a negative CPI will result in a decrease in the application fee, and (3) use the actual CPI for 2010 in developing the final rule with comment period and establishing the application fee that must be paid by providers and suppliers in 2011.

Response: We agree and, as previously explained, have incorporated more accurate CPI–U rates into this final rule with comment period. A negative CPI would result in a fee decrease; however, the RIA projects a continued increase in the CPI.

Comment: A commenter noted that CMS states in the RIA that 400,000 providers and suppliers would need to revalidate their enrollment over a 5 year period. However, CMS excluded groups and clinics from the impact of the application fee. The commenter did not believe there are 400,000 providers and suppliers to revalidate, since a large number of providers and suppliers are designated as medical groups/clinics. The commenter recommended that CMS furnish a breakdown of the providers and suppliers that would be required to revalidate their enrollment in Medicare and adjust, if necessary, the amount collected via the application fee. The commenter also suggested that CMS provide the number of providers and suppliers by year that were subject to revalidation since 2006.

Response: We do not believe that a specific breakdown by provider type and year is necessary, and maintain our view that approximately 400,000 providers and suppliers will revalidate their enrollment over a 5 year period—even accounting for medical groups/clinics. This figure, admittedly, may be a little high, but we would prefer to overestimate the potential burden than underestimate it.

In light of these comments, we have revised our calculations based on new and more accurate CPI–U rates and have added an "Alternative Considered" section.

C. Anticipated Effects

1. Medicare

a. Enhanced Screening Procedures—Medicare

Based on statistics obtained from PECOS and our Medicare contractors, there are approximately 400,000 providers and suppliers currently enrolled in the Medicare program. (This does not include eligible professionals.) This figure includes ambulance service suppliers; ambulatory surgical centers; community mental health centers; comprehensive outpatient rehabilitation facilities; suppliers of DMEPOS; end-stage renal disease facilities; federally qualified health centers; histocompatibility laboratories; home health agencies; hospices; hospitals, including physician-owned specialty hospitals; critical access hospitals; independent clinical laboratories; independent diagnostic testing facilities; Indian health service facilities; mammography centers; mass immunizers (roster billers); medical groups/clinics, including single and multi-specialty clinics; organ procurement organizations; outpatient physical therapy/occupational therapy/speech pathology services; portable x-ray suppliers; skilled nursing facilities; radiation therapy centers; religious non-medical health care institutions; and rural health clinics. We note the following in section III. of this final rule with comment period:

- Based on 2009 experience we estimated that there will be 7,000 DMEPOS suppliers and HHAs that will submit an application to become a new Medicare enrolled provider in 2011. We would require approximately 35,000 individuals (7,000 providers/suppliers x 5 individuals per applicant) to undergo fingerprinting to participate in the Medicare program as an owner of an HHA or supplier of DMEPOS. We have found that the cost of having a set (two prints) of fingerprints done through law enforcement is approximately $50.00 per individual. (This includes the time spent in obtaining the fingerprints.) The cost of this fingerprinting requirement would therefore be $1.75 million per year (35,000 individuals x $50).
- We estimated that 10,000 individuals (2,000 providers or suppliers × 5 individuals per applicant) would undergo fingerprinting following the lifting of a moratorium on a particular provider or supplier type, at a cost of $500,000 per year (10,000 × $50). Should requests be made of 5,000 providers or suppliers, the annual figure would be $1,250,000 (5,000 × 5 individuals per applicant × $50). Should requests be made of 10,000 providers or suppliers, the annual figure would be $2.5 million (10,000 × 5 × $50).
- We estimate that 500 physicians would undergo fingerprinting per year, at a cost of $25,000.

This results in a total cost of the fingerprinting requirement of $2,275,000 per year ($1,750,000 + $500,000 + $25,000), or $11,375,000 over 5 years. If 5,000 post-moratorium requests are made, the annual cost is $3,025,000, with a 5 year cost of $15,125,000. Should 10,000 post-moratorium requests be made, the annual cost is $4,275,000, with a 5 year cost of $21,375,000.

As we believe that 2,000 post-moratorium requests is the most likely scenario, we will hereafter use the $2,275,000 amount as the annual cost of this requirement. This results in an estimated 5 year cost of $11,375,000.

b. Application Fee—Medicare

The Secretary shall impose an application fee on each institutional provider. The amount of the fee is $500 per provider or supplier for 2010. For 2011 and each subsequent year, the fee amount will be determined by the statutorily required formula using the consumer price index for all urban consumers (CPI–U). The enrollment application fee does not apply to individual eligible professionals (for example, physicians). The fee is to be paid by institutional providers only. The new screening provisions are applicable to new and revalidating providers and suppliers effective March 25, 2011, and to currently enrolled providers and suppliers as of March 23, 2012. We will to begin collecting the enrollment application fee for new providers and suppliers and for currently enrolled providers revalidating enrollment effective March 25, 2011.

c. General Enrollment Framework

(1) New Enrollment

Medicare contractors report that over the last several years, approximately 32,000 is the annual number of newly enrolling providers and suppliers that would—without accounting for the possible granting of waivers—be subject to the enrollment application fee—(approximately 20,000 for Medicare Part B, approximately 7,000 DMEPOS suppliers and HHAs (as explained in the Collection of Information section), and approximately 5,000 non-HHA Medicare Part A providers).[7]

We assumed that no more than 2.5 percent of these 32,000 providers and suppliers—or 800—will receive a hardship exception; as indicated earlier, exceptions will only be approved infrequently.

In CY 2011, we reduced the estimate number of institutional providers subject to the application fee by 25 percent because the application fee will not begin until March 25, 2011. Accordingly, the number of institutional providers that we anticipate paying the application fee will be 23,400 (or 31,200 × .75) in CY 2011. Therefore, the impacts of the enrollment application fee are as follows. If we use 23,400 as the number of newly enrolling providers and suppliers in 2011 and multiply this number by an application fee of $505 (or $500 × 1.0 percent), we get $ 11,817,000 collected for the first year (that is, CY 2011). If we assume that the number of newly enrolling providers and suppliers will remain constant at 31,200 for years 2012 through 2015, the cost to the number of newly enrolling providers and suppliers would be $78,054,600. Although we have no way to predict that the number of new enrollments will change in future years, it is possible that the number of enrolling providers and suppliers vary from what has been the norm. If our estimate of the number of newly enrolling providers is inaccurate and we enroll a different number of providers and suppliers after the effective date of the new screening and other provisions contained in the ACA, we estimate based on the $500 enrollment application fee—a rough difference of $1 million for each increment of 2,000 new enrollments, whether fewer or greater.

TABLE 11—CUMULATIVE APPLICATION FEES FOR NEWLY ENROLLING MEDICARE PROVIDERS AND SUPPLIERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Newly enrolling institutional providers and suppliers	Newly enrolling institutional providers and suppliers paying the application fee (based on a 2.5% hardship exception rate)	CPI–U increase (%)	Consumer price index adjusted fee in dollars *	Total fees for each year in dollars	Cumulative fees in dollars
2011	24,000	23,400	1.0	505	11,817,000	11,817,000
2012	32,000	31,200	2.0	515	16,068,000	27,885,000
2013	32,000	31,200	2.0	525	16,380,000	44,265,000
2014	32,000	31,200	2.0	536	16,723,200	60,988,200
2015	32,000	31,200	2.0	547	17,066,400	78,054,600
Total					78,054,600	78,054,600

* As already mentioned, section 6401(a)(3) of the ACA called for a $500 application fee for institutional providers in 2010. Since the effective date of this final rule with comment period is March 25, 2011, we have added a 1.0 percent increase to the $500 fee for 2011. Moreover, each fee amount in this category was rounded up to the nearest dollar.

(2) Revalidation

There are approximately 100,000 currently enrolled suppliers of DMEPOS who are required to revalidate their enrollment every 3 years and 300,000 additional providers and suppliers that do not provide DMEPOS that are required to revalidate their enrollment every 5 years. On a yearly basis, we estimate that approximately 33,000 DMEPOS suppliers (one-third of the total) and 60,000 other, non-DMEPOS providers/suppliers (one-fifth of the total) would revalidate their enrollment in Medicare, for an annual total of 93,000. Since, as explained earlier, we estimate that no more than 2.5 percent of these providers and suppliers will receive a waiver from the application fee, we project that 90,675 such providers and suppliers will be subject to the fee.

This final rule with comment period contemplates collecting the application fee for currently enrolled providers that revalidate their enrollment on or after March 25, 2011—almost 3 months into CY 2011. Therefore, we have adjusted the number of existing Medicare institutional providers subject to an application fee by 25 percent, from 90,675 to 68,006 (or 90,675 × .75) in CY 2011. With respect to the period between CY 2012 and 2015, it is possible that, as previously alluded to in the preemble, we may perform an elevated number of revalidations early in this 4-year timeframe—specifically, in CY 2012. This would be done

[7] For purposes of the calculations in this RIA, newly-enrolling Medicare providers and suppliers include those that were once enrolled, departed, and are now seeking to enroll again.

pursuant to our authority under § 424.515(e) to require off-cycle revalidations. We cannot say for certain how many will be performed in CY 2012. For purposes of this RIA only, however, we will estimate that 111,000 will be conducted in CY 2012, with 87,000 performed in each of the remaining 3 years. Further accounting for projected annual CPI–U rate increases, we estimate that the cost associated with these fees for revalidating providers and suppliers would be approximately $226,477,505 over the first 5 years that the ACA provisions are in effect, as shown in Table 12.

TABLE 12—CUMULATIVE APPLICATION FEES FOR REVALIDATING MEDICARE PROVIDERS AND SUPPLIERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Revalidating institutional providers and suppliers	Revalidating institutional providers & suppliers paying application fee (based on 2.5% hardship exception rate)	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year (in dollars)	Cumulative fees (in dollars)
2011	69,750	68,006	1.0%	505	34,343,030	34,343,030
2012	111,000	108,225	2.0%	515	55,735,875	90,078,905
2013	87,000	84,825	2.0%	525	44,533,125	134,612,030
2014	87,000	84,825	2.0%	536	45,466,200	180,078,230
2015	87,000	84,825	2.0%	547	46,399,275	226,477,505
Total					226,477,505	226,477,505

Therefore, we estimate that the total impact of the provisions for the application fee to be approximately $304,532,105 over the next 5 years. This number was approximated by adding the cumulative application fees for newly enrolling providers and suppliers ($78,054,600 as shown in Table 11) to the cumulative application fees for revalidating providers and suppliers ($226,477,505).

2. Medicaid

a. Enhanced Screening Procedures

Although our data on Medicaid provider enrollment at the national level is very limited, we do collect annual data on State Medicaid program integrity activities. This annual data collection, known as the State Program Integrity Assessment (SPIA) program, consists of self-reported data by States regarding a variety of program integrity related activities. The information is self-reported and has not been independently verified by CMS, and it undoubtedly represents some unknown degree of duplication among providers across States. Consequently, the estimated number of Medicaid providers nationally is likely overstated. According to SPIA data for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2-year period of FFY 2007 and FFY 2008. This universe of Medicaid providers includes all provider types, both institutional providers and individual practitioners. In the Medicare program, eligible practitioners make up approximately 70 percent of the total universe of providers, suppliers, and eligible practitioners. Because we do not have detailed information regarding the breakdown of Medicaid providers by type nationally, we will apply the same ratio to determine the percentage of institutional Medicaid providers. Therefore, we estimate that there are approximately 556,521 Medicaid-only providers nationally that are not individual practitioners.

We also estimate almost all CHIP providers are also Medicaid providers. So, for purposes of this section, we are considering CHIP providers to also be Medicaid providers and will subsequently refer to them only as Medicaid providers.

As previously stated in the Medicare section of the analysis, we estimated that we would require the following:

- Approximately 35,000 individuals will undergo fingerprinting to enroll in the Medicare program as owners, of a home health agency or supplier of DMEPOS. Based on data collected as part of the State survey and certification activities for home health agencies, less than 1 percent of home health agencies are Medicaid-only. And, although there is no data available on the number of Medicaid-only suppliers of DMEPOS, we estimated that the number is minimal as well, as a number of States require suppliers of DMEPOS to be enrolled in Medicare prior to enrolling in Medicaid. Therefore, we estimated that States may require approximately 1,000 additional individuals with ownership interests in suppliers of DMEPOS or home health agencies, to undergo fingerprinting for enrollment in the Medicaid program. The cost of this fingerprinting requirement would be approximately $50,000 (1,000 × $50 = $50,000), though we solicited comments on the accuracy of this figure.
- We anticipated that Medicare contractors will perform the screening activities for the overwhelming majority of providers following the lifting of a Secretary-imposed temporary moratorium and for the limited circumstances in which physicians may be fingerprinted. However, given that States may also classify certain Medicaid-only providers as "high" categorical risks, we are estimating that States may require approximately 25,000 additional individuals to undergo fingerprinting prior to enrolling in a State's Medicaid program, at a cost of $1,250,000 (25,000 × $50 = $1,250,000).

Consequently, we estimated that fingerprinting individuals for purposes of Medicaid enrollment will cost $1,300,000. When averaged across 50 States, the District of Columbia and Puerto Rico, the annual cost of fingerprinting per State will be $26,000.

b. Application Fee—Medicaid

For those providers not screened by Medicare, the State may impose a fee on each institutional provider being screened. The amount of the fee is $500 per provider for 2010. For 2011 and each subsequent year, the amount will be determined by the statutorily-required formula using the consumer price index for all urban consumers (CPI–U).

c. General Enrollment Framework

For purposes of this section, we assume that 80 percent of institutional Medicaid providers will be dually participating in both Medicare and Medicaid, and thus will be subject to the application fee as part of the Medicare screening and enrollment. Therefore we estimated that 20 percent, or 111,304 (556,521 × 20 percent), of the institutional Medicaid-only providers will not be screened by Medicare and thus will be subject to the application fee under Medicaid. We project that a significant number of existing and future Medicaid providers will request a hardship exception, or that a State will request a waiver of the application fee for certain Medicaid provider types of the application fee on the basis of ensuring access to care. For purposes of this section, although we have no way to estimate the exact number of providers that will ultimately request and be approved for a hardship exception, or the number of States that will request a waiver of the fee for certain Medicaid provider types, we predict that 25 percent of all Medicaid providers subject to the fee will receive the hardship exception or be granted a waiver of the fee on the basis of ensuring beneficiary access to care. We recognize that this 25 percent figure is significantly higher than the 2.5 percent waiver rate we are using for Medicare application fees. Yet we believe the difference is justified because of the greater access to care issues that may arise in Medicaid. Consequently, we estimated that 83,478 existing Medicaid providers will be required to pay the application fee (111,304 existing Medicaid providers that are not dually enrolled less 25 percent or 27,826 existing providers).

(1) New Enrollments

We apply the 80 percent rate for newly-enrolling Medicaid institutional providers that will be dually participating in both Medicare and Medicaid and thus not subject to the fee under Medicaid, and 25 percent hardship exception rate to the annual number of newly-enrolling Medicaid institutional providers not dually enrolled. The 45,000 newly-enrolling Medicare institutional providers annually represent 80 percent of the total newly-enrolling Medicaid institutional providers annually. Therefore, we estimate that there will be 11,250 newly-enrolling Medicaid institutional providers annually that are subject to the application fee under Medicaid (45,000 providers divided by 80 percent, − 45,000 = 11,250). We project another 25 percent will be exempted for hardship or be granted a waiver of the fee on the basis of ensuring beneficiary access to care, resulting in 8,438 newly-enrolling Medicaid institutional providers being subject to the application fee each year nationally.

Consistent with the Medicare analysis, in CY 2011, we reduced the estimated number of institutional providers subject to the application fee by 25 percent because the application fee will not begin until March 25, 2011. Accordingly, the number of institutional providers that we anticipate paying the application fee will be 6,329 in CY 2011. Consequently, we projected the dollars due from application fees for newly-enrolling Medicaid institutional providers who are not dually enrolled to be $21,110,019 for the first 5 years in total. When averaged across 50 States, the District of Columbia and Puerto Rico, the total application fees for the 5 years in total per State will be approximately $405,962.

TABLE 13—CUMULATIVE APPLICATION FEES FOR NEWLY ENROLLED MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	New Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee (in dollars)	Total fees for each year (in dollars)	Cumulative fees (in dollars)
2011	6,329	1.0%	505	3,196,145	3,196,145
2012	8,438	2.01.1%	515	4,345,570	7,541,715
2013	8,438	2.0%	525	4,429,950	11,971,665
2014	8,438	2.0%	536	4,522,768	16,494,433
2015	8,438	2.0%	547	4,615,586	21,110,019
Total				21,110,019	21,110,019

(2) Re-enrollment

This rule contemplates that States would require Medicaid providers to re-enroll every 5 years. On a yearly basis, we estimate that approximately 16,696 Medicaid institutional providers (one fifth of the total) would re-enroll with the State Medicaid agency. We contemplate collecting the application fee for currently enrolled providers beginning on March 24, 2011. States would not collect an application fee with any re-enrollments until that time—almost 3 months into CY 2011. Therefore, we have adjusted the number of existing Medicaid institutional providers subject to an application fee by 25 percent, from 16,696 to 12,522 in CY 2011. Consequently, we project the dollars due from application fees for currently-enrolled Medicaid institutional providers who are not dually enrolled is $41,769,218 for the first 5 years in total. When averaged across 50 States, the District of Columbia and Puerto Rico, the total application fees for the 5 years in total per State will be approximately $803,254.

TABLE 14—CUMULATIVE APPLICATION FEES FOR RE-ENROLLING MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION

Calendar year	Existing Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year in dollars	Cumulative fees in dollars
2011	12,522	1.0%	505	6,323,610	6,323,610

TABLE 14—CUMULATIVE APPLICATION FEES FOR RE-ENROLLING MEDICAID PROVIDERS FOR THE FIRST 5 YEARS OF THE PROVISION—Continued

Calendar year	Existing Medicaid providers not exempted from the application fee	CPI–U increase	Consumer price index adjusted fee in dollars	Total fees for each year in dollars	Cumulative fees in dollars
2012	16,696	2.0%	515	8,598,440	14,922,050
2013	16,696	2.0%	525	8,765,400	23,687,450
2014	16,696	2.0%	536	8,949,056	32,636,506
2015	16,696	2.0%	547	9,132,712	41,769,218
Total				41,769,218	41,769,218

3. Medicare and Medicaid

a. Moratoria on Enrollment of New Medicare Providers and Suppliers and Medicaid Providers

Although we have no way of predicting the exact cost savings associated with enrollment moratoria, we expect there will be program savings achieved by implementation of this section. As stated previously, these provisions will enable us to restrict the entry of certain providers and suppliers into Medicare in order to prevent or combat fraud, waste, and abuse. However, there are no cost burdens to the public or to the provider community. Therefore, we have not estimated the cost impacts of this provision.

b. Suspension of Payments in Medicare and Medicaid

As with payment moratoria, although we have no way of predicting the exact cost savings to Medicare and Medicaid associated with implementation of the provisions contained in this final rule with comment period, we certainly expect that there will be program savings that result from implementation of this provision. CMS and its law enforcement partners already have a process for payment suspension when possible fraud is involved. The changes finalized in this rule will strengthen the existing process and its applicability to Medicaid, but it will not create any different impact or burden on the provider community in circumstances of payment suspension. There are no new cost burdens to the public or the provider community associated with this provision.

D. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement. This statement only addresses: (1) The costs of the fingerprinting requirement, and (2) the monetary transfer associated with the application fee. It does not address the potential financial benefits of these two requirements from the standpoint of their possible effectiveness in deterring certain unscrupulous providers and suppliers from enrolling in or maintaining their enrollment in Medicare and Medicaid. This is because it is impossible for us to quantify these benefits in monetary terms. Moreover, we cannot predict how many potentially fraudulent providers and suppliers will be kept out of the Medicare and Medicaid programs due to these requirements.

1. Medicare

As stated previously, we estimate a total cost of the fingerprinting requirement of $2,275,000 per year ($1,750,000 + $500,000 + $25,000), or $11,375,000 over 5 years, if 2,000 post-moratorium requests are made. If 5,000 post-moratorium requests are made, the annual cost is $3,025,000, with a 5 year cost of $15,125,000. Should 10,000 post-moratorium requests be made, the annual cost is $4,275,000, with a 5 year cost of $21,375,000. We also stated in the RIA that the expected total application fees:

- For newly enrolling providers and suppliers would be $11,817,000 in 2011, $16,068,000 in 2012, $16,380,000 in 2013, $16,723,200 in 2014, and $17,066,400 in 2015. This results in a 5 year total of $78,054,600.
- For revalidating providers and suppliers would be $34,343,030 in 2011, $55,735,875 in 2012, $44,533,125 in 2013, $45,466,200 in 2014, and $46,399,275 in 2015. This results in a 5-year total of $226,477,505.

The accounting statement reflects the: (1) Annual cost of the fingerprinting requirement, and (2) the application of the 3 percent and 7 percent discount rate to the combined amounts of the application fees for CY 2012—that is, $16,068,000 (newly enrolling) plus $55,735,875 (revalidations), for a total of $71,803,875; this constitutes a transfer of funds to the Federal government. We chose the CY 2012 figures so as to reflect the maximum amount of transferred funds in a given year during the initial 5-year period.

2. Medicaid

As stated in the RIA, we estimate that the annual cost of the fingerprint requirement for Medicaid will be $1,300,000, or $6,500,000 over a 5 year period. We also stated in the RIA that the expected total application fees:

- For newly enrolling providers and suppliers would be $3,196,145 in 2011, $4,345,570 in 2012, $4,429,950 in 2013, $4,522,768 in 2014, and $4,615,586 in 2015. This results in a 5-year total of $21,110,019.
- For revalidating providers and suppliers would be $6,323,610 in 2011; $8,598,440 in 2012; $8,765,400 in 2013; $8,949,056 in 2014; and $9,132,712 in 2015. This results in a 5-year total of $41,769,218.

The accounting statement reflects: (1) The annual cost of the fingerprinting requirement: And (2) the application of the 3 percent and 7 percent discount rate to the combined amounts of the application fees for CY 2015—specifically, $4,615,586 (new applicants) plus $9,132,712 (revalidations), for a total of $13,748,298. This constitutes a transfer of funds to the Federal government. We chose the figures from CY 2015 for Medicaid so as to reflect the maximum amount of transferred funds in a given year during the initial 5-year period.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES AND COSTS FROM CY 2011 TO CY 2015 (IN MILLIONS)

Medicare Fingerprint Requirement	COSTS	
Annualized Monetized Costs (2,000 post-moratorium requests)	3 percent Discount Rate $2.275	7 percent Discount Rate $2.275
Annualized Monetized Costs (5,000 post-moratorium requests)	$3.025	$3.025
Annualized Monetized Costs (10,000 post-moratorium requests)	$4.275	$4.275
Who is Affected?	Providers and Suppliers	
Medicare Application Fee	TRANSFERS	
Annualized Monetized Transfers (through 2015)	3 percent Discount Rate $48.2	7 percent Discount Rate $47.3
From Whom to Whom?	Providers and Suppliers to Federal Government	
Medicaid Fingerprint Requirement	COSTS	
Annualized Monetized Costs	3 percent Discount Rate $1.3	7 percent Discount Rate $1.3
Who is Affected?	Providers and Suppliers	
Medicaid Application Fee	TRANSFERS	
Annualized Monetized Costs	3 percent Discount Rate $10.1	7 percent Discount Rate $10.0
From Whom to Whom?	Providers and Suppliers to Federal Government	
	BENEFITS	

Qualitative: The above-referenced requirements will: (1) Allow CMS to more closely screen providers and suppliers that pose risks to the Medicare and Medicaid programs; (2) help offset the costs of administering the Medicare and Medicaid programs; (3) limit, via the imposition of moratoria, the entry of certain categories of providers and suppliers into Medicare if this is deemed necessary to protect the Medicare Trust Fund; and (4) suspend payments to certain providers and suppliers that pose a risk to the Trust Fund. We believe these and other financial benefits outlined in this rule will exceed the costs outlined above.

E. Alternatives Considered

1. General Burden Minimization Efforts

The RFA requires agencies to analyze options for the regulatory relief of small entities. In compliance with section 604 of the RFA, we have incorporated several options designed to minimize the burden of the requirements in this final rule with comment period.

First, we have waived the application fee for individual physicians, non-physician practitioners, and physician and non-physician practitioner groups, which are generally small businesses. We believe this is consistent with congressional intention as expressed in section 6401(a) of ACA. We also believe this will ease the financial burden on this large category of small businesses.

Second, the high-risk category is limited to relatively few types of providers and suppliers. We could have elected to include many more providers and supplier types within this category and, subsequently, subjected them to the enhanced screening requirements of fingerprint-based criminal background checks. However, in part so as not to overly burden these entities, many of which are small businesses, we chose to restrict the high-risk category to a limited number of provider types.

2. Fingerprinting

We received several comments proposing alternatives to fingerprinting as a screening mechanism. The two principal suggested alternatives were the submission of a: (1) U.S. or foreign passport; and (2) copies of the individual's Federal tax returns. However, we explained in the preamble, we are adopting fingerprint-based criminal background checks.

There are several reasons for our decision to proceed with fingerprinting as opposed to passports and tax returns. First, we are, to a large extent, combining the fingerprinting and criminal background check processes for providers and suppliers. These will be done though the FBI IAFIS, which we believe is the most reliable and appropriate avenue available. The submission of fingerprints is the only way to obtain a criminal history record check from the FBI IAFIS. Information from a U.S. or foreign passport or a Federal tax return, on the other hand, could only be used to process a name-based criminal history record check—and the FBI does not process name-based requests for non-criminal justice purposes.

Second, we believe that fingerprinting—more than any other mechanism—will allow us to conclusively identify the individuals that will be participating in the Medicare program. Indeed, a tax return, while containing certain identifying information, does not—in our view—produce the level of assurance in this area that fingerprinting does.

Finally, the use of passports or tax returns would require CMS to forgo the unified approach of the FBI IAFIS and instead have two separate processes—one for verifying identify and another for analyzing the person's criminal history. This would result in: (1) A verification process that is not as reliable as fingerprinting, and (2) a

distinct and potentially costly process for criminal background checks through private entities that, we believe, will probably not involve access to the scope of data that the FBI has.

We believe that the overall costs involved in maintaining such a two-part approach would, in the end, exceed that of the FBI IAFIS approach, especially if—as we expect—the overwhelming majority of individuals subject to the fingerprinting requirement submit them electronically. Indeed, with respect to the cost differential between the paper and electronic fingerprinting processes, we stated earlier in the RIA that we estimate an average annual cost of the fingerprinting requirement of $2,275,000 (if 2,000 post-moratorium requests are made), based on: (1) The fingerprinting of 45,500 individuals; and (2) a $50 cost per person for obtaining a set of fingerprints via the FD–258. We believe that the per person cost for submitting fingerprints electronically will be approximately $35. If we assume that 40,000 of the 45,500 individuals submit fingerprints electronically and the remaining 5,500 use the FD–258, this results in an annual cost of $1,675,000, or $600,000 less than $2,275,000. This leads to a savings over 5 years of $3,000,000 ($600,000 × 5).

It is not possible for us to quantify the costs involved in having the FBI IAFIS perform the criminal background checks. However, we can estimate that it would cost approximately $40 per person to perform a criminal background check via private entities. This would result in an annual cost of $1,820,000, or $9,100,000 over 5 years. With the efficiency furnished through the use of the FBI–IAFIS, we do not believe the cost of these checks would ultimately exceed $9,100,000.

We concede that the submission of a passport or tax return would not involve the processing costs that would come with fingerprinting. But the ability to verify one's identity via fingerprinting is, we believe, sufficiently greater than with the latter two documents, such that the overall program integrity savings would substantially exceed any additional cost incurred in using fingerprints in lieu of passports and tax returns.

3. Other Suggested Alternatives

We received several other suggested alternatives to our proposed provisions. One was to assess the application fee based on the NPI or TIN. As stated earlier in this RIA, we did not believe this approach was appropriate because the requirement to submit an enrollment application is separate from the requirement to have an NPI or a TIN. We believe that basing the fee on the submission of an application is most consistent with the statute. Another involved taking into account factors such as: (1) Error rates; (2) past history with Medicare, Medicaid and other health plans; and (3) ownership, when assessing a provider or supplier's risk. In section II of this final rule with comment period, we stated that the ACA requires levels of screening according to the risk of fraud, waste, and abuse posed by categories of providers and suppliers as a whole. The approach taken in this final rule with comment period whereby we assign specific categories of providers and suppliers to screening levels determined by risk of fraud, waste, and abuse is consistent with the requirements of the statute. Therefore, in general, we chose to use a categorical approach to our classifications, rather than assign individual providers within a particular provider type to certain risk levels.

F. Conclusion

This final rule with comment period contains provisions that are of critical importance in the transition of CMS' antifraud activities from "pay and chase" to fraud prevention. "Pay and chase" refers to the traditional approach under which we met our obligations to provide beneficiaries access to qualified providers and suppliers and to pay claims quickly by making it relatively easy for providers to sign up to bill Medicare, Medicaid or CHIP, paying their claims rapidly, and then detecting overpayments or fraudulent bills and pursuing recoveries of overpayments after the fact. That system functions reasonably well when the problems arise with legitimate providers and suppliers that will be solvent and in business when CMS seeks to recover overpayments or law enforcement pursues civil or criminal penalties. It is not adequate when the fraud is committed by sham operations that provide no services or supplies and exist simply to steal from Medicare or Medicaid and thrive on stealing or subverting the identities of beneficiaries and providers.

This final rule with comment period strikes a balance that will permit us to continue to assure that eligible beneficiaries receive appropriate services from qualified providers whose claims are paid on a timely basis while implementing enhanced measures to prevent outright fraud. The new and strengthened provisions in the ACA that are the subject of this final rule with comment period will help assure that only legitimate providers and suppliers are enrolled in Medicare, Medicaid, and CHIP, and that only legitimate claims will be paid. These provisions are applied according to the level of risk of fraud, waste, and abuse posed by different provider and supplier types. We will use screening tools for a particular provider or supplier type based on 3 distinct categories of risk: (1) Limited; (2) moderate; and (3) high. Limited risk providers will have enrollment requirements, license and database verifications; moderate risk will have those verifications plus unscheduled site visits; high risk will have verifications, unscheduled site visits, criminal background check and fingerprinting. CMS and the States will impose moratoria on the enrollment of new providers in situations when doing so is necessary to protect against a high risk of fraud. Working in conjunction with the OIG, CMS and States will suspend payments pending an investigation of a credible allegation of fraud and legitimate providers will be assisted in avoiding problems by implementing effective compliance programs.

This final rule with comment period is an essential tool in protecting public resources and assuring that they are devoted to providing health care rather than enriching fraudulent actors.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and Rural areas.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, and Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 1007

Administrative practice and procedure, Fraud, Grant programs—health, Medicaid, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV and the Office of the Inspector General amends 42 CFR chapter V, as set forth below:

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

■ 2. The authority citation for subpart C is revised to read as follows:

Authority: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

■ 3. In subpart C, remove the phrase "intermediary or carrier" wherever it appears and add the phrase "Medicare contractor" in its place.

■ 4. Section 405.370 is amended as follows:

■ A. In paragraph (a), adding the definitions of "Credible allegation of fraud," "Medicare contractor," and "Resolution of an investigation" in alphabetical order.

■ B. In paragraph (a), revising the definitions of "Offset," "Recoupment," and "Suspension of payment".

The additions and revisions read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. A credible allegation of fraud is an allegation from any source, including but not limited to the following:

(1) Fraud hotline complaints.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Medicare contractor. Unless the context otherwise requires, includes, but is not limited to the any of following:

(1) A fiscal intermediary.

(2) A carrier.

(3) Program safeguard contractor.

(4) Zone program integrity contractor.

(5) Part A/Part B Medicare administrative contractor.

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Resolution of an investigation. An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

Suspension of payment. The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

* * * * *

■ 5. Section 405.371 is revised to read as follows:

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules.* Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be—

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination;

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments; or

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(b) *Good cause exceptions applicable to payment suspensions.*

(1) CMS may find that good cause exists not to suspend payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(i) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(ii) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(iii) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare funds than would implementing a payment suspension; or

(iv) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.

(2) Every 180 days after the initiation of a suspension of payments based on credible allegations of fraud, CMS will—

(i) Evaluate whether there is good cause to not continue such suspension under this section; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under investigation warranting continuation of the suspension.

(3) Good cause not to continue to suspend payments to an individual or

entity against which there are credible allegations of fraud must be deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, except CMS may extend a payment suspension beyond that point if —

(i) The case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties); or such administrative action is pending or

(ii) The Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil action or both or based on a pending criminal or civil action or both. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to conclude the criminal or civil proceeding or both.

(C) A statement of why or how criminal or civil action or both may be affected if the requested extension is not granted.

(c) *Steps necessary for suspension of payment, offset, and recoupment.*

(1) Except as provided in paragraph (d) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) *Suspension of payment in the case of unfiled cost reports.* (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

■ 6. Section 405.372 is amended as follows:

■ A. Remove the phrase "intermediary, carrier" wherever it appears and adding the phrase "Medicare contractor" in its place.

■ B. Revising paragraphs (a)(4), (c), and (d)(3).

■ C. In paragraph (e), removing the cross-reference "§ 405.371(b)" and adding the cross-reference "§ 405.371(a)" in its place.

§ 405.372 Proceeding for suspension of payment.

(a) * * *

(4) *Fraud.* If the intended suspension of payment involves credible allegations of fraud under § 405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

* * * * *

(c) *Subsequent action.* (1) If a suspension of payment is put into effect under § 405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.

(i) CMS or the Medicare contractor makes all reasonable efforts to expedite the determination.

(ii) As soon as the determination is made, CMS or the Medicare contractor informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(2)(i) If a suspension of payment is based upon credible allegations of fraud in accordance with § 405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists.

(ii) The rescission of the suspension and the issuance of a final overpayment determination to the provider or supplier may be delayed until resolution of the investigation.

(d) * * *

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 7. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 8. Section 424.57 is amended by revising paragraph (e) to read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(e) *Revalidation of billing privileges.* A supplier must revalidate its application for billing privileges every 3 years after the billing privileges are first granted. (Each supplier must complete a new application for billing privileges 3 years after its last revalidation.)

* * * * *

■ 9. Section 424.502 is amended by adding the definition of "Institutional provider" in alphabetical order to read as follows:

§ 424.502 Definitions.

* * * * *

Institutional provider means any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and nonphysician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

* * * * *

■ 10. Section 424.514 is added to read as follows:

§ 424.514 Application fee.

(a) *Application fee requirements for prospective institutional providers.* Beginning on or after March 25, 2011, prospective institutional providers that are submitting an initial application or currently enrolled institutional providers that are submitting an application to establish a new practice location must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(b) *Application fee requirements for revalidating institutional providers.* Beginning March 25, 2011, institutional providers that are subject to CMS revalidation efforts must submit either or both of the following:

(1) The applicable application fee.

(2) A request for a hardship exception to the application fee at the time of filing a Medicare enrollment application.

(c) *Hardship exception for disaster areas.* CMS will assess on a case-by-case basis whether institutional providers enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) should receive an exception to the application fee.

(d) *Application fee.* The application fee and associated requirements are as follows:

(1) For 2010, $500.00.

(2) For 2011 and subsequent years—

(i) Is adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year;

(ii) Is effective from January 1 to December 31 of a calendar year;

(iii) Is based on the submission of an initial application, application to establish a new practice location or the submission of an application in response to a CMS revalidation request;

(iv) Must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted;

(v) Is nonrefundable, except if submitted with one of the following:

(A) A request for hardship exception that is subsequently approved;

(B) An application that is rejected prior to initiation of screening processes;

(C) An application that is subsequently denied as a result of the imposition of a temporary moratorium;

(e) *Denial or revocation based on application fee.* A Medicare contractor may deny or revoke Medicare billing privileges of a provider or supplier based on noncompliance if, in the absence of a written request for a hardship exception from the application fee that accompanies a Medicare enrollment application, the bank account on which the check that is submitted with the enrollment application is drawn does not contain sufficient funds to pay the application fee.

(f) *Information needed for submission of a hardship exception request.* A provider or supplier requesting an exception from the application fee must include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception.

(g) *Failure to submit application fee or hardship exception request.* A Medicare contractor may—

(1) Reject an enrollment application from a newly-enrolling institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(2) Revoke the billing privileges of a currently enrolled institutional provider that, with the exceptions described in § 424.514(b), is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee.

(3)(i) Notwithstanding the foregoing, the contractor must first inform the provider that the application fee was not submitted in accordance with this section.

(ii) Within 30 days after the date of the notification, the contractor may reject the application of the newly-enrolling institutional provider or revoke the billing privileges of the currently enrolled institutional provider that has not submitted the fee.

(h) *Consideration of hardship exception request.* CMS has 60 days in which to approve or disapprove a hardship exception request. If a provider submits a request for hardship exception to the fee and the provider or supplier has not already submitted the fee consistent with provisions in § 424.514(a) and (b), and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception request was not approved and allows the provider or supplier 30 days from the date of notification to submit the application fee.

(1) A Medicare contractor does not—

(i) Begin processing an enrollment application that is accompanied by a hardship exception request until CMS has made a decision to approve or disapprove the hardship exception request; and

(ii) Deny an enrollment application that is accompanied by a hardship exception request unless the hardship exception request is denied by CMS and the provider or supplier fails to submit the required application fee within 30 days of being notified that the request for a hardship exception was denied.

(2) A hardship exception determination made by CMS is appealable using § 405.874 of this chapter.

■ 11. Section 424.515 is amended by adding a new paragraph (e) to read as follows:

§ 424.515 Requirements for reporting changes and updates to, and the periodic revalidation of Medicare enrollment information.

* * * * *

(e) *Additional off-cycle revalidation.* On or after March 23, 2012, Medicare providers and suppliers, including DMEPOS suppliers, may be required to revalidate their enrollment outside the routine 5-year revalidation cycle (3-year DMEPOS supplier revalidation cycle).

(1) CMS will contact providers or suppliers to revalidate their enrollment for off-cycle revalidation.

(2) As with all revalidations, revalidations described in this paragraph are conducted in accordance with the screening procedures specified at § 424.518.

■ 12. Section 424.518 is added to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

A Medicare contractor is required to screen all initial applications, including applications for a new practice location, and any applications received in response to a revalidation request based on a CMS assessment of risk and assignment to a level of "limited," "moderate," or "high."

(a) *Limited categorical risk.* (1) *Limited categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as "limited" categorical risk:

(i) Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.

(ii) Ambulatory surgical centers.

(iii) Competitive Acquisition Program/Part B Vendors.

(iv) End-stage renal disease facilities.

(v) Federally qualified health centers.

(vi) Histocompatibility laboratories.

(vii) Hospitals, including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned hospital facilities.

(viii) Health programs operated by an Indian Health Program (as defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

(ix) Mammography screening centers.

(x) Mass immunization roster billers

(xi) Organ procurement organizations.

(xii) Pharmacies newly enrolling or revalidating via the CMS–855B application.

(xiii) Radiation therapy centers.
(xiv) Religious non-medical health care institutions.
(xv) Rural health clinics.
(xvi) Skilled nursing facilities.
(2) *Limited screening level: Screening requirements.* When CMS designates a provider or supplier as a "limited" categorical level of risk, the Medicare contractor does all of the following:
(i) Verifies that a provider or supplier meets all applicable Federal regulations and State requirements for the provider or supplier type prior to making an enrollment determination.
(ii) Conducts license verifications, including licensure verifications across State lines for physicians or nonphysician practitioners and providers and suppliers that obtain or maintain Medicare billing privileges as a result of State licensure, including State licensure in States other than where the provider or supplier is enrolling.
(iii) Conducts database checks on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider/supplier type.
(b) *Moderate categorical risk.* (1) *Moderate categorical risk: Provider and supplier categories.* CMS has designated the following providers and suppliers as "moderate" categorical risk:
(i) Ambulance service suppliers.
(ii) Community mental health centers.
(iii) Comprehensive outpatient rehabilitation facilities.
(iv) Hospice organizations.
(v) Independent clinical laboratories.
(vi) Independent diagnostic testing facilities.
(vii) Physical therapists enrolling as individuals or as group practices.
(viii) Portable x-ray suppliers.
(ix) Revalidating home health agencies.
(x) Revalidating DMEPOS suppliers.
(2) *Moderate screening level: Screening requirements.* When CMS designates a provider or supplier as a "moderate" categorical level of risk, the Medicare contractor does all of the following:
(i) Performs the "limited" screening requirements described in paragraph (a)(2) of this section.
(ii) Conducts an on-site visit.
(c) *High categorical risk.* (1) *High categorical risk: Provider and supplier categories.* CMS has designated the following home health agencies and suppliers of DMEPOS as "high" categorical risk:
(i) Prospective (newly enrolling) home health agencies.
(ii) Prospective (newly enrolling) DMEPOS suppliers.
(2) *High screening level: Screening requirements.* When CMS designates a provider or supplier as a "high" categorical level of risk, the Medicare contractor does all of the following:
(i) Performs the "limited" and "moderate" screening requirements described in paragraphs (a)(2) and (b)(2) of this section.
(ii)(A) Requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and
(B) Conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier.
(3) *Adjustment in the categorical risk.* CMS adjusts the screening level from "limited" or "moderate" to "high" if any of the following occur:
(i) CMS imposes a payment suspension on a provider or supplier at any time in the last 10 years.
(ii) The provider or supplier—
(A) Has been excluded from Medicare by the OIG; or
(B) Had billing privileges revoked by a Medicare contractor within the previous 10 years and is attempting to establish additional Medicare billing privileges by—
(*1*) Enrolling as a new provider or supplier; or
(*2*) Billing privileges for a new practice location;
(C) Has been terminated or is otherwise precluded from billing Medicaid;
(D) Has been excluded from any Federal health care program; or
(E) Has been subject to any final adverse action, as defined at § 424.502, within the previous 10 years.
(iii) CMS lifts a temporary moratorium for a particular provider or supplier type and a provider or supplier that was prevented from enrolling based on the moratorium, applies for enrollment as a Medicare provider or supplier at any time within 6 months from the date the moratorium was lifted.
(d) *Fingerprinting requirements.* An individual subject to the fingerprint-based criminal history record check requirement specified in paragraph (c)(2)(ii)(B) of this section—
(1) Must submit a set of fingerprints for a national background check.
(i) Upon submission of a Medicare enrollment application; or
(ii) Within 30 days of a Medicare contractor request.
(2) In the event the individual(s) required to submit fingerprints under paragraph (c)(2) of this section fail to submit such fingerprints in accordance with paragraph (d)(1) of this section, the provider or supplier will have its billing privileges—
(i) Denied under § 424.530(a)(1); or
(ii) Revoked under § 424.535(a)(1).

■ 13. Section 424.525 is amended by:
■ A. Revising paragraph (a) introductory text.
■ B. Adding a new paragraph (a)(3).

The revision and addition read as follows:

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider's or supplier's enrollment application for any of the following reasons:
* * * * *
(3) The prospective institutional provider or supplier does not submit the application fee in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.
* * * * *

■ 14. Section 424.530 is amended by adding new paragraphs (a)(9) and (a)(10) to read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *
(9) *Application fee/hardship exception.* An institutional provider's or supplier's hardship exception request is not granted, and the provider or supplier does not submit the application fee within 30 days of notification that the hardship exception request was not approved.
(10) *Temporary moratorium.* A provider or supplier submits an enrollment application for a practice location in a geographic area where CMS has imposed a temporary moratorium.
* * * * *

■ 15. Section 424.535 is amended as follows:
■ A. Revising paragraph (a)(6).
■ B. Adding a new paragraph (a)(12).
■ C. Revising paragraph (c).

§ 424.535 Revocation of enrollment billing and billing privileges in the Medicare program.

(a) * * *
(6) *Grounds related to provider and supplier screening requirements.* (i)(A) An institutional provider does not submit an application fee or hardship exception request that meets the requirements set forth in § 424.514 with

the Medicare revalidation application; or

(B) The hardship exception is not granted and the institutional provider does not submit the applicable application form or application fee within 30 days of being notified that the hardship exception request was denied.

(ii)(A) Either of the following occurs:

(*1*) CMS is not able to deposit the full application amount into a government-owned account.

(*2*) The funds are not able to be credited to the U.S. Treasury.

(B) The provider or supplier lacks sufficient funds in the account at the banking institution whose name is imprinted on the check or other banking instrument to pay the application fee; or

(C) There is any other reason why CMS or its Medicare contractor is unable to deposit the application fee into a government-owned account.

* * * * *

(12) *Medicaid termination.* (i) Medicaid billing privileges are terminated or revoked by a State Medicaid Agency.

(ii) Medicare may not terminate unless and until a provider or supplier has exhausted all applicable appeal rights.

* * * * *

(c) *Reapplying after revocation.* (1) After a provider, supplier, delegated official, or authorizing official has had its billing privileges revoked, it is barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar.

(2) The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.

(3) CMS may waive the re-enrollment bar if it has revoked a provider or supplier under § 424.535(a)(6)(i) based upon the failure of the provider or supplier to submit an application fee or a hardship exception request with an enrollment application upon revalidation.

* * * * *

■ 16. A new § 424.570 is added to read as follows:

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a) *Temporary moratoria.* (1) *General rules.* (i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area.

(ii) CMS will announce the temporary enrollment moratorium in a **Federal Register** document that includes the rationale for imposition of the temporary enrollment moratorium.

(iii) The temporary moratorium does not apply to changes in practice location, changes in provider or supplier information such as phone number, address or changes in ownership (except changes in ownership of home health agencies that would require an initial enrollment under § 424.550).

(iv) The temporary enrollment moratorium does not apply to any enrollment application that has been approved by the enrollment contractor but not yet entered into PECOS at the time the moratorium is imposed.

(2) *Imposition of a temporary moratorio.* CMS may impose the temporary moratorium if—

(i) CMS determines that there is a significant potential for fraud, waste or abuse with respect to a particular provider or supplier type or particular geographic area or both. CMS's determination is based on its review of existing data, and without limitation, identifies a trend that appears to be associated with a high risk of fraud, waste or abuse, such as a—

(A) Highly disproportionate number of providers or suppliers in a category relative to the number of beneficiaries; or

(B) Rapid increase in enrollment applications within a category;

(ii) A State Medicaid program has imposed a moratorium on a group of Medicaid providers or suppliers that are also eligible to enroll in the Medicare program;

(iii) A State has imposed a moratorium on enrollment in a particular geographic area or on a particular provider or supplier type or both; or

(iv) CMS, in consultation the HHS OIG or the Department of Justice or both and with the approval of the CMS Administrator identifies either or both of the following as having a significant potential for fraud, waste or abuse in the Medicare program:

(A) A particular provider or supplier type.

(B) Any particular geographic area.

(b) *Duration of moratoria.* A moratorium under this section may be imposed for a period of 6 months and, if deemed necessary by CMS, may be extended in 6-month increments. CMS will publish a document in the **Federal Register** when it extends a moratorium.

(c) *Denial of enrollment: Moratoria.* A Medicare contractor denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium as specified in paragraph (a) of this section.

(d) *Lifting moratoria.* CMS will publish a document in the **Federal Register** when a moratorium is lifted. CMS may lift a temporary moratorium at any time after imposition of the moratorium if one of the following occur:

(1) The President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act).

(2) Circumstances warranting the imposition of a moratorium have abated or CMS has implemented program safeguards to address the program vulnerability.

(3) The Secretary has declared a public health emergency under section 319 of the Public Health Service Act in the area subject to a temporary moratorium.

(4) In the judgment of the Secretary, the moratorium is no longer needed.

PART 447—PAYMENT FOR SERVICES

■ 19. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 20. A new § 447.90 is added to subpart A to read as follows:

§ 447.90 FFP: Conditions related to pending investigations of credible allegations of fraud against the Medicaid program.

(a) *Basis and purpose.* This section implements section 1903(i)(2)(C) of the Act which prohibits payment of FFP with respect to items or services furnished by an individual or entity with respect to which there is pending an investigation of a credible allegation of fraud except under specified circumstances.

(b) *Denial of FFP.* No FFP is available with respect to any amount expended for an item or service furnished by any individual or entity to whom a State has failed to suspend payments in whole or part as required by § 455.23 of this chapter unless—

(1) The item or service is furnished as an emergency item or service, but not including items or services furnished in an emergency room of a hospital; or

(2) The State determines and documents that good cause as specified at § 455.23(e) or (f) of this chapter exists not to suspend such payments, to suspend payments only in part, or to discontinue a previously imposed payment suspension.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 21. The authority citation for part 455 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 22. Section 455.2 is amended by adding the definition of "Credible allegation of fraud" to read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. A credible allegation of fraud may be an allegation, which has been verified by the State, from any source, including but not limited to the following:

(1) Fraud hotline complaints.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

Allegations are considered to be credible when they have indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

* * * * *

■ 23. Section 455.23 is revised to read as follows:

§ 455.23 Suspension of payments in cases of fraud.

(a) *Basis for suspension.* (1) The State Medicaid agency must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part.

(2) The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments.

(3) A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of suspension.* (1) The State agency must send notice of its suspension of program payments within the following timeframes:

(i) Five days of taking such action unless requested in writing by a law enforcement agency to temporarily withhold such notice.

(ii) Thirty days if requested by law enforcement in writing to delay sending such notice, which request for delay may be renewed in writing up to twice and in no event may exceed 90 days.

(2) The notice must include or address all of the following:

(i) State that payments are being suspended in accordance with this provision.

(ii) Set forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.

(iii) State that the suspension is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which the suspension will be terminated.

(iv) Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.

(v) Inform the provider of the right to submit written evidence for consideration by State Medicaid Agency.

(vi) Set forth the applicable State administrative appeals process and corresponding citations to State law.

(c) *Duration of suspension.* (1) All suspension of payment actions under this section will be temporary and will not continue after either of the following:

(i) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider.

(ii) Legal proceedings related to the provider's alleged fraud are completed.

(2) A State must document in writing the termination of a suspension including, where applicable and appropriate, any appeal rights available to a provider.

(d) *Referrals to the Medicaid fraud control unit.* (1) Whenever a State Medicaid agency investigation leads to the initiation of a payment suspension in whole or part, the State Medicaid Agency must make a fraud referral to either of the following:

(i) To a Medicaid fraud control unit established and certified under part 1007 of this title; or

(ii) In States with no certified Medicaid fraud control unit, to an appropriate law enforcement agency.

(2) The fraud referral made under paragraph (d)(1) of this section must meet all of the following requirements:

(i) Be made in writing and provided to the Medicaid fraud control unit not later than the next business day after the suspension is enacted.

(ii) Conform to fraud referral performance standards issued by the Secretary.

(3)(i) If the Medicaid fraud control unit or other law enforcement agency accepts the fraud referral for investigation, the payment suspension may be continued until such time as the investigation and any associated enforcement proceedings are completed.

(ii) On a quarterly basis, the State must request a certification from the Medicaid fraud control unit or other law enforcement agency that any matter accepted on the basis of a referral continues to be under investigation thus warranting continuation of the suspension.

(4) If the Medicaid fraud control unit or other law enforcement agency declines to accept the fraud referral for investigation the payment suspension must be discontinued unless the State Medicaid agency has alternative Federal or State authority by which it may impose a suspension or makes a fraud referral to another law enforcement agency. In that situation, the provisions of paragraph (d)(3) of this section apply equally to that referral as well.

(5) A State's decision to exercise the good cause exceptions in paragraphs (e) or (f) of this section not to suspend payments or to suspend payments only in part does not relieve the State of the obligation to refer any credible allegation of fraud as provided in paragraph (d)(1) of this section.

(e) *Good cause not to suspend payments.* A State may find that good cause exists not to suspend payments, or not to continue a payment suspension previously imposed, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Law enforcement officials have specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation.

(2) Other available remedies implemented by the State more effectively or quickly protect Medicaid funds.

(3) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of the payment suspension, that the suspension should be removed.

(4) Recipient access to items or services would be jeopardized by a payment suspension because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.

(5) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(6) The State determines that payment suspension is not in the best interests of the Medicaid program.

(f) *Good cause to suspend payment only in part.* A State may find that good cause exists to suspend payments in part, or to convert a payment suspension previously imposed in whole to one only in part, to an individual or entity against which there is an investigation of a credible allegation of fraud if any of the following are applicable:

(1) Recipient access to items or services would be jeopardized by a payment suspension in whole or part because of either of the following:

(i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.

(2) The State determines, based upon the submission of written evidence by the individual or entity that is the subject of a whole payment suspension, that such suspension should be imposed only in part.

(3)(i) The credible allegation focuses solely and definitively on only a specific type of claim or arises from only a specific business unit of a provider; and

(ii) The State determines and documents in writing that a payment suspension in part would effectively ensure that potentially fraudulent claims were not continuing to be paid.

(4) Law enforcement declines to certify that a matter continues to be under investigation per the requirements of paragraph (d)(3) of this section.

(5) The State determines that payment suspension only in part is in the best interests of the Medicaid program.

(g) *Documentation and record retention.* State Medicaid agencies must meet the following requirements:

(1) Maintain for a minimum of 5 years from the date of issuance all materials documenting the life cycle of a payment suspension that was imposed in whole or part, including the following:

(i) All notices of suspension of payment in whole or part.

(ii) All fraud referrals to the Medicaid fraud control unit or other law enforcement agency.

(iii) All quarterly certifications of continuing investigation status by law enforcement.

(iv) All notices documenting the termination of a suspension.

(2)(i) Maintain for a minimum of 5 years from the date of issuance all materials documenting each instance where a payment suspension was not imposed, imposed only in part, or discontinued for good cause.

(ii) This type of documentation must include, at a minimum, detailed information on the basis for the existence of the good cause not to suspend payments, to suspend payments only in part, or to discontinue a payment suspension and, where applicable, must specify how long the State anticipates such good cause will exist.

(3) Annually report to the Secretary summary information on each of following:

(i) Suspension of payment, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension.

(ii) Situation in which the State determined good cause existed to not suspend payments, to suspend payments only in part, or to discontinue a payment suspension as described in this section, including describing the nature of the suspected fraud and the nature of the good cause.

■ 24. Section 455.101 is amended by adding the definitions of "Health insuring organization (HIO)," "Managed care entity (MCE)," "Prepaid ambulatory health plan (PAHP)," "Prepaid inpatient health plan (PIHP)," "Primary care case manager (PCCM)," and "Termination" in alphabetical order to read as follows:

§ 455.101 Definitions.

* * * * *

Health insuring organization (HIO) has the meaning specified in § 438.2.

* * * * *

Managed care entity (MCE) means managed care organizations (MCOs), PIHPs, PAHPs, PCCMs, and HIOs.

* * * * *

Prepaid ambulatory health plan (PAHP) has the meaning specified in § 438.2.

Prepaid inpatient health plan (PIHP) has the meaning specified in § 438.2.

Primary care case manager (PCCM) has the meaning specified in § 438.2.

* * * * *

Termination means—

(1) For a—

(i) Medicaid or CHIP provider, a State Medicaid program or CHIP has taken an action to revoke the provider's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired; and

(ii) Medicare provider, supplier or eligible professional, the Medicare program has revoked the provider or supplier's billing privileges, and the provider has exhausted all applicable appeal rights or the timeline for appeal has expired.

(2)(i) In all three programs, there is no expectation on the part of the provider or supplier or the State or Medicare program that the revocation is temporary.

(ii) The provider, supplier, or eligible professional will be required to reenroll with the applicable program if they wish billing privileges to be reinstated.

(3) The requirement for termination applies in cases where providers, suppliers, or eligible professionals were terminated or had their billing privileges revoked for cause which may include, but is not limited to—

(i) Fraud;

(ii) Integrity; or

(iii) Quality.

* * * * *

■ 25. Section 455.104 is revised to read as follows:

§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

(a) *Who must provide disclosures.* The Medicaid agency must obtain disclosures from disclosing entities, fiscal agents, and managed care entities.

(b) *What disclosures must be provided.* The Medicaid agency must require that disclosing entities, fiscal agents, and managed care entities provide the following disclosures:

(1)(i) The name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. The address for corporate entities must include as applicable primary business address, every business location, and P.O. Box address.

(ii) Date of birth and Social Security Number (in the case of an individual).

(iii) Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) or in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest.

(2) Whether the person (individual or corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity) is related to another person with ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling; or whether the person (individual or corporation) with an ownership or control interest in any subcontractor in which the disclosing entity (or fiscal agent or managed care entity) has a 5 percent or more interest is related to another person with

ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.

(3) The name of any other disclosing entity (or fiscal agent or managed care entity) in which an owner of the disclosing entity (or fiscal agent or managed care entity) has an ownership or control interest.

(4) The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(c) *When the disclosures must be provided.*

(1) *Disclosures from providers or disclosing entities.* Disclosure from any provider or disclosing entity is due at any of the following times:

(i) Upon the provider or disclosing entity submitting the provider application.

(ii) Upon the provider or disclosing entity executing the provider agreement.

(iii) Upon request of the Medicaid agency during the re-validation of enrollment process under § 455.414.

(iv) Within 35 days after any change in ownership of the disclosing entity.

(2) *Disclosures from fiscal agents.* Disclosures from fiscal agents are due at any of the following times:

(i) Upon the fiscal agent submitting the proposal in accordance with the State's procurement process.

(ii) Upon the fiscal agent executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the fiscal agent.

(3) *Disclosures from managed care entities.* Disclosures from managed care entities (MCOs, PIHPs, PAHPs, and HIOs), except PCCMs are due at any of the following times:

(i) Upon the managed care entity submitting the proposal in accordance with the State's procurement process.

(ii) Upon the managed care entity executing the contract with the State.

(iii) Upon renewal or extension of the contract.

(iv) Within 35 days after any change in ownership of the managed care entity.

(4) *Disclosures from PCCMs.* PCCMs will comply with disclosure requirements under paragraph (c)(1) of this section.

(d) *To whom must the disclosures be provided.* All disclosures must be provided to the Medicaid agency.

(e) *Consequences for failure to provide required disclosures.* Federal financial participation (FFP) is not available in payments made to a disclosing entity that fails to disclose ownership or control information as required by this section.

■ 26. A new subpart E is added to part 455 to read as follows:

Subpart E—Provider Screening and Enrollment

Sec.

Subpart E—Provider Screening and Enrollment

§ 455.400 Purpose.

This subpart implements sections 1866(j), 1902(a)(39), 1902(a)(77), and 1902(a)(78) of the Act. It sets forth State plan requirements regarding the following:

(a) Provider screening and enrollment requirements.

(b) Fees associated with provider screening.

(c) Temporary moratoria on enrollment of providers.

§ 455.405 State plan requirements.

A State plan must provide that the requirements of § 455.410 through § 455.450 and § 455.470 are met.

§ 455.410 Enrollment and screening of providers.

(a) The State Medicaid agency must require all enrolled providers to be screened under to this subpart.

(b) The State Medicaid agency must require all ordering or referring physicians or other professionals providing services under the State plan or under a waiver of the plan to be enrolled as participating providers.

(c) The State Medicaid agency may rely on the results of the provider screening performed by any of the following:

(1) Medicare contractors.

(2) Medicaid agencies or Children's Health Insurance Programs of other States.

§ 455.412 Verification of provider licenses.

The State Medicaid agency must—

(a) Have a method for verifying that any provider purporting to be licensed in accordance with the laws of any State is licensed by such State.

(b) Confirm that the provider's license has not expired and that there are no current limitations on the provider's license.

§ 455.414 Revalidation of enrollment.

The State Medicaid agency must revalidate the enrollment of all providers regardless of provider type at least every 5 years.

§ 455.416 Termination or denial of enrollment.

The State Medicaid agency—

(a) Must terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider did not submit timely and accurate information and cooperate with any screening methods required under this subpart.

(b) Must deny enrollment or terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with the Medicare, Medicaid, or title XXI program in the last 10 years, unless the State Medicaid agency determines that denial or termination of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(c) Must deny enrollment or terminate the enrollment of any provider that is terminated on or after January 1, 2011, under title XVIII of the Act or under the Medicaid program or CHIP of any other State.

(d) Must terminate the provider's enrollment or deny enrollment of the provider if the provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit timely or accurate information, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(e) Must terminate or deny enrollment if the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency within 30 days of a CMS or a State Medicaid agency request, unless the State Medicaid

agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(f) Must terminate or deny enrollment if the provider fails to permit access to provider locations for any site visits under § 455.432, unless the State Medicaid agency determines that termination or denial of enrollment is not in the best interests of the Medicaid program and the State Medicaid agency documents that determination in writing.

(g) May terminate or deny the provider's enrollment if CMS or the State Medicaid agency—

(1) Determines that the provider has falsified any information provided on the application; or

(2) Cannot verify the identity of any provider applicant.

§ 455.420 Reactivation of provider enrollment.

After deactivation of a provider enrollment number for any reason, before the provider's enrollment may be reactivated, the State Medicaid agency must re-screen the provider and require payment of associated provider application fees under § 455.460.

§ 455.422 Appeal rights.

The State Medicaid agency must give providers terminated or denied under § 455.416 any appeal rights available under procedures established by State law or regulations.

§ 455.432 Site visits.

The State Medicaid agency—

(a) Must conduct pre-enrollment and post-enrollment site visits of providers who are designated as "moderate" or "high" categorical risks to the Medicaid program. The purpose of the site visit will be to verify that the information submitted to the State Medicaid agency is accurate and to determine compliance with Federal and State enrollment requirements.

(b) Must require any enrolled provider to permit CMS, its agents, its designated contractors, or the State Medicaid agency to conduct unannounced on-site inspections of any and all provider locations.

§ 455.434 Criminal background checks.

The State Medicaid agency—

(a) As a condition of enrollment, must require providers to consent to criminal background checks including fingerprinting when required to do so under State law or by the level of screening based on risk of fraud, waste or abuse as determined for that category of provider.

(b) Must establish categorical risk levels for providers and provider categories who pose an increased financial risk of fraud, waste or abuse to the Medicaid program.

(1) Upon the State Medicaid agency determining that a provider, or a person with a 5 percent or more direct or indirect ownership interest in the provider, meets the State Medicaid agency's criteria hereunder for criminal background checks as a "high" risk to the Medicaid program, the State Medicaid agency will require that each such provider or person submit fingerprints.

(2) The State Medicaid agency must require a provider, or any person with a 5 percent or more direct or indirect ownership interest in the provider, to submit a set of fingerprints, in a form and manner to be determined by the State Medicaid agency, within 30 days upon request from CMS or the State Medicaid agency.

§ 455.436 Federal database checks.

The State Medicaid agency must do all of the following:

(a) Confirm the identity and determine the exclusion status of providers and any person with an ownership or control interest or who is an agent or managing employee of the provider through routine checks of Federal databases.

(b) Check the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the Excluded Parties List System (EPLS), and any such other databases as the Secretary may prescribe.

(c)(1) Consult appropriate databases to confirm identity upon enrollment and reenrollment; and

(2) Check the LEIE and EPLS no less frequently than monthly.

§ 455.440 National Provider Identifier.

The State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

§ 455.450 Screening levels for Medicaid providers.

A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment or revalidation of enrollment request based on a categorical risk level of "limited," "moderate," or "high." If a provider could fit within more than one risk level described in this section, the highest level of screening is applicable.

(a) *Screening for providers designated as limited categorical risk.* When the State Medicaid agency designates a provider as a limited categorical risk, the State Medicaid agency must do all of the following:

(1) Verify that a provider meets any applicable Federal regulations, or State requirements for the provider type prior to making an enrollment determination.

(2) Conduct license verifications, including State licensure verifications in States other than where the provider is enrolling, in accordance with § 455.412.

(3) Conduct database checks on a pre- and post-enrollment basis to ensure that providers continue to meet the enrollment criteria for their provider type, in accordance with § 455.436.

(b) *Screening for providers designated as moderate categorical risk.* When the State Medicaid agency designates a provider as a "moderate" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" screening requirements described in paragraph (a) of this section.

(2) Conduct on-site visits in accordance with § 455.432.

(c) *Screening for providers designated as high categorical risk.* When the State Medicaid agency designates a provider as a "high" categorical risk, a State Medicaid agency must do both of the following:

(1) Perform the "limited" and "moderate" screening requirements described in paragraphs (a) and (b) of this section.

(2)(i) Conduct a criminal background check; and

(ii) Require the submission of a set of fingerprints in accordance with § 455.434.

(d) *Denial or termination of enrollment.* A provider, or any person with 5 percent or greater direct or indirect ownership in the provider, who is required by the State Medicaid agency or CMS to submit a set of fingerprints and fails to do so may have its—

(1) Application denied under § 455.434; or

(2) Enrollment terminated under § 455.416.

(e) *Adjustment of risk level.* The State agency must adjust the categorical risk level from "limited" or "moderate" to "high" when any of the following occurs:

(1) The State Medicaid agency imposes a payment suspension on a provider based on credible allegation of fraud, waste or abuse, the provider has

an existing Medicaid overpayment, or the provider has been excluded by the OIG or another State's Medicaid program within the previous 10 years.

(2) The State Medicaid agency or CMS in the previous 6 months lifted a temporary moratorium for the particular provider type and a provider that was prevented from enrolling based on the moratorium applies for enrollment as a provider at any time within 6 months from the date the moratorium was lifted.

§ 455.452 Other State screening methods.

Nothing in this subpart must restrict the State Medicaid agency from establishing provider screening methods in addition to or more stringent than those required by this subpart.

§ 455.460 Application fee.

(a) Beginning on or after March 25, 2011, States must collect the applicable application fee prior to executing a provider agreement from a prospective or re-enrolling provider other than either of the following:

(1) Individual physicians or nonphysician practitioners.

(2)(i) Providers who are enrolled in either of the following:

(A) Title XVIII of the Act.

(B) Another State's title XIX or XXI plan.

(ii) Providers that have paid the applicable application fee to—

(A) A Medicare contractor; or

(B) Another State.

(b) If the fees collected by a State agency in accordance with paragraph (a) of this section exceed the cost of the screening program, the State agency must return that portion of the fees to the Federal government.

§ 455.470 Temporary moratoria.

(a)(1) The Secretary consults with any affected State Medicaid agency regarding imposition of temporary moratoria on enrollment of new providers or provider types prior to imposition of the moratoria, in accordance with § 424.570 of this chapter.

(2) The State Medicaid agency will impose temporary moratoria on enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program.

(3)(i) The State Medicaid agency is not required to impose such a moratorium if the State Medicaid agency determines that imposition of a temporary moratorium would adversely affect beneficiaries' access to medical assistance.

(ii) If a State Medicaid agency makes such a determination, the State Medicaid agency must notify the Secretary in writing.

(b)(1) A State Medicaid agency may impose temporary moratoria on enrollment of new providers, or impose numerical caps or other limits that the State Medicaid agency identifies as having a significant potential for fraud, waste, or abuse and that the Secretary has identified as being at high risk for fraud, waste, or abuse.

(2) Before implementing the moratoria, caps, or other limits, the State Medicaid agency must determine that its action would not adversely impact beneficiaries' access to medical assistance.

(3) The State Medicaid agency must notify the Secretary in writing in the event the State Medicaid agency seeks to impose such moratoria, including all details of the moratoria; and obtain the Secretary's concurrence with imposition of the moratoria.

(c)(1) The State Medicaid agency must impose the moratorium for an initial period of 6 months.

(2) If the State Medicaid agency determines that it is necessary, the State Medicaid agency may extend the moratorium in 6-month increments.

(3) Each time, the State Medicaid agency must document in writing the necessity for extending the moratorium.

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 27. The authority citation for part 457 continues to read as follows:

Authority: Section 1102 of the Social Security Act (42 U.S.C. 1302).

■ 28. Section 457.900 is amended by adding a new paragraph (a)(2)(x) to read as follows:

§ 457.900 Basis, scope and applicability.

(a) * * *

(2) * * *

(x) Sections 1902(a)(77) and 1902(kk) of the Act relating to provider and supplier screening, oversight, and reporting requirements.

* * * * *

■ 29. A new § 457.990 is added to subpart I to read as follows:

§ 457.990 Provider and supplier screening, oversight, and reporting requirements.

The following provisions and their corresponding regulations apply to a State under title XXI of the Act, in the same manner as these provisions and regulations apply to a State under title XIX of the Act:

(a) Part 455, Subpart E, of this chapter.

(b) Sections 1902(a)(77) and 1902(kk) of the Act pertaining to provider and supplier screening, oversight, and reporting requirements.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 30. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 31. Section 498.5 is amended by adding a new paragraph (l)(4) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(l) * * *

(4) *Scope of review.* For appeals of denials based on § 424.530(a)(9) of this chapter related to temporary moratoria, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency's basis for imposing a temporary moratorium is not subject to review.

CHAPTER V-OFFICE OF INSPECTOR GENERAL-HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

■ 32. The authority citation for part 1007 continues to read as follows:

Authority: 42 U.S.C. 1320 and 1395hh.

■ 33. Section 1007.9 is amended by adding paragraphs (e) through (g) to read as follows:

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

* * * * *

(e)(1) The unit may refer any provider with respect to which there is pending an investigation of a credible allegation of fraud under the Medicaid program to the State Medicaid agency for payment suspension in whole or part under § 455.23 of this title.

(2) Referrals may be brief, but must be in writing and include sufficient information to allow the State Medicaid agency to identify the provider and to explain the credible allegations forming the grounds for the payment suspension.

(f) Any request by the unit to the State Medicaid agency to delay notification to the provider of a payment suspension under § 455.23 of this title must be in writing.

(g) When the unit accepts or declines a case referred by the State Medicaid agency, the unit notifies the State Medicaid agency in writing of the acceptance or declination of the case.

Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 14, 2011.

Donald Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 21, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–1686 Filed 1–24–11; 12:15 pm]

BILLING CODE 4120–01–P

Projected Annual Expenditures for Medicare and Medicaid

Year	Medicare	Medicaid
2010	$514,747,000,000	$412,042,000,000
2011	$544,361,000,000	$446,986,000,000
2012	$585,670,000,000	$478,268,000,000
2013	$626,798,000,000	$513,209,000,000
2014	$672,812,000,000	$551,744,000,000
2015	$714,012,000,000	$593,342,000,000
2016	$767,388,000,000	$638,298,000,000
2017	$830,043,000,000	$686,778,000,000
2018	$900,785,000,000	$738,965,000,000
2019	$977,816,000,000	$794,312,000,000

Source: National Health Expenditure Data, Office of the Actuary, CMS
https://www.cms.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp

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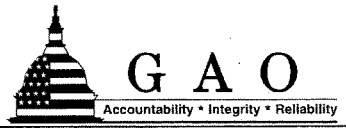

GAO-11-278

GAO
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Highlights

Highlights of GAO-11-278, a report to congressional committees on GAO's High-Risk Series

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This biennial update describes the status of high-risk areas listed in 2009 and identifies any new high-risk area needing attention by Congress and the executive branch. Solutions to high-risk problems offer the potential to save billions of dollars, improve service to the public, and strengthen the performance and accountability of the U.S. government.

What Remains to Be Done

This report contains GAO's views on progress made and what remains to be done to bring about lasting solutions for each high-risk area. Perseverance by the executive branch in implementing GAO's recommended solutions and continued oversight and action by Congress are essential to achieving progress. GAO is dedicated to continue working with Congress and the executive branch to help ensure additional progress is made.

View GAO-11-278 or key components. For more information, contact J. Christopher Mihm at (202) 512-6806 or mihmj@gao.gov.

What GAO Found

In January 2009, GAO detailed 30 high-risk areas and, in July 2009, added a 31st—Restructuring the U.S. Postal Service to Achieve Sustainable Financial Viability. GAO has determined that sufficient progress has been made to remove the high-risk designation from two areas: the DOD Personnel Security Clearance Program and the 2010 Census.

- High-level attention by DOD, OMB, and the Office of the Director of National Intelligence, along with consistent congressional oversight, has led to significant improvements in processing security clearances. For example, DOD processed 90 percent of all initial clearances in an average of 49 days in fiscal year 2010 and thus met the 60-day statutory timeliness objective. Furthermore, DOD has reduced the average time it takes to process 90 percent of initial security clearances for industry personnel from 129 days in 2008 to 63 days in 2010. DOD has also developed and is implementing quality assessment tools and has issued adjudicative standards for addressing incomplete investigations.
- The Census Bureau (Bureau), with active congressional oversight, took steps to address problems GAO pointed out since designating the 2010 Census a high-risk area in March 2008. Those steps included efforts to control costs, better manage operations, strengthen its risk management activities, and enhance the testing of automated systems. The Bureau generally completed its data collection activities consistent with its plans and released the data used to apportion Congress on December 21, 2010, several days ahead of the legally required end-of-year deadline.

This year, GAO is designating one new high-risk area—Interior's Management of Federal Oil and Gas Resources. Interior does not have reasonable assurance that it is collecting its share of billions of dollars of revenue from oil and gas produced on federal lands and it continues to experience problems in hiring, training, and retaining sufficient staff to provide oversight and management of oil and gas operations on federal lands and waters. Further, Interior recently began restructuring its oil and gas program, which is inherently challenging, and there are many open questions about whether Interior has the capacity to undertake this reorganization while carrying out its range of responsibilities, especially in a constrained resource environment.

In the past 2 years, progress has been made, to varying degrees, in most areas that remain on GAO's High-Risk List. Congressional oversight and legislative action, high-level administration attention, and efforts of the responsible agencies have been central to progress. For example, Congress passed the Improper Payments Elimination and Recovery Act (IPERA) of 2010 to enhance reporting and recovering of improper payments in federal programs. In addition, in November 2009, the President issued Executive Order 13520, Reducing Improper Payments and Eliminating Waste in Federal Programs. Congress also passed the Weapon Systems Acquisition Reform Act of 2009, which requires DOD to provide more realistic cost estimates and terminate programs with high cost growth.

Medicare Program

Why Area Is High Risk

GAO has designated Medicare as a high-risk program because its complexity and susceptibility to improper payments, added to its size, have led to serious management challenges. In 2010, Medicare covered 47 million elderly and disabled beneficiaries had estimated outlays of $509 billion. Medicare had estimated improper payments of almost $48 billion in fiscal year 2010. However, this improper payment estimate did not include all of the program's risk, since it did not include improper payments in its prescription drug benefit, for which the agency has not yet estimated a total amount. The Centers for Medicare & Medicaid Services (CMS), which administers Medicare, is responsible for implementing payment methods that encourage efficient service delivery, managing the program to serve beneficiaries and safeguard it from loss, and overseeing patient safety and care. CMS faces growing challenges in coming years, given the rapid growth expected in the number of Medicare beneficiaries and program spending.

What GAO Found

The Medicare program remains on a path that is fiscally unsustainable over the long term. This fiscal pressure heightens the need for CMS to improve Medicare's payment methods to achieve efficiency and savings, and its management, program integrity, and oversight of patient care and safety.

Reforming and refining payments. Since January 2009, CMS has implemented payment reforms for Medicare Advantage, and inpatient hospital, home health, and end-stage renal disease services. The agency has also begun to provide feedback to physicians on their resource use and is developing a value-based payment method for physician services that accounts for the quality and cost of care. Efforts to provide feedback and encourage efficiency are crucial because physician influence on the use of other services is estimated to account for up to 90 percent of health care spending.

In addition, CMS has taken steps to ensure that some physician fees recognize efficiencies when certain services are furnished together, but the agency has not targeted the services with the greatest potential for savings. Under the budget neutrality requirement, the savings that have been generated have been redistributed to increase physician fees for other services. Therefore, GAO recommended in 2009 that Congress consider exempting savings from adjusting physician fees to recognize efficiencies from budget neutrality to ensure that Medicare realizes these savings.

GAO's work has also shown that payment for imaging services may benefit from refinements. Specifically, CMS could add more front-end approaches to better ensure appropriate payments, such as requiring physicians to obtain prior authorization from Medicare before ordering an imaging service. CMS also has opportunities to improve the way it adjusts physician payments to account for geographical differences in the costs of providing care in different localities. GAO has recommended that the agency examine and revise the physician payment localities it uses for this purpose by using an approach that is uniformly applied to all states and based on the most current data. CMS agreed to consider the recommendation, but was concerned about its redistributive effects. The agency subsequently initiated a study of physician payment locality adjustments. The study is ongoing and CMS has not implemented any change.

Improving program management. CMS's implementation of competitive bidding for medical equipment and supplies and its new Medicare Administrative Contractors (MAC) have progressed, with some delays. Congress halted the first round of competitive bidding and required CMS to improve its implementation. In regard to contracting reform, due to delays because of protests filed in connection with the procurement process, CMS did not meet the target that it set for 2009 and 2010 in transferring workload to MACs. As of December 2010, CMS transferred Medicare's fee-for-service claims workload to the new MACs in all but six jurisdictions. For those six jurisdictions, CMS is transferring claims workload in two jurisdictions, and has ongoing procurement activity in the remainder. Some new MACs had delays in paying providers' claims, but overall, CMS's contractors continued to meet the agency's performance targets for timeliness of claims processing in 2009.

Regarding Medicare Advantage, CMS has not complied with statutory requirements to mail information on plan disenrollment to beneficiaries but did take steps to post this information on its Web site. In addition, the agency took enforcement actions for inappropriate marketing against at least 73 organizations that sponsored Medicare Advantage plans from January 2006 to February 2009.

In regard to CMS's management of its contracting function, GAO found pervasive internal control deficiencies that put billions of taxpayer dollars at risk of improper payments or waste and recommended that CMS take actions to address them. Recently, CMS has taken several actions to address the recommendations and correct certain deficiencies we noted, such as revising policies and procedures, and developing a centralized

tracking mechanism for employee training. However, CMS has not made sufficient progress to complete actions to address recommendations related to clarifying the roles and responsibilities for implementing certain contractor oversight responsibilities, clearing a backlog of contracts that are overdue for closeout, and finishing its investigation of over $70 million in payments GAO questioned in 2007.

Enhancing program integrity. New directives, implementing guidance, and legislation will impact CMS's efforts to reduce improper payments in the next few years. The administration has issued Executive Order 13520 on Reducing Improper Payments in 2009 and related implementing guidance in 2010. In addition, the Improper Payments Elimination, and Recovery Act of 2010 (IPERA) amended the Improper Payments Information Act of 2002 and established additional requirements related to accountability, recovery auditing, compliance and noncompliance determinations, and reporting. Further, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 contain provisions designed to help reduce improper payments in the Medicare program.

CMS has already taken action in some areas—for example, as required by law, it implemented a national Medicare Recovery Audit Contractors (RAC) program in 2009. CMS has set a key performance measure to reduce improper fee-for-service and Part C payments and is developing measures of improper payment for Part D. CMS was not able to demonstrate sustained progress at reducing its fee-for-service error rate, because changes made to improve the methodology for measurement make current year estimates noncomparable to any issued before 2009. Its 2010 fee-for-service payment error rate of 10.5 percent will serve as the baseline for setting targets for future reduction efforts. However, with a 2010 Part C improper payment rate of 14.1 percent, the agency met its target to have its 2010 improper payment rate lower than 14.3 percent. For Part D, the agency is working to develop a composite improper payment rate, and for 2010 has four nonaddable estimates, with the largest being $5.4 billion.

Other recent CMS program integrity efforts include issuing regulations, tightening provider enrollment requirements and creating a Center for Program Integrity, responsible for addressing program vulnerabilities leading to improper payments. However, having corrective action processes to address the vulnerabilities that lead to improper payments is also important to effectively managing them. CMS did not develop an adequate process to address the vulnerabilities to improper payments identified by the RACs.

Further, several recommendations GAO made to improve the targeting of claims review for services with high rates of improper billing have not been addressed. Our February 2009 report indicated that Medicare continued to pay some home health agencies for services that are not medically necessary or not rendered. To help address the issue, GAO recommended that postpayment reviews be conducted on claims submitted by home health agencies with high rates of improper billing identified through prepayment review and that CMS require that physicians receive a statement of home health services beneficiaries received based on the physicians' certification. In addition, GAO recommended that CMS require its contractors to develop thresholds for unexplained increases in billing by providers and use them to develop automated prepayment controls as a way to reduce improper payments. CMS has not implemented these three recommendations because the agency indicated it had taken other actions; however, GAO believes these actions will not have the same effect.

CMS's oversight of Part D plan sponsors' programs to deter fraud and abuse has been limited. However, CMS has taken some actions to increase it. For example, CMS officials indicated that they had conducted expanded desk audits and were implementing an oversight strategy.

Overseeing patient care and safety. CMS's oversight of the quality of nursing home care has increased significantly in recent years, but weaknesses remain in surveillance that could understate care quality problems. Under contract with CMS, states conduct surveys at nursing homes to help ensure compliance with federal quality standards, but a substantial percentage of state nursing home surveyors and state agency directors identified weaknesses in CMS's survey methodology and guidance. In addition to these methodology and guidance weaknesses, workforce shortages and insufficient training, inconsistencies in the focus and frequency of the supervisory review of deficiencies, and external pressure from the nursing home industry may lead to understatement of serious care problems.

CMS established the Special Facility Focus (SFF) Program in 1998 to help address poor nursing home performance. The SFF Program is limited to 136 homes because of resource constraints, but according to GAO's estimate, almost 4 percent (580) of the roughly 16,000 nursing homes in the United States could be considered the most poorly performing. CMS's current approach for funding state surveys of facilities participating in Medicare and Medicaid is ineffective yet these surveys are meant to ensure that these facilities provide safe, high-quality care. GAO found serious

weaknesses in CMS's ability to (1) equitably allocate more than $250 million in federal Medicare funding to states according to their workload, (2) determine the extent to which funding or other factors affected states' ability to accomplish their workload, and (3) guarantee appropriate state contributions. These weaknesses make assessing the adequacy of funding difficult.

However, CMS has implemented many recommendations that GAO has made to improve oversight of nursing home care. Of the 96 recommendations made by GAO from July 1998 through March 2010, CMS has fully implemented 45, partially implemented 4, is taking steps to implement 29, did not implement 18. Examples of key recommendations implemented by CMS include (1) a new survey methodology to improve the quality and consistency of state nursing home surveys and (2) new complaint and enforcement databases to better monitor state survey activities and hold nursing homes accountable for poor care.

What Remains to Be Done

CMS has not met GAO's criteria for having the Medicare program removed from the High-Risk List—for example, the agency is still developing its Part D improper payment rate methodology and has not yet been able to demonstrate sustained progress in lowering its fee-for-service and Part C improper payment rates. CMS needs a plan with clear measures and benchmarks for reducing Medicare's risk for improper payments, inefficient payment methods, and issues in program management and patient care and safety. One important step relates to how well CMS implements IPERA and earlier requirements to identify the causes of improper payments and take appropriate action on them. Identifying the causes of improper payments and implementing GAO's recommendation to develop an adequate corrective action process to address vulnerabilities could strengthen CMS's efforts to reduce improper payments. Without an adequate corrective action process that uses information on vulnerabilities identified by the agency, its contractors, and others, CMS will not be able to effectively address its challenges related to improper payment. CMS has implemented certain GAO recommendations, such as in the area of nursing home oversight; however, further action is needed on GAO's recommendations to improve management of key activities. To refine payment methods to encourage efficient provision of services CMS should take action to

- ensure the implementation of an effective physician profiling system;

- better manage payments for services, such as imaging;
- systematically apply payment changes to reflect efficiencies achieved by providers when services are commonly furnished together; and
- refine the geographic adjustment of physician payments by revising the physician payment localities using an approach uniformly applied to all states and based on current data.

In addition, further action is needed by CMS to establish policies to improve contract oversight, better target review of claims for services with high rates of improper billing, and improve the monitoring of nursing homes with serious care problems.

GAO Contact

For additional information about this high-risk area, contact Cynthia A. Bascetta at (202) 512-7114 or bascettac@gao.gov.

Related GAO Products

Medicare Recovery Audit Contracting: Weaknesses Remain in Addressing Vulnerabilities to Improper Payments, Although Improvements Made to Contractor Oversight. GAO-10-143. Washington, D.C.: March 31, 2010.

Medicare Contracting Reform: Agency Has Made Progress with Implementation, but Contractors Have Not Met All Performance Standards. GAO-10-71. Washington, D.C.: March 25, 2010.

Nursing Homes: Addressing the Factors Underlying Understatement of Serious Care Problems Requires Sustained CMS and State Commitment. GAO-10-70. Washington, D.C.: November 24, 2009.

Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program. GAO-10-27. Washington, D.C.: November 6, 2009.

Centers for Medicare and Medicaid Services: Deficiencies in Contract Management Internal Control Are Pervasive. GAO-10-60. Washington, D.C.: October 23, 2009.

Medicare Physician Payments: Fees Could Better Reflect Efficiencies Achieved When Services Are Provided Together. GAO-09-647. Washington, D.C.: July 31, 2009.

Medicare: Improvements Needed to Address Improper Payments in Home Health. GAO-09-185. Washington, D.C.: February 27, 2009.

Medicare Advantage: Characteristics, Financial Risks, and Disenrollment Rates of Beneficiaries in Private Fee-for-Service Plans. GAO-09-25. Washington, D.C.: December 15, 2008.

Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices. GAO-08-452. Washington, D.C.: June 13, 2008.

Medicare: Focus on Physician Practice Patterns Can Lead to Greater Program Efficiency. GAO-07-307. Washington, D.C.: April 30, 2007.

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In January 2009, GAO detailed 30 high-risk areas and, in July 2009, added a 31st—Restructuring the U.S. Postal Service to Achieve Sustainable Financial Viability. GAO has determined that sufficient progress has been made to remove the high-risk designation from two areas: the DOD Personnel Security Clearance Program and the 2010 Census.

- High-level attention by DOD, OMB, and the Office of the Director of National Intelligence, along with consistent congressional oversight, has led to significant improvements in processing security clearances. For example, DOD processed 90 percent of all initial clearances in an average of 49 days in fiscal year 2010 and thus met the 60-day statutory timeliness objective. Furthermore, DOD has reduced the average time it takes to process 90 percent of initial security clearances for industry personnel from 129 days in 2008 to 63 days in 2010. DOD has also developed and is implementing quality assessment tools and has issued adjudicative standards for addressing incomplete investigations.
- The Census Bureau (Bureau), with active congressional oversight, took steps to address problems GAO pointed out since designating the 2010 Census a high-risk area in March 2008. Those steps included efforts to control costs, better manage operations, strengthen its risk management activities, and enhance the testing of automated systems. The Bureau generally completed its data collection activities consistent with its plans and released the data used to apportion Congress on December 21, 2010, several days ahead of the legally required end-of-year deadline.

This year, GAO is designating one new high-risk area—Interior's Management of Federal Oil and Gas Resources. Interior does not have reasonable assurance that it is collecting its share of billions of dollars of revenue from oil and gas produced on federal lands and it continues to experience problems in hiring, training, and retaining sufficient staff to provide oversight and management of oil and gas operations on federal lands and waters. Further, Interior recently began restructuring its oil and gas program, which is inherently challenging, and there are many open questions about whether Interior has the capacity to undertake this reorganization while carrying out its range of responsibilities, especially in a constrained resource environment.

In the past 2 years, progress has been made, to varying degrees, in most areas that remain on GAO's High-Risk List. Congressional oversight and legislative action, high-level administration attention, and efforts of the responsible agencies have been central to progress. For example, Congress passed the Improper Payments Elimination and Recovery Act (IPERA) of 2010 to enhance reporting and recovering of improper payments in federal programs. In addition, in November 2009, the President issued Executive Order 13520, Reducing Improper Payments and Eliminating Waste in Federal Programs. Congress also passed the Weapon Systems Acquisition Reform Act of 2009, which requires DOD to provide more realistic cost estimates and terminate programs with high cost growth.

Medicaid Program

Why Area Is High Risk

GAO designated Medicaid as a high-risk program in part due to concerns about the adequacy of fiscal oversight, which is necessary to prevent inappropriate program spending. Medicaid, the federal-state program that covered acute health care, long-term care and other services for over 65 million low-income people in fiscal year 2009, consists of more than 50 distinct state-based programs that cost the federal government and states an estimated $381 billion that year. The program accounts for more than 20 percent of states' expenditures and exerts continuing pressure on state budgets. The federal government matches state expenditures for most Medicaid services using the Federal Medical Assistance Percentage, a statutory formula based on each state's per capita income. The Centers for Medicare & Medicaid Services (CMS) in the Department of Health and Human Services (HHS) is responsible for overseeing the program at the federal level, while the states administer their respective programs' day-to-day operations.

What GAO Found

Strong federal oversight of Medicaid is warranted as the program continues to grow in size and cost to states and the federal government. For example, under the Patient Protection and Affordable Care Act (PPACA), the cost of the Medicaid expansion is estimated to exceed $430 billion over the next 10 years, with the federal government responsible for paying over 90 percent of these increased costs. CMS will need new tools and resources, including more reliable data for assessing expenditures and measuring performance, as the law is implemented. Medicaid remains at high-risk due to concerns about the adequacy of fiscal oversight of this large, diverse, and growing program. Areas of concern include the following:

Improper payments to Medicaid providers serving program beneficiaries. Improper payments to providers that submit inappropriate claims can result in substantial financial losses to states and the federal government. Medicaid payments can be improper for various reasons; such as if payments are made for people not eligible for Medicaid or made for services not provided. In its 2010 agency financial report, HHS estimated—on the basis of individual state error rates from a sample of 17 states reviewed on a rotating basis each year—a national improper payment rate for Medicaid of 9.4 percent (with the federal share estimated at $22.5 billion) for fiscal year 2010. Certain services may be more susceptible to improper payments. For example, in 2009 GAO found that Medicaid beneficiaries and providers were involved in potentially wasteful or abusive purchases of controlled substances in five selected states. Specifically, GAO found that Medicaid paid over $2 million in controlled

substance prescriptions during fiscal years 2006 and 2007 that were written or filled by 65 medical practitioners and pharmacies barred, excluded, or both from federal health care programs, including Medicaid. GAO recommended that CMS issue guidance to states to implement processes that better prevent payment of improper claims for controlled substances in Medicaid. CMS generally agreed with GAO recommendations; however, guidance had not been issued as of the end of 2010.

Positive steps toward improving the transparency over and reducing improper payments have been taken in recent years, including issuance of Presidential Memoranda and a 2009 Executive Order, *Reducing Improper Payments*, along with the enactment of the Improper Payments Elimination and Recovery Act of 2010 (IPERA). CMS has also taken steps to address improper payments. For example, in 2010 the agency issued guidance to states in response to PPACA provisions requiring the establishment of a Recovery Audit Contractor Program for Medicaid and implementation of standard prepayment edits for Medicaid claims in all states. In addition, CMS's Medicaid Integrity Group was elevated and incorporated into the agency's overall program integrity program. However, it is too soon to assess the effectiveness of CMS's actions and the activities called for in the Presidential Memoranda, Executive Order, and IPERA in reducing improper payments.

Managed care rate setting and quality of data used to set such rates has not been consistently reviewed by CMS. Requirements for Medicaid managed care rates to be actuarially sound are key safeguards in efforts to ensure that federal spending is appropriate. In 2010, GAO reported that CMS had been inconsistent in ensuring that states are complying with the actuarial soundness requirements. Further, GAO found that CMS efforts were not sufficient to ensure the quality of the data used by states to set managed care rates. With limited information on data quality, CMS cannot ensure that states' managed care rates are appropriate, which places billions of dollars at risk for misspending. GAO recommended that CMS implement a mechanism to track state compliance with actuarial soundness requirements, clarify federal guidance on rate-setting reviews, and make use of information on data quality in overseeing states' rate setting. HHS agreed with the recommendations and described efforts begun to improve CMS's oversight.

Financing methods that are inappropriate and large supplemental payments that are not always transparent. Some states have established varied financing arrangements involving Medicaid supplemental payments that inappropriately increase federal Medicaid matching payments. Subject to certain requirements, states may make supplemental payments to Medicaid providers that are separate from and in addition to standard state Medicaid payments for services. In fiscal year 2010, states made more than $31 billion in supplemental payments; the federal share was more than $19 billion. GAO and others have reported concerns with states' Medicaid supplemental payments over the last decade, including the use of supplemental payment arrangements to increase federal funding without a commensurate increase in state funding.

A variety of federal legislative and CMS actions have helped curb inappropriate arrangements, but gaps remain. In 2003 CMS began an initiative to closely review state supplemental payments and required states to end those it found inappropriate, however, in 2008, GAO reported that CMS had not reviewed all supplemental payment arrangements to ensure payments were appropriate and for Medicaid purposes. In 2009, GAO found that ongoing federal oversight of supplemental payments was warranted in part because states' Medicaid supplemental payments to certain hospitals through Disproportionate Share Hospital (DSH) payments for uncompensated hospital care did not account for other Medicaid payments the hospitals had received. In 2011, improved transparency and accountability requirements will go into effect for state DSH payments, including standards for state calculations of DSH payment limits, state reporting of DSH payments on a facility basis, and independent auditing of state DSH payment reports and calculations. Similar standards for calculating and reporting of other types of Medicaid supplemental payments, such as non-DSH supplemental payments made under the Medicaid upper payment limit, have not been established.

Congress has capped overall federal expenditures for DSH payments and created a hospital DSH payment limit that caps DSH payments to individual hospitals. And under the Patient Protection and Affordable Care Act (PPACA), reductions to DSH allocations to states in future years will occur. Similar limits have not been established for non-DSH supplemental payments, which appear to be increasing in amounts. In 2006 states reported making $6.3 billion (federal share $3.7 billion) in non-DSH supplemental payments, but not all states were reporting their payments. By 2010 this amount had grown to $14 billion (federal share $9.6 billion) in non-DSH supplemental payments; however, according to CMS officials

reporting is likely incomplete. Some key GAO recommendations aimed at improving federal oversight of non-DSH payments have not yet been implemented. GAO has recommended, among other things, that CMS establish uniform guidance for states setting forth acceptable methods for calculating payment amounts, require facility specific reporting of supplemental payments and develop a strategy to ensure all state supplemental payment arrangements have been reviewed.

Demonstrations that inappropriately increase federal costs. HHS has authority to waive certain statutory provisions to allow states to implement demonstrations that test ideas for achieving program objectives. By policy, demonstrations should not increase federal costs. However, GAO reported in 2008 that HHS had approved two state demonstrations that could increase the federal financial liability substantially. At the time of our work in 2007, HHS disagreed with our recommendation to improve the demonstration review process through steps such as clarifying the criteria for reviewing and approving states' proposed spending limits and ensuring that valid methods were used to demonstrate budget neutrality. Consequently, we elevated this recommendation to the Congress for consideration. HHS subsequently reported taking steps, such as monitoring the budget neutrality of ongoing demonstrations, to improve its oversight. However, no changes are planned in the approval process and methods used to determine budget neutrality of demonstrations to ensure that demonstrations do not increase the federal financial liability.

What Remains to Be Done

Congress, HHS and CMS have taken steps to improve the fiscal integrity of Medicaid, and CMS has implemented certain GAO recommendations, such as improving the information collected on certain supplemental payments. More federal oversight of Medicaid's fiscal and program integrity is needed, however, in addition to state actions. For example, CMS needs to ensure states develop adequate corrective action processes to address vulnerabilities to improper Medicaid payments to providers, and issue guidance to states to better prevent payment of improper claims for controlled substances in Medicaid. States also have key roles in reducing improper payments to providers in developing, implementing, and evaluating the effectiveness of corrective plans to reduce improper payments.

CMS should also continue taking steps to improve oversight of Medicaid managed care payment rate-setting and Medicaid supplemental payments. CMS needs to identify and review the appropriateness of all Medicaid

supplemental payment arrangements; establish guidance to states on appropriate methods for calculating non-DSH Medicaid supplemental payments; improve reporting on non-DSH supplemental payments, and ensure that states account for all Medicaid payments when calculating DSH payment limits for payments to hospitals for uncompensated care.

GAO Contact

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Related GAO Products

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