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S. HRG. 115–708

EXAMINING EFFORTS TO PREVENT OPIOID OVERUTILIZATION AND MISUSE IN MEDICARE AND MEDICAID

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH CARE

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

SECOND SESSION

MAY 29, 2018



Printed for the use of the Committee on Finance

U.S. GOVERNMENT PUBLISHING OFFICE

38–217—PDF WASHINGTON : 2019

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EXAMINING EFFORTS TO PREVENT OPIOID OVERUTILIZATION AND MISUSE IN MEDICARE AND MEDICAID

TUESDAY, MAY 29, 2018

U.S. SENATE,
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Bensalem, Pa.

The subcommittee was convened, pursuant to notice, at 1 p.m., in the Bensalem Township Municipal Building, 2400 Byberry Road, Bensalem, PA, Hon. Patrick J. Toomey (chairman of the subcommittee), presiding.

Senator TOOMEY. Good afternoon, everyone. Before we get started, I would like to recognize Congressman Fitzpatrick.

STATEMENT OF HON. BRIAN K. FITZPATRICK, A U.S. CONGRESSMAN FROM PENNSYLVANIA

Representative FITZPATRICK. Thank you all for being here today.

Senator Toomey, I speak on behalf of all of our local elected officials here: Mayor DiGirolamo, Public Safety Director Fred Harran, Commissioner Rob Loughery. We really appreciate you choosing Bucks County to have this discussion. And as everybody here knows, dealing with the opioid crisis requires an ongoing message mission to problems we are having here in Bensalem Township—with close to 60,000 residents—and to those who have been on the front lines of this epidemic.

So, Senator, on behalf of all of Bucks County, we appreciate you choosing Bucks to have this hearing. We have a fine panel here, and I just wanted to thank you for being here.

Thanks.

OPENING STATEMENT OF HON. PATRICK J. TOOMEY, A U.S. SENATOR FROM PENNSYLVANIA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE, COMMITTEE ON FINANCE

Senator TOOMEY. Thank you very much, Congressman.

We will now begin a hearing of the United States Senate Committee on Finance Subcommittee on Health Care, a field hearing, where we will discuss and examine efforts to prevent opioid overutilization and misuse in Medicare and Medicaid.

First, I want to thank the Bensalem Township Council for hosting this field hearing.

Mayor DiGirolamo, thank you very much.

A special thank you to the Director of Public Safety here, Fred Harran, for his help in pulling this together.

I want to thank the witnesses for making themselves available and for contributing their time and expertise to what I am sure will be an illuminating discussion.

To the various public officials who are here from various places around the Commonwealth and around the county, I appreciate your dedication to this issue, in particular.

I want to thank Congressman Fitzpatrick, who has been a stalwart in the work that he has done in the House of Representatives.

But I also want to recognize two special guests who are with us. One is joining us from the Middle District of Pennsylvania, the U.S. Attorney, David Freed. David, thank you for joining us. And from the Eastern District, Bill McSwain. Bill, thank you for being here.

If we have time, I hope we might be able to get a couple of thoughts from each of you, because I know so much of your work is involved in this space.

Also, to the public who is here—because I know, like all of us, we are all interested in how we can make progress and eventually defeat this terrible scourge.

There are many lessons relevant to the current experience we are having, believe it or not, from the history of our country. This opioid epidemic actually has a precedent of sorts. It is not the first time, sadly, that our country has found itself in the depths of a public health crisis precipitated by the overuse of opium and its derivatives.

In the 19th and early 20th centuries, medical advances, like the development of morphine and the adoption of the hypodermic syringe, made a very powerful reliever of pain readily available to the masses. The addictive qualities and negative effects of opium and morphine use were not fully appreciated, not then, not until it was too late for many.

It is unfortunate that we find ourselves today in a predicament with such a clear precedent, but it is not too late to learn from the experience. There was no simple solution to that public health crisis, and there will be no simple solution today.

Then, the transition away from dependence on opioids was enabled in part by developing ways to resolve the underlying disease that gave rise to pain, such as improving sanitation. It was enabled in part by embracing alternative treatments, such as the adoption of aspirin as an analgesic beginning in 1899. It was enabled in part by improving pharmaceutical controls and restricting the importation of opium itself and its derivatives. And finally, there was a significant shift in medical practice and the culture of medicine to appreciate that in many, though not all cases, the dangers associated with this particular treatment could outweigh the benefits.

Then and now, the correlation between an increased availability of opioids and very negative societal repercussions, such as substance use disorder and overdose, cannot be ignored. This correlation is too powerful to dismiss it. Opium became the most commonly dispensed medical item by 1834. From that time until the tide was finally turned in the late 1890s, the number of individuals struggling with opiate-related substance misuse grew six-fold.

Fast forward to the 21st century and opioids are, once again, among the most popularly prescribed class of medications. From 1999 to 2016, opioid-related overdoses quintupled. This chart created by the Centers for Disease Control shows the clear correlation between opioid-related sales, the growth of which is depicted on the green line, and opioid-related deaths, which is the blue line. By the way, this does not include the recent wave of heroin- and fentanyl-related deaths, but just prescription opioid-related deaths, and it shows the first wave of the crisis.

When we look at this issue in the present day, and we look by region, the trends are even more clear. This is another chart by the CDC. The size of the yellow circle depicts the number of painkillers sold per 10,000 in population. So, clearly, the larger yellow circles reflect a greater prevalence of opioid prescriptions per number of individuals. The shade of blue indicates the drug overdose rate per 100,000, and the darker the color blue, the greater the frequency of overdose deaths. There is a lot going on in a chart that shows 50 American States. But one thing that is pretty clear is the large yellow circles, the preponderance of prescription opioids, correspond to the dark blue, which is where there are very high death rates.

Now we have another chart that illustrates this in an even more compelling way, and it is a direct comparison of two distinct regions of the country. High prescribing, which is the big yellow circles, and high overdose rates, the dark blue, go hand in hand throughout much of Appalachia, while at the same period of time, much lower prescribing rates, the very small yellow circles, and significantly lower overdose rates, the light blue color, are the norm in the upper Midwest. Folks, this is not a uniform national crisis. It is really several intense regional crises.

Another point of comparison that I think is useful is looking at opioid consumption internationally. The data that is displayed here comes from the United Nations International Narcotics Control Board, and it shows the most recent period of time for which we have data, which is 2012 through 2014. And in that period of time, the United States, after adjusting for population, so this is all on a per-citizen basis, still utilizes—look at this graph. This is the United States in a bar graph that shows the opioid consumption by prescription, and in the United States, we consumed in this period of time eight times the rate of opioid prescriptions in Italy, six times that of France, four times that of Great Britain, and more than 1½ times the rate of opioid prescriptions of the number two country in the world, which is our neighbor, Canada.

Now, all of that is very discouraging at some level, for me anyway, but it is not to say that we have not made significant progress in recent years. It appears that the peak of opioid prescriptions was in 2011, and there has been a significant falloff, as you can see, since then. In fact, the total fall has been about 29 percent. That is very significant, and that is real progress.

I think it is attributable in part to increased awareness, both throughout the medical profession and the public as a whole. I think it has come in part because of developments such as the endorsement of guidelines for prescribing opioids for chronic pain by the Centers for Disease Control and Prevention. These sorts of things have had a profound effect. The adoption of prescription

drug monitoring programs allows physicians to know in a moment what other prescriptions have been prescribed for a given patient. This was only recently introduced here in the Commonwealth of Pennsylvania, and it has given health-care providers a powerful new tool to inform their judgment about whether or not to prescribe another opioid.

But despite all this progress, the amount of opioids being dispensed today, after a 29-percent decline from the peak—today we are still prescribing roughly five times the volume of prescriptions as recently as 1992. Let me say that again. Today, we are prescribing five times the level that was being prescribed in 1992.

In 2016, there were 215 million opioid prescriptions written across the country. In our State of Pennsylvania, there are still counties where, in a given year, there are more prescriptions for opioids than there are people. Fayette County—129 prescriptions in 2016 for every 100 people. Lackawanna County—112 for every 100 people. Mercer County—109 prescriptions for every 100 people. Let me reiterate. That is more than one opioid prescription for every man, woman, and child in that county.

I am going to ask our witnesses at the appropriate time whether it could possibly make sense that we need to prescribe that many opioids throughout the population of our country.

But another question and a related question that we are going to explore today is: what are our Nation's largest payers of health care, Medicare and Medicaid, doing to prevent opioid overutilization and misuse? With the implementation of the Medicare prescription drug benefit in 2006, commonly referred to as Medicare Part D, the Federal Government became the single largest purchaser of opioids in the world. Let me say that again as well so that we are all very clear about this. The world's largest purchaser of opioids, by far, is the United States Federal Government through these programs.

This is a chart that ran in the *Journal of Health Affairs.* The dark red—which you can see going from a minute little line in the early years to a very large portion of the column in the latter years—that is the volume of opioids paid for by Medicare alone. Medicaid is the dark blue portion of the columns, and Medicaid does not spend as much money on opioids as the Federal counterpart for the aged and disabled, which is Medicare.

But Medicaid beneficiaries receive average annual doses that are twice as high as those who are privately insured, and Medicaid beneficiaries are much more likely than the general population to be diagnosed with substance use disorder or suffer an overdose. I am not suggesting that I know the cause and effect here. I am simply suggesting that these are facts that are occurring at the same time.

So the approaches of Medicare and Medicaid programs to deal with this, to prevent opioid overutilization and misuse, have been underway for some time, and they have been multifaceted. Let me touch on a few of these, because they are important.

Some examples: Congress worked with the previous administration to decouple questions related to pain management in patient surveys from Medicare hospital reimbursement. It used to be that a hospital would get a bump-up in their reimbursements from

Medicare if, in patient surveys, patients indicated a high level of satisfaction with pain management. It really was a mechanism for creating a financial incentive to prescribe more opioids. We ended that.

The Centers for Medicare and Medicaid Services, plan sponsors, States, health systems, medical professional societies, and other stakeholders have undergone a noteworthy campaign of education, especially for prescribers. CMS is implementing a 7-day initial fill limit for what they call opioid-naive patients. That is a patient who has had no opioid prescription for at least the previous year. So a 7-day initial fill limit means you do not leave with more than a 7-day supply. If you need a greater supply than that, you go back and get a prescription refilled.

Medicare, State Medicaid programs, and plan sponsors have utilized drug management programs that incorporate tools like prior authorization, point-of-sale edits, and patient review and restriction, sometimes referred to as lock-in programs, to encourage more appropriate prescribing. Law enforcement has aggressively worked to crack down on those working to defraud Medicare and Medicaid programs for monetary gain.

Today, we will hear from witnesses who should give us insight into the effectiveness of all of these efforts and how we may improve upon them and what other ones we may explore. Specifically, we want to explore whether the efforts focus on a large enough portion of the total beneficiaries who are at risk of harm. Are we doing enough to ensure that when potential fraud is identified, appropriate action is being taken? Are we doing enough to equip providers with the information that they need? Are the efforts currently underway in the Medicare and Medicaid programs having any noticeable impact at the local level, including with law enforcement? These are some of the things we are going to explore during the course of this afternoon.

So again, I want to thank everyone for being here today. I look forward to the discussion. I do remain confident that by working together at the Federal, State, and local levels and, essentially, with health-care providers, insurance, and the various plans, that we can continue to make the substantial progress we have been making. But it is clear to me we still have a very long way to go.

[The prepared statement of Senator Toomey appears in the appendix.]

Senator TOOMEY. Our first witness this afternoon is Dr. Mary Denigan-Macauley. She is Acting Director of Health Care at the U.S. Government Accountability Office, a graduate of the University of Delaware with a Ph.D. from Arizona State. Dr. Denigan-Macauley has been at GAO since 2001. She had previously taught public policy at Sam Houston State University in Texas and Troy University in Japan. Her recent work focuses on the effectiveness of Federal programs to promote and ensure public health and to prevent and respond to public health emergencies such as the opioid epidemic.

We will then turn to Ms. Maureen Dixon. Ms. Dixon is the Special Agent in Charge of the Philadelphia Office of the United States Department of Health and Human Services' Office of the Inspector General. Ms. Dixon graduated from Syracuse University and, prior

to entering law enforcement, was an emergency medical technician. In her current capacity, Ms. Dixon manages all Health and Human Services Office of Inspector General operations in Pennsylvania, Maryland, West Virginia, Delaware, and the District of Columbia.

She will be followed by Dr. Richard Snyder. Dr. Snyder is the senior vice president and chief medical officer of Independence Blue Cross. Dr. Snyder is a graduate of Franklin and Marshall College and the Medical College of Pennsylvania and is board-certified by the American Board of Family Medicine. He is the chief clinical spokesperson for Independence Blue Cross, the largest provider of health insurance in our region. At Independence, Dr. Snyder has overall responsibility for medical quality, pharmacy management, and all clinical policies and programs.

Then we will hear from Ms. Heather Malone. Ms. Malone is a constituent who joins us from Delaware County. Following a traumatic childhood, Ms. Malone was prescribed opioids for back pain resulting from a car accident she had at the age of 18. She continued to use opioids for the next 2 years. Dependence and misuse eventually led to heroin and some very harrowing experiences. Ms. Malone has been in recovery for 6 months now. We are looking forward to hearing from her.

And finally, we will hear from Mr. Matthew Weintraub. Mr. Weintraub is the District Attorney for Bucks County. A graduate of Ursinus College and Temple Law, he previously worked as an Assistant D.A. in both Bucks and Lehigh Counties. He has tried more than 100 criminal cases, including the successful prosecution of four Philadelphia heroin dealers who had sold fatal doses to Bucks County residents. D.A. Weintraub has also taught criminal justice at Rowan, DeSales, and Delaware Valley Universities.

So thank you to the witnesses. Your full testimony will be submitted for the record. I ask you to keep your oral testimony this afternoon to approximately 3 minutes each so that we will have time for a robust discussion, and I would like to ask Dr. Denigan-Macauley to begin.

STATEMENT OF MARY DENIGAN-MACAULEY, Ph.D., ACTING DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE, WASHINGTON, DC

Dr. DENIGAN-MACAULEY. Good afternoon, Chairman Toomey and Congressman Fitzpatrick. Thank you for the opportunity to testify today on the oversight of opioid prescribing in the Medicare program.

Prescription opioids are critical for treating both acute and chronic pain, and it is important we maintain access to them for those in need. Unfortunately, misuse of prescription drugs has become a serious public health problem, including for Medicare and Medicaid beneficiaries. The Centers for Disease Control and Prevention reported that from 1999 to 2013, the rate of deaths from prescription opioids nearly quadrupled. Today, I would like to point out two areas where the Federal Government can do more to protect Medicare beneficiaries from harm.

First, the Centers for Medicare and Medicaid Services, also known as CMS, do not know how many of their Medicare beneficiaries receive doses of opioids that are high enough to put them

at risk for addiction, overdose, and death. We found in 2017 that this is because CMS only monitors the total number of beneficiaries who receive prescriptions for high doses of opioids if those prescriptions also come from a certain number of providers and pharmacies. CMS estimated that in 2015, it would have captured more than 20 times the number of individuals at risk, from 33,223 to more than 720,000 beneficiaries, if it did not tie prescription monitoring to that number of providers and pharmacies.

According to the Centers for Disease Control and Prevention, long-term use of high doses of opioids is associated with significant risk of harm and should be avoided if possible. This is particularly the case for patients age 65 and older, because the drugs can more easily accumulate in the body and become toxic. We recommended and CMS concurred that it should gather this information.

Second, we found that CMS lacks key information to ensure proper opioid prescribing because it does not require its private insurers to report on the actions they take against doctors and others who may inappropriately prescribe opioids. We recommended that CMS make this a requirement. CMS did not concur, noting concerns about overburdening the private insurers with new regulatory requirements. We continue to believe that this should be a requirement so that CMS has the information it needs to assess progress in reducing the over-prescribing of high doses of opioids.

In conclusion, it is important that patients receive appropriate and safe pain treatment based on benefits and risks. Having information on beneficiaries receiving harmful levels of these opioids and on providers inappropriately prescribing them could help CMS reduce the risk of opioid addiction, overdose, and death.

Chairman Toomey, Congressman Fitzpatrick, this concludes my statement, and I look forward to your questions.

Senator TOOMEY. Thank you very much.

[The prepared statement of Dr. Denigan-Macauley appears in the appendix.]

Senator TOOMEY. Ms. Dixon?

STATEMENT OF MAUREEN DIXON, SPECIAL AGENT IN CHARGE, PHILADELPHIA REGIONAL OFFICE, OFFICE OF INVESTIGATIONS, OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, PHILADELPHIA, PA

Ms. DIXON. Good afternoon, Chairman Toomey and Congressman Fitzpatrick. Thank you for the opportunity to appear before you today to discuss OIG's efforts to combat the opiate epidemic in Federal health-care programs.

Given our long history of health-care fraud enforcement, program knowledge, and data analytics, OIG is uniquely positioned to help lead the fight against illegal opiate prescribing in Medicare and Medicaid. My testimony today will highlight our work to prevent opiate-related fraud and abuse, detect questionable prescribing and billing patterns, and enforce laws and regulations governing opiate prescribing.

Opiate-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to addiction fraud treatment. Developing these investigations is complex, requiring our full

range of law enforcement techniques to gather evidence of crimes often committed by corrupt doctors, pharmacists, and criminal networks. In the worst cases, we have uncovered evidence of illegal prescribing resulting in deaths from overdose.

OIG's partnership with DOJ, FBI, DEA, and State Medicaid fraud control units is critical to the success of our efforts. OIG and our Medicare Fraud Strike Force partners led the 2017 national health-care fraud takedown, the largest health-care fraud enforcement action ever, resulting in over 400 charged defendants across the country.

OIG has also shifted resources to support the Attorney General's Opiate Fraud and Abuse Detection Unit, a multiagency effort capitalizing on data analytics. Agents in the Philadelphia regional office are assigned to support this initiative, which focuses solely on investigating and prosecuting opiate-related health-care fraud cases.

OIG uses advanced data analytics to put timely, actionable information about prescribing, billing, and utilization trends in the hands of investigators, auditors, evaluators, and government partners. Our July 2017 data brief uncovered that half a million Medicare beneficiaries receive opiates in excess of CDC guidelines.

Further, nearly 90,000 beneficiaries are at serious risk of opiate misuse or overdose. To get at the source of this extreme use, OIG identified about 400 prescribers with questionable opiate prescribing patterns for these beneficiaries at serious risk. OIG will release an update to the data brief later this summer based on more recent data. OIG will also release an analyst toolkit based on the methodology we developed in our extensive work on opiates to assist our public- and private-sector partners with analyzing their own prescription drug data to help combat the opiate crisis.

OIG's work holds criminals accountable and results in impactful recommendations to improve program integrity, save tax dollars, and protect HHS beneficiaries from harm.

I appreciate the opportunity to speak with you today, and I would be happy to answer any questions you may have.

Thank you.

Senator TOOMEY. Thank you, Ms. Dixon.

[The prepared statement of Ms. Dixon appears in the appendix.]

Senator TOOMEY. Dr. Snyder?

STATEMENT OF RICHARD SNYDER, M.D., SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, INDEPENDENCE BLUE CROSS, PHILADELPHIA, PA

Dr. SNYDER. Senator Toomey, Congressman Fitzpatrick, thank you for having me. The detailed written testimony that I provided has a lot more detail, but I wanted to focus on this problem using sort of a physician's disease model approach, because I think it may shed some light on what otherwise seems like a very large morass of issues that we need to tackle simultaneously.

I think of diseases as manageable if you think of primary prevention—that would be like an immunization—secondary prevention, which would be identified with screening and then treating the patient, and obviously, tertiary, intervening when the patient crashes. So if we think about the people who take opioids in that light, pri-

mary prevention should focus on those people who are opioid-naive. You mentioned this, Senator Toomey—they have not had opioids in the past. We need to prevent that.

I sat on the Mayor's task force in Philadelphia to address this, and one of the stories I heard over and over was young people who became addicted to heroin by first encountering opioids in a loved one's medicine cabinet—the one room in the house that you can enter, lock the door, and no one would think different while you are in there looking through the medicine cabinet. You need to prevent that. And even here today, a couple of people mentioned to me that after minor procedures they received 30 oxycontin at the point of discharge. We cannot do that. You take one or two, and they end up in a medicine cabinet. That is very problematic.

So we need to educate physicians and patients, the beneficiaries, about the risks of opioids and put some kind of blockade in place to prevent that arbitrary prescribing of opioids for minor procedures—wisdom teeth, minor surgical procedures.

A close friend who is a cardiothoracic surgeon, upon having his bladder removed for bladder cancer, received only IV Tylenol because of the risk of getting addicted to opioids—did not want it, did not need it.

We can manage things differently and prevent the exposure and, more importantly, the lingering of opioids in people's possession at home.

The secondary prevention concept is one that we do not do a very good job of as a medical community, and that is screening people who are at risk for opioids before we continue to administer them. It is very common that physicians will not ask about past history, and there are lots of examples where that has resulted in perpetuating a problem with patients.

Screening tools are available, and we at Independence will be making a tool available midyear this year online that physicians or members can access supported by computerized cognitive behavioral therapy to help intervene. If you do not want to publicly go out and meet with your physician about that issue, you can try to do it on your own.

In addition to that, one thing we cannot do as a payer—and I assume you also are running into that issue in the Office of the Inspector General—is use all the data that is available. There is a lot of data sitting in PDMPs that I cannot access to couple with diagnostic information as well as other prescribing information about our members that would allow me to then intervene prospectively before they have a crisis and try to help them, as we would with any other chronic condition—medical conditions, heart failure, diabetes, et cetera.

We would like to be prospective, not wait until the patient is in the hospital in crisis, and intervene with a security net of services to help them address their chronic problem. We are not allowed to do that with opioid use disorder, substance use disorder, as a result of HIPAA and 42 CFR part 2 and State laws which interfere with that. So if mental health parity is ever going to really exist for patient care, we need to somehow address that, which would allow us to find people who are at risk and treat them and support them through the transition.

And then, thinking about this from a tertiary prevention perspective, obviously, in crisis, patients are identified either by a loved one or emergency medical services, and we need to make the rescue medications Narcan and naloxone more readily available. We have tried to do that by eliminating member cost share where possible and encouraging patients to have it available if they are dealing with a loved one who may be subject to opioid use and abuse.

Warm hand-off programs are another thing. When people are in crisis, it is very effective to have someone who has been down that path help the patient to walk into treatment. We, in a study commissioned here in this region looking at our own data, have identified that with warm hand-off programs in place, there is an 89-percent greater chance that the patient will actually enter into treatment. And with treatment, obviously, there is recidivism, but we can at least have a fighting chance to support them.

And last, I think there is a big opportunity for payers and providers to collaborate more than they do today, if we can get past some of the issues with the privacy laws as they stand.

On behalf of Independence and our CEO, Dan Hilferty, I appreciate the opportunity to be here and testify.

Senator TOOMEY. Thank you very much, Dr. Snyder.

[The prepared statement of Dr. Snyder appears in the appendix.]

Senator TOOMEY. Ms. Malone?

STATEMENT OF HEATHER MALONE,
PERSON IN RECOVERY, MEDIA, PA

Ms. MALONE. Thank you, Senator Toomey and Congressman Fitzpatrick. Thank you, fellow witnesses, for your testimony.

Six months ago, I made a decision to better my life for myself. For so long, I lived in fear, darkness, and chaos. I was using heroin every single day, and it left me lost and alone. My family wanted nothing to do with me, and my children did not know their mother.

Looking back, it was really easy to blame my past and how I turned out on situations that led up to things. I never learned any coping mechanisms on how to deal with all the pain. I came from a mother who was an addict, and she was never around. She had a lot of live-in babysitters, and, eventually, my aunt and her boyfriend filled this role of my mother. My aunt's boyfriend molested me, and when he moved out, my aunt committed suicide. I then had to move in with my father, who was very emotionally and physically abusive, and at age 14, I attempted to take my own life.

At 18, my mother reentered my life, and I thought I would be able to grow close to her, but this did not happen. She wanted someone to get high with, and after a minor car accident, she took me to a doctor, and all I had to do was tell the doctor that I had serious back pain and I was prescribed medication.

The first time taking a pill was a memory that I will never forget. I thought I had found the answers to all my pain and problems. The pill gave me a numbing effect that I fell in love with. As time progressed, the strength of medications increased, as did my addiction. Pills were so easily accessible, and they were legal, so I did not see a problem with them.

Eventually, prescriptions ran out, and pills became too expensive, and I graduated to heroin, and that became my new best

friend. This took me down a dark path with more pain and suffering. I was raped, and selling my body was an easy way to pay for my next fix. Jails and institutions and running and using became my life. There were bouts of sobriety thanks to Suboxone and methadone.

I went back to school and I worked with people like myself, and I excelled, and I was admitted to an honor society. I was picked to give a speech at a ceremony, and I should have been happy and I should have been proud, but I was not. I never made it to that speech that night, because that night, I tried to take my life once again.

As years went on, things got worse, and addiction became my full-time job. I was consumed with that numbing effect. I did not want to live, but if I had to, I did not want to feel anything. I lived to use, and I used to live. Eventually, I got back into a relationship with a person who was in active addiction and very abusive, and I thought that we loved each other, because, to me, pain equaled love.

All the people who were ever supposed to love me ended up hurting me, and physical abuse meant that I did not have to feel that internal pain.

Last December 8th, the abuse went to a whole new level. I woke up to my girlfriend choking me, and I begged her to end my life. She cut my throat, she hit me with a bat, and she hung me over a balcony. My father arrived and stopped this, and I should have gone right to the hospital because I had black eyes, bruises on my neck, and a fractured hip, and all I could do was beg him to take me to Kensington to get my next fix so I could feel that numbness once again. He took me, and I promised that I would go to rehab.

I showed up at rehab badly physically beaten. I was at an all-time low. I was emotionally and spiritually bankrupt and broken. After 3 days in rehab, I got up enough strength to look at myself in the mirror, and I realized I did not want this anymore. I wanted something better. Due to DBT therapy, they finally helped me share stories and secrets that I would never share with anyone before.

As my discharge date approached, I agreed, after talking with my counselors, to live at MVP—Motivation, Vitality, and Perseverance Recovery House. This program is helping me so much. It is helping me recognize my defects coming out and how to work through them so that I can be a better person. Perfecting this process is unrealistic, and I fall short at times. But because of MVP and the community that I am in now, I am able to work towards being a productive member of society.

Today, I am accountable for my actions. I am able to be a daughter, a friend, and most of all a mother. I am still in a lot of pain on a daily basis due to my fractured hip. I need to get a partial hip replacement, and I fear the aftermath, because to recover, a doctor might write me a prescription for pain medication. If I do not notify them ahead of time that I am in recovery, it is almost automatic that they will prescribe me opiates.

My demise of addiction all began with a simple script written from a doctor.

I want to recover. I do not want to be defined as a statistic, and hopefully, things can change to help implement changes to avoid over-prescribing or prescribing to people who are at risk.

In treatment, they asked us what our 5-year goal was in life, and people wanted houses and cars and families. When it was my turn to share, all I wanted was genuine happiness, because I never had that before, and I honestly thought that pure happiness was unattainable for a person like myself, and I definitely did not think that I would be able to achieve it within 5 years. But today, I can tell you I am truly happy, and I am truly grateful to be exactly where I need to be.

Thank you. [Applause.]

Senator TOOMEY. Ms. Malone, I just want to thank you for having the courage to be here today and share this experience and to assure you that it is very likely, in my view, that you are encouraging and inspiring other people who are facing the kind of circumstances you were in, and you are inspiring them by proving that they can recover. So thanks very much.

[The prepared statement of Ms. Malone appears in the appendix.]

Ms. MALONE. Thank you for this opportunity.

Senator TOOMEY. We appreciate it.

Ms. MALONE. Thank you.

Senator TOOMEY. D.A. Weintraub?

STATEMENT OF MATTHEW WEINTRAUB, DISTRICT ATTORNEY, BUCKS COUNTY, DOYLESTOWN, PA

Mr. WEINTRAUB. Good afternoon. Thank you, Chairman Toomey and Congressman Fitzpatrick, for the opportunity to provide this testimony to the committee. As Bucks County D.A., I will try to focus on the challenges of the opioid epidemic as I see them, with a specific focus on why prevention is so important.

But I want to go off script for just a second and say that I applaud Ms. Malone's bravery. But we are surrounded by people in recovery every day, and they will help us to destigmatize recovery if they will step forward and be brave like Ms. Malone has been today.

Bucks County is particularly challenged because of our proximity to Philadelphia, to Allentown, and to Trenton. We are fortunate and unfortunate both in that we border these three very challenged areas that have been hit hard by the opioid epidemic. This makes it easy for those suffering from addiction to obtain these drugs. These drugs—we try our best to stop them from infiltrating our county, but they are easy to obtain with a very short drive, literally minutes, and that is why our regional and national response is vital.

No one county or entity within the county can do it alone. We have D.A. Kat Copeland here from Delaware County. We need her help, and we work hand in hand. We also have the regional law enforcement to help us as well, and we work closely together, all as a team. But we need more help. The following is a great example of where cross-county collaboration thwarted a pill-dealing drug ring.

In 2018, this very year, the Bucks County Drug Strike Force, which we started with the aid of our Commissioners—and I will point out that Commissioner Rob Loughery is here today—conducted an investigation in which 10 people were arrested in Berks County, which does not even neighbor Bucks County, for making and passing fraudulent prescriptions. Over 106 fraudulent prescriptions were filled in the Bucks County and Philadelphia area, which resulted in these individuals obtaining 12,500 oxycodone pills. These pills, unfortunately, were then distributed on the streets in Bucks County and Philadelphia.

Our medication take-back program demonstrates the overprescribing problem that we face, and it is illustrated by the amount of unneeded medication in our community. One of the other testifiers stated that we leave our unused, old, expired medication in our medicine cabinets, and if we know that, that is where somebody who craves these medications knows to look for them as well.

It is a good news-bad news situation. We here in Bucks County are number one in the State in medication take-back. We have collected over 107,000 pounds since this program's inception. That is over 53 tons. This is a lot of medication that can no longer be diverted to hurt or to kill somebody ever again. That is a lot of medication, period, and that is part of the problem, as you pointed out, Mr. Chairman.

Medicare and Medicaid are two of the largest payers for prescription opioids and, therefore, hold a critical role in making sure that we reduce the amount of excess opioids in circulation in the first place. Congress recently dedicated an unprecedented $4.6 billion to combat the opioid crisis in fiscal year 2018. I think that is wonderful. We need every penny of that.

It is important to make sure that funding reaches the places where it is needed the most through the programs that will be the most effective. Such programs that could benefit from such funding right here in Bucks County include drug recovery programs in our jails that can educate and successfully begin to treat our inmates so that they never return. That is really the point.

Another innovative program we are looking to expand is Bucks Police Aiding in Recovery. I would love to give a shout-out. That was started right here in Bensalem as Bensalem Police Aiding in Recovery. This helps increase treatment access to those who seek it voluntarily.

Finally, we have spent so much time focused on heroin, which is critical, of course, but we have turned our attention away from other substances. One phenomenon that we are seeing is what we now call a rising twin epidemic, which pairs stimulants like methamphetamine and opiates, like oxy or heroin. We are finding that many opioid users are also abusing meth in order to ease their painful physical withdrawal symptoms experienced as they seek their next opioid fix.

We must also continue to focus on underage drinking and marijuana use and educating our youth in the schools, which will continue to be issues for our community.

I appreciate the opportunity to address the committee today, Senator Toomey, to talk about the challenges of the opioid epidemic as I see them.

Thank you.

Senator TOOMEY. Thank you very much, D.A. Weintraub.

[The prepared statement of Mr. Weintraub appears in the appendix.]

Senator TOOMEY. Let me begin questions, and let me begin with an issue that both Dr. Denigan-Macauley and Ms. Dixon touched on. Dr. Snyder, I think, at least in your written testimony, you had something to say about this as well. This is the manner in which CMS, the Centers for Medicare and Medicaid Services, attempts and to some degree does monitor the utilization of opioids by people whom they deem to be at risk. Specifically, what I want to get at is the perception of who is at risk.

So the data that I have seen suggests that if you use the Centers for Disease Control criteria, specifically, their criteria for the daily volume of opioids above which they consider someone to be at risk, at risk of a serious adverse health consequence and at risk to addiction—if you use CDC's criteria, then in 2016, the number may be as high as 1.6 million Medicare beneficiaries who would be at risk. Yet CMS, under the new criteria, which are a little bit looser than their old criteria, as I understand it—their overutilization monitoring system, which is meant to track these folks, will be, when the new system is implemented next year, monitoring something on the order of 44,000 people instead of 1.6 million people. It is fewer than 3 percent of the people whom the Centers for Disease Control believe are at risk based on the quantities that they are receiving.

We have a chart here that might be a little bit tricky to follow. Let me just explain this briefly, and then I would love to get your thoughts on how we could do this differently. This circle is meant to reflect all Medicare beneficiaries. The large share in a given year do not get an opioid prescription, but a very substantial portion do. This would be represented by this slice of this pie—12.6 million in the year for which this graph was developed.

Of those 12.6 million who received opioid prescriptions through Medicare, the vast—let me make sure I have this right—a substantial portion, this part right here, received a quantity that is above the level at which the CDC would say that is an at-risk population. It would be the size of that green slice of the pie.

And yet the number who are actually going to be monitored by CMS is that little black line, that little tiny, tiny line, meaning, to this layman's view of this, that a very large number of people who might be at serious risk are not even being subject to the monitoring of their consumption that Medicare is approving and paying for. I find that surprising and disturbing, and I wonder—maybe we could start with Dr. Denigan-Macauley and then go on to Ms. Dixon and Dr. Snyder—if (a) you agree that my analysis is about right in terms of who is being monitored, and why should we believe that the Centers for Disease Control got it wrong and CMS got it right, and, if not, what should we do about it?

Dr. DENIGAN-MACAULEY. I would be happy to answer that question. So basically, the Federal Government, CMS, has an overutilization monitoring system program, and they track the number of beneficiaries at risk of high dose, even at the 90 milligrams level, which is the more stringent standard. When they track that, they

tie that to the number of providers and pharmacies rather than tracking that individual number, and, therefore, that is why you get to the smaller proportion of people whom they are tracking.

Senator TOOMEY. Could I just try to put this in a different way and see if you agree that I have this right? My understanding is what CMS says is, it is not sufficient for you to have a high quantity of opioids being prescribed for us to choose to monitor your consumption. You must also get it from multiple providers and/or multiple pharmacies. Is that about right?

Dr. DENIGAN-MACAULEY. That is correct, and we made a recommendation in our 2017 report that they need to decouple that and to be able to track what you are asking them to track. They agreed, and they are working on that.

Senator TOOMEY. It seems to me that it is almost irrelevant how many doctors—I mean, irrelevant is not the best term—but for the purpose of determining whether someone has too much opioid going into their system, I do not think it matters how many pharmacies you go to. It matters how many prescriptions you are getting filled, regardless of the number of pharmacies. Is that what you mean?

Dr. DENIGAN-MACAULEY. Correct. We would agree with that.

Senator TOOMEY. Ms. Dixon, do you have any thoughts on this issue?

Ms. DIXON. Thank you, sir. As I am not with CMS, I cannot comment specifically on CMS's mindset for this. But I can assure you that the OIG has shared our programming code and methodology with CMS regarding our July 2017 data brief, which will allow them to start proactively monitoring patients for high risk of opiates.

Senator TOOMEY. Thank you.

Dr. Snyder?

Dr. SNYDER. Yes; I will share a clinical sort of perspective and then as well a business perspective as to why CMS ought to care about this. First, from a clinical perspective, many of the costs that the system incurs can be not only related to the actual cost of the opioids but, in addition to that, the consequences of taking opioids, such as fall risks resulting in hip fractures and other types of injuries and, as well, just overdose risk itself. It is interesting that CMS separately tracks opioids from the potentiators of opioids, the drugs that can lead to a greater impact, clinical impact, of the opioids.

I think one of the opportunities would also be to consolidate within OMS opioid prescribing and then the drugs that potentiate opioids or put you at greater risk, for example benzodiazepines, and I will transition into the business case momentarily. If we track them together with the diagnoses of patients, we would have a lot more useful information for intervening and helping those patients.

True clinical story——

Senator TOOMEY. Could I ask a quick question just for clarification?

Dr. SNYDER. Yes.

Senator TOOMEY. Are you saying there is a category of drugs that makes a person more vulnerable to becoming addicted to opioids if they are prescribed opioids in addition to that category?

Dr. SNYDER. Or that increases the risks——

Senator TOOMEY. Increases the risks——

Dr. SNYDER [continuing]. Of taking the opioids. It could be a fall risk or anything else. It could be—the effect on your mind and your body of the opioids can be accentuated by certain drugs.

Senator TOOMEY. Okay.

Dr. SNYDER. True story. One of our executive's father and mother were sharing their opioids, both getting them from one doctor, one pharmacy, going to ERs in between when they would fall short, when their new physician refused to prescribe opioids. They were deemed—at least the father was deemed to be slightly demented—and when they could no longer get opioids prescribed, I assisted in helping them be admitted to a facility for detox and rehabilitation.

The mental health function tests improved dramatically. The patient is off opioids, taking non-steroidals at this point in time, and was on very large doses, far in excess of 90 milligrams a day, of opioids. So there is hope. There are a lot of people who are senior citizens walking around on large doses of opioids who could do very well mentally and physically without being on opioids and using alternatives.

The business case. Why should CMS care? Our average member cost is about $5,000 a year across all of our members. That would be a little higher for Medicare. The year that a patient is diagnosed with opioid use disorder, they roughly cost us about $28,000 that year, partially because you have treatment that is invoked. And if they stay on medication-assisted therapy after that, the cost drops by about $9,000 a year—reason to get people treated and keep them on medication-assisted therapy.

The interesting thing—and the reason I go back to my comments about OMS and the need to bring in the information on drugs that can potentiate opioids—we actually at one point in time had 1,600 people who carried a diagnosis of opioid use disorder and still were getting prescription opiates. Why? Perhaps because the PDMP was not in effect at the time. But that is not clinically sound, and the cost of those people is about $45,000 a year.

Now, you add the potentiator, the benzodiazepines, onto it—we are at $68,000 a year. If there is not a business case there for treating people and barring people from access to those kinds of combinations, I do not know what would be a good business case for it.

Senator TOOMEY. Thank you, Doctor.

Just continuing on this topic a little bit here, Ms. Dixon, you referred to the June 2017 data brief and described how HHS OIG made some disturbing discoveries. My understanding is 500,000 Medicare beneficiaries received over the 120-milligram morphine equivalent dose—MED—daily for at least 3 months—500,000. Now, mind you, CMS is going to be monitoring 44,000.

But of that 500,000, 70,000 Medicare beneficiaries received over 240—and again, CDC establishes 90-milligram MED, morphine equivalent doses, as a threshold above which people are at a risk. At 240 milligrams MED for an entire year—first, Dr. Snyder, just very briefly, would a large percentage of the population who are receiving a 240-milligram MED for an entire year already be addicted at that point?

Dr. SNYDER. Yes.

Senator TOOMEY. So what Dr. Snyder in his professional medical judgment is telling us is that there are tens of thousands of Medicare beneficiaries who are simply routinely having their addiction satisfied by ongoing prescriptions of opioids, and we are not even monitoring—still, nevertheless, they do not qualify even to have their situation monitored.

Ms. Dixon, my understanding is you will be doing a follow-up analysis, and in the subsequent analysis, will we be able to look at, to the extent to which these beneficiaries begin to be monitored, whether we have a reduction in the number of people who are receiving these very elevated volumes for long periods of time?

Ms. DIXON. Thank you for the question, Senator. Yes, we are doing a follow-up study which will, hopefully, be released this summer. It will be based on the same methodology and programming code as our previous study that we referenced in my testimony. This will be updated using 2017 Medicare data, prescription drug data.

We will look to identify the extent to which Part D beneficiaries are still receiving high amounts of opiates. Additionally, we will be looking for serious risks of opiate misuse or overdose as well in our beneficiary population, and also looking again to identify, potentially, prescribers who are prescribing out of the norm for our beneficiaries as well.

Based on our study last time, we were also able to get CMS to send comparative billing reports to prescribers who appear to be billing inconsistent with their peers. So that was a good step that came out of our last study.

Once this new study is released, we will be able to determine what those numbers are and make comparisons at that point.

Senator TOOMEY. Thank you. Still in the category of whether CMS is monitoring enough people as they should be, my understanding is there was a recent study of Pennsylvania Medicaid beneficiaries who suffered a nonfatal opioid-related overdose. In 60 percent of those nonfatal overdoses, the people had received legal opioid prescriptions before this life-threatening but nonfatal overdose. But what is truly amazing is about 60 percent received a subsequent opioid prescription in the following 6 months. This is after having an overdose.

My question to, really, all three of our experts in this area is, should CMS consider a nonfatal overdose as a criterion for being in the monitoring system?

Dr. Snyder, do you have a thought on that?

Dr. SNYDER. Yes, I absolutely think they should. I think it is—you know, there is an ethical, a moral, a clinical, and a business case for policing the prescribers who would continue to prescribe. If they are using the PDMP appropriately, obviously, they should know that the patient has been on opioids. They may not know about the overdose, which is one of the faults that I alluded to earlier. We need to link that data. If we link the data, and we know that the patient had an overdose previously, then I think most physicians would not prescribe additional opioids.

Senator TOOMEY. Ms. Dixon, do you have any thoughts on that?

Ms. DIXON. I can assure you that OIG is committed to using data to identify areas where we can make improvements as well. So any additional data that is accurate and timely that we would receive from—whether it was Medicaid programs—would be helpful in this area.

Senator TOOMEY. Thank you.

Dr. Denigan-Macauley?

Dr. DENIGAN-MACAULEY. Yes, the GAO works to provide support, whether it is Medicare or Medicaid, that CMS needs to identify those at risk.

Senator TOOMEY. But specifically, do you believe—and if you do not have an opinion on it, that is fine. But do you have a view as to whether a recent prior nonfatal overdose ought to constitute a criterion for being included in that monitoring system?

Dr. DENIGAN-MACAULEY. We did not look at that specifically, but it falls in the at-risk category.

Senator TOOMEY. Thank you.

A quick question for Dr. Snyder. So we talked earlier about the staggering volumes of prescriptions in the United States. Based on the data from the UN survey of 2012 through 2014, the U.S. could reduce consumption by 40 percent and we would still be the number one consumer in the world. If we reduced our consumption by 80 percent, we would be roughly on par with the rest of the developed world.

So, Dr. Snyder, it is pretty clear. Either we have it right, or the rest of the world has it right. Who do you think is more likely to be closer to being in the right ball park in terms of the volume of prescribed opioids?

Dr. SNYDER. I think you can probably imagine what my position is, and I think it is the rest of the world. I will give you a couple of—I mean, you know the story. In 1996, the American Pain Society said we should treat pain as a fifth vital sign. Shortly thereafter, the Veterans Administration put a focus on it with a strategy, and then shortly after that, the Joint Commission started the process of including a standard around assessing pain and treating pain, and then we rewarded the provider community for treating the pain.

It is easy to see how that cascade resulted in utilization levels where they are today.

The anecdote I want to share with you is sitting in on the Mayor's Task Force in Philadelphia and listening to young people tell how they encountered medicine in medicine cabinets. And just anecdotally, talking to people and understanding that many people get 30 tablets, use one or two, and put the rest on a shelf, I made the decision to unilaterally just put a limit on our members, commercial members, not Medicare, obviously, at 5 days and 90 MEDs. That went into effect July 1st.

Several things happened. We had a 22-percent drop in the number of patients getting opioids in the second half of the year compared to the first and a 26-percent drop in the actual number of prescriptions. Not a lot of member noise, some appeals for patients who wanted some of the medication. What I was really intrigued by was the number of physician calls I got who thanked me for putting the target on my back rather than their back when they would

refuse to write a prescription for an expectant patient, someone who wanted and thought they would get a script.

So physicians are creatures of habit, and I think, you know, if it worked in the past, it will work now. And we keep doing things, but when you really challenge them to think a little differently about what they are going to prescribe, they can do it, they will do it, they are okay and happy doing it, and they actually feel good about it. I have been the recipient of those calls from physicians. So I think we are clearly the outlier, and the rest of those countries are closer to the right answer.

Senator TOOMEY. It does look like we may have turned a corner, but it certainly seems that we still have a long way to go.

This question is for both Dr. Denigan-Macauley and Ms. Dixon. The GAO and the OIG made recommendations that prompted me to introduce legislation that is called the Strengthening Partnerships to Prevent Opioid Abuse Act, and the idea is that this bill would create an online portal that would facilitate information sharing on corrective actions by plans, audit contractors, and CMS on referred cases of opioid-related fraud and abuse. Could you elaborate a little bit on why you think that is important and how that would be helpful?

Dr. DENIGAN-MACAULEY. Yes. In our 2017 report, we found that CMS did not require the reporting of this information either to CMS itself or to the audit contractor, and, therefore, they really do not have a complete understanding of who the bad actors might be. So we would concur with the idea of introducing such legislation.

Senator TOOMEY. Ms. Dixon?

Ms. DIXON. OIG also has a recommendation, an open recommendation, right now which is focused on having the Medicare Part D sponsors report all incidents of fraud, waste, and abuse. This would be very helpful to CMS in order to determine how well each plan is doing in preventing fraud, waste, and abuse. Additionally, it would be very helpful to my office as law enforcement, as it would give us an opportunity to possibly identify trends occurring earlier, and we could use that to be proactive in our investigations.

Senator TOOMEY. One more quick question, and then I want to ask Ms. Malone a couple of questions.

The data analysis that the OIG has done has found a very large—hundreds of prescribers with very, very troubling prescribing patterns, hundreds of doctors prescribing for patients over 240 milligrams MED for an entire year and longer, that sort of thing. Here is my question. What is the process by which—when you identify physicians who are prescribing at, like, really unusually high volumes, what is the process of referring them to law enforcement?

Ms. DIXON. Thank you for the question, Senator. Of the 400 prescribers that I believe you are referencing from our report, OIG shared all that information within all of our components, which includes the Office of Investigations, and, additionally, we have also spoken with CMS and our partners in other law enforcement agencies such as DOJ and DEA and FBI, and we are currently working a number of cases—I cannot provide specifics—and we have also referred a number of these specifically to DOJ, FBI, and CMS.

We have shared our code, actual programming code, with CMS, so that way, they would be able to conduct this type of study on an ongoing basis to identify patients who are at risk and may be at risk for an overdose or could use some additional case management monitoring. We are going to also release our code and methodology to the general public as well as our private-sector partners later this summer in the form of a toolkit so all individual plans—and that includes States—who have prescription data information will be able to run the exact same report and, hopefully, identify any beneficiaries they have who might be in need of additional services.

Senator TOOMEY. Mr. Weintraub, are there any challenges that you face that are unique to building a case on fraudulent opioid prescribing or heroin trafficking that would be useful for the Federal Government to deal with, any legislative or other changes we could make that would make it easier for you to do your job?

Mr. WEINTRAUB. The one that comes to my mind, I think, has been tackled a bit but with not much success, and that is—all these transactions occur via cell phone now, and that is how we investigate these. When we find, unfortunately, a fatal overdose or even when we are trying to investigate a drug dealing enterprise, it is all done over the cell phones, and sometimes the technology is so advanced in the cell phones that we cannot crack it.

And as you know, some of the cell phone companies are not cooperative with law enforcement, and they continue to put out new products. We have just recently been beset by a—well, the law of the land right now, in the Federal and State law of the land, is that the cell phones cannot even be manipulated. They cannot even be turned on and be put on an airplane mode without a search warrant. That was through the United States Supreme Court very recently in a decision that came down.

So we are that much further behind the bad guy whom we are trying to catch when we come upon a cell phone that might have that vital information to help us make those connections.

Senator TOOMEY. I am not sure there is a Federal legislative solution to that, but it is useful information. Thank you.

Ms. Malone, thanks again for sharing your story with us. When you were originally prescribed opioids around the age of 18—you had had a car accident—the doctor that prescribed the opioids, did he explain to you the risks that were associated with them and sort of have a discussion with you about whether or not that was a good idea?

Ms. MALONE. No; no discussion.

Senator TOOMEY. No explanation of the possible risk of addiction or anything like that?

Ms. MALONE. No.

Senator TOOMEY. And during the 2 years when you were misusing prescription opioids, did you receive prescriptions from multiple doctors?

Ms. MALONE. Correct; yes.

Senator TOOMEY. That was part of the strategy, right, to go to multiple doctors?

Ms. MALONE. Yes.

Senator TOOMEY. So if you had just one or two lessons that you would like for Congress to take away from the experiences that you have had, what would they be? What would that be?

Ms. MALONE. You just touched base on it—increased awareness, you know—and as a mother, more youth education, and even to equip the providers with more information for us patients walking into a place like that, you know, to give us a heads-up that this is what can potentially happen. Maybe if I would have had something like that given to me and that information, I may not have had to go down this deep dark path. I am grateful that I did, but, you know, that is something that I definitely would like everyone to take today from me, you know, just increased awareness and education on the dangers associated with prescription medication, overprescribing, and how easy—it is so accessible; so easy.

Senator TOOMEY. So you are now 6 months into what certainly appears to be a remarkable recovery, and we all wish you all the best. Do you have any message for other people who might still be struggling with substance abuse disorder and anything that you would like to convey to them?

Ms. MALONE. Thank you for that recognition. It means a lot to me. I would not be where I am today without you, Mr. Corson, and MVP Recovery. You have done so much for my life.

And the most important thing is, there is this stigma placed on us people as addicts. You know, I am a normal person, and I have just been through a lot of things, but due to that path that I went down, there is this stigma of me as a drug addict, and they do not see the other side and that there is hope and recovery is possible and it is a beautiful thing, and as long as we work for it, we do recover. That is the biggest thing.

We do recover as long as we want it, and it is not easy, and it is a fight that I take every single day, but it is worth it, and I want to live today, and it is just—life is beautiful. They say "world beyond your wildest dreams," and that sounds like a cliché, and it is not. It really is. Today, I am sitting up here with you, and, you know, the conversation we had earlier—never in a million years did I think that I would have an opportunity to just be among you people and like a part of society and on a positive.

Yes, recovery is possible in the end, and I am just so grateful to be here and grateful for my life today.

Senator TOOMEY. Well, we are grateful you are here too. [Applause.]

My last question—and then I think my staff is going to get very angry when I turn the mic over to my Federal colleagues in law enforcement for a couple of quick thoughts from our U.S. Attorneys.

But, Mr. Weintraub, we have established that the total volume of prescription opioids is down a little bit, right? We have been making some progress since 2011, and, in addition, some communities have launched very aggressive medicine take-back programs. You alluded to yours. Bucks County has a very substantial and, to my understanding, a successful program.

But here is the $64,000 question. Has it actually resulted in any observable or measurable or noticeable reduction in prescription opioids on the streets? Is it having an effect yet?

Mr. WEINTRAUB. I would say that, by and large, it has. But as you know, Senator, it takes an all-out approach. It takes educating the doctors. It takes educating the public.

But one of the things that we have been successful in doing is shifting the mind thought on this issue now. Just like when people get in their cars, they know to put their seatbelts on. It is the same thing with their unused, old, expired medications. People in Bucks County know they have to get rid of them, because every pill that is left out of that 30-pill prescription can be a potential deadly dose, and people in Bucks County have gotten it. We have pretty much assailed them on this. We have beaten it into their heads with constant marketing and advertising, and we are seeing a difference.

That is certainly one prong of it, but it is a critical prong, because it is going to take an all-out effort for us to win this battle that we are in.

Senator TOOMEY. Thanks very much.

I am going to wrap up the formal part of this hearing, and in compliance with the very strict rules we have in the Senate Finance Committee, we will wrap this up, and then I will immediately recognize our two U.S. Attorneys for just a brief thought, if they would.

But first, I do want to once again thank the folks from Bensalem Township. I want to thank our witnesses for being here. This has been very, very helpful for me.

A couple of the conclusions that come to my mind are, first of all, there are still many, many people getting very large quantities of prescription opioids through Federal Government programs, and their consumption of these opioids is not being properly monitored, in my opinion. It is huge doses. The fact that you could have a nonfatal but nevertheless very serious overdose on opioids and then promptly get another prescription from Medicare is amazing and problematic in my mind.

We have made progress in overutilization, but clearly we are not finished. Some health-care providers and insurance plans have made more progress than others. I really appreciate the input that we have gotten from Dr. Snyder with Independence Blue Cross. It is a very encouraging story about where the private sector can and has made progress. But we still have a very, very serious problem that manifests itself, and the causes are many, and the Federal Government needs to do more and to do better.

So again, this has been very, very helpful testimony, and I welcome your ongoing thoughts as we continue to address this.

So this will conclude the formal part of the hearing, and at this point, I would like to ask the U.S. Attorney from the Middle District of Pennsylvania, Mr. David Freed, if he would like to take the podium and just share—there is a mic right here—just share your thoughts as the top law enforcement officer in the central part of Pennsylvania.

Mr. FREED. Sure. Good afternoon, everyone. Senator and Congressman Fitzpatrick, thank you for your leadership on this issue. I have to say Matt Weintraub, even before he was District Attorney in Bucks County, was a leader in fighting the heroin and opioid epidemic. I am thinking back to following him on Twitter in years

past, and he has been really essential in getting the word out about this scourge.

And, Ms. Malone, what a pleasure to be in your presence. Congratulations.

Senator, we are fighting similar battles with our State and local colleagues on the Federal side. We have a greater opportunity to go after over-prescribers, I think, with the resources that we enjoy. We have been tasked—and U.S. Attorney McSwain may allude to this issue as well. We have been tasked by Attorney General Sessions with reducing deaths. He is telling the U.S. Attorneys that we want to reduce deaths.

One of the ways that we think we can do that is using civil proceedings against folks who bill through Medicare, and if it works in conjunction with the criminal investigation, using civil process, perhaps an injunction or some other civil process, to stop them from prescribing right away. It may be before DEA can take the license. It may be before a criminal case is ready to go. We can institute civil process and stop that right away.

We are working on some of those cases now in the Middle District of Pennsylvania, and they are being worked on throughout the country. In fact, there is a specific group on the civil side of the Department of Justice working on just this issue.

So I think the hearing today is timely. The discussion about cooperation is timely. That is one of the things that we are doing to try to stop the overprescribing. Providers have come a long, long way in the last few years.

Ms. Dixon and her group—the only thing that limits their effectiveness is resources. I can tell you even in the short time I have been in the U.S. Attorney's Office that the HHS OIG group is great. They are doing great work, not just in Pennsylvania but throughout the region.

So, Senator, again, I thank you for your leadership. Thank you for having us here today for this most important hearing.

Senator TOOMEY. U.S. Attorney Bill McSwain from the Eastern District of Pennsylvania.

Mr. MCSWAIN. Thank you, Senator, and thank you, everybody, for showing up at this hearing today. Just a couple of preliminary points and then two observations.

First, Ms. Malone, again, I wanted to congratulate you for having the courage to be here. And I think when we all leave here today, the thing that we are going to remember the most is your story. So thank you for sharing that with us.

I wanted to make—there is a lot of bad news here that we are talking about: the overprescribing, the problem we have with the use of opioids in our country. But there is also some good news, in that what I have seen in the first 2 months of my job—because I was sworn in on April 6th and have been on the job for about 2 months—is tremendous collaboration, among law enforcement in particular.

My office has a great relationship with Dave's office, Matt's office. We have a great relationship with Special Agent Dixon's office. We have an Opioid Law Enforcement Task Force that we stood up in February that meets bi-monthly at the U.S. Attorney's office. I attended that meeting in April. We have a great relationship with

Kat Copeland's office in Delaware County, who is also here, and she has attended the Opioid Law Enforcement Task Force meetings, as Matt has.

Philadelphia police, local law enforcement, Federal law enforcement—we are all working together, and we have all got our oar in the water, pulling in the same direction. So I think that is positive.

But when I think about what we can do as law enforcement—there are basically three prongs to this problem. There is treatment, there is prevention, there is law enforcement. We are law enforcement, so that is what I think about the most. You know, we are doing a lot of cases. We are attacking it from sort of two different directions, dealing with the overprescribing, dealing with the doctors' offices, essentially, and we are also dealing with what I will call the street part of it—the illicit drug organizations—and we could use some more tools.

One tool that has been brought to my attention that we really need—again, it is probably not something that your committee would deal with, but I want you to be aware of it—is we have the ability in law enforcement to do wiretaps on cell phones, for example, where we can listen to the conversations of drug dealers and figure out what they are doing and then use that as evidence in cases in order to dismantle and destroy those organizations.

One thing we do not have the ability to do right now is, we cannot monitor Internet-based applications, and that is what a lot of these drug organizations are starting to use. They are starting to use these Internet-based apps as opposed to cell phones, because they know that the cell phones are being listened to and the Internet-based apps are not.

So I know that that is a big ask of the legislative branch, because there are privacy concerns, there are powerful lobbyists, you know, and there are folks who do not necessarily want there to be legislation when it comes to Internet-based applications. But I think I probably speak for all law enforcement here that we really need that, because the criminals sometimes are pretty crafty and pretty smart. So I would just raise that for your consideration with your colleagues, that I think the future of law enforcement is really going to need that.

But that aside, I will say that there is good news in that we are all focused on this problem. There is the political will to deal with it, as demonstrated by your leadership and being here and having this kind of hearing, and there is the will among law enforcement, and we will eventually win this battle. But we need to do it, hopefully, as quickly as possible.

Thank you.

Senator TOOMEY. Thank you very much. The hearing is adjourned.

[Whereupon, at 2:24 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF MARY DENIGAN-MACAULEY, PH.D., ACTING DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

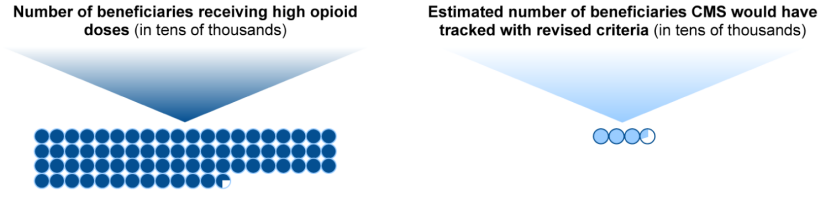
Prescription Opioids: Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries

WHAT GAO FOUND

In October 2017, GAO found that the Centers for Medicare and Medicaid Services (CMS) provided guidance on the monitoring of Medicare beneficiaries who received opioid prescriptions to plan sponsors—private organizations that implement the Medicare drug benefit, Part D—but it lacked information on most beneficiaries at risk of harm from opioid use. Specifically, GAO found that:

- CMS provided guidance to plan sponsors on how they should monitor opioid overutilization among Medicare Part D beneficiaries, and required them to implement drug utilization review systems that use criteria similar to CMS's. Prior to 2018, the agency's criteria focused on beneficiaries who did all the following: (1) received prescriptions of high doses of opioids, (2) received prescriptions from four or more providers, and (3) filled prescriptions at four or more pharmacies. According to CMS, this approach focused actions on beneficiaries the agency determined to have the highest risk of harm. For 2018, CMS revised the criteria to include more at-risk beneficiaries.
- CMS's criteria, including recent revisions, did not provide sufficient information about the larger population of potentially at-risk beneficiaries. CMS estimated that, in 2015, 727,016 beneficiaries would have received high doses of opioids regardless of the number of providers or pharmacies, but only 33,223 would have met its revised criteria. In 2016, CMS began to collect information on some of these beneficiaries using a higher dosage threshold for opioid use. However, based on Centers for Disease Control and Prevention guidelines, CMS's approach also missed some who could be at risk of harm. As a result, CMS had limited information to assess progress against the goals of the Medicare and Medicaid programs' Opioid Misuse Strategy, which includes activities to reduce risk of harm to beneficiaries.

CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-585T

CMS provided oversight on prescribing of drugs at high risk of abuse through a variety of projects, but did not analyze data specifically on opioids. According to CMS officials, CMS and plan sponsors identified providers who prescribed large amounts of drugs with a high risk of abuse, and those suspected of fraud or abuse may be referred to law enforcement. However, GAO found that CMS did not identify providers who may be inappropriately prescribing large amounts of opioids separately from other drugs, and did not require plan sponsors to report actions they take when they identified such providers. As a result, CMS lacked information that it could use to assess how opioid prescribing patterns are changing over time, and whether its efforts to reduce harm are effective.

Chairman Toomey, Ranking Member Stabenow, and members of the subcommittee, I am pleased to be here to discuss our October 2017 report on oversight of opioid prescribing in the Medicare program.[1] Misuse of prescription opioids, which are used to treat both acute and chronic pain, has become a serious public health problem for the U.S. population, including Medicare and Medicaid beneficiaries. The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), reported that from 1999 to 2013 the rate of drug poisoning deaths from prescription opioids nearly quadrupled, and that in 2016, alone, there were more than 17,000 overdose deaths from prescription opioids.[2]

The Centers for Medicare and Medicaid Services (CMS), also within HHS, administers Medicare and Medicaid, two of the Nation's largest health care programs. Medicare is a Federal health insurance program for people age 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease. Within Medicare is Part D, the program's outpatient prescription drug benefit.[3] Medicaid is a joint Federal-State program that finances health care coverage for certain low-income and medically needy individuals.[4] Due to concerns about adequacy of oversight, both Medicare and Medicaid are on our list of high-risk programs.[5]

HHS's Office of Inspector General (HHS–OIG) reported that 14.4 million people (about one-third) who participated in Medicare Part D in 2016 received at least one prescription for opioids, and that Part D spending for opioids in 2016 was almost $4.1 billion.[6] We and the HHS-OIG have previously reported on inappropriate activities that can be associated with such prescriptions, including "doctor shopping" to receive multiple opioid prescriptions from different providers; the diversion of prescription drugs for uses other than what was intended; and questionable prescribing practices by providers.[7]

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[1] See GAO, *Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm,* GAO–18–15 (Washington, DC: Oct. 6, 2017). In January of 2018, we also testified before the Subcommittee on Oversight, Committee on Ways and Means, House of Representatives on the findings and recommendations from this report. See *GAO, Prescription Opioids: Medicare Should Expand Oversight Efforts to Reduce the Risk of Harm,* GAO–18–336T (Washington, DC: Jan. 17, 2018).

[2] See Department of Health and Human Services, Centers for Disease Control and Prevention, *Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics—United States, 1999–2013,* Morbidity and Mortality Weekly Report, vol. 64, no. 1 (Atlanta, GA.: Jan. 16, 2015); and P. Seth, L. Scholl, et. al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016,* Morbidity and Mortality Weekly Report, vol. 67, no. 12, Centers for Disease Control and Prevention (Mar. 30, 2018).

[3] Medicare consists of Parts A, B, C, and the Part D prescription drug program. Parts A and B are known as traditional Medicare or Medicare fee-for-service. Medicare Part C, also known as Medicare Advantage, is a private plan alternative to traditional Medicare, and covers all traditional Medicare services.

[4] Within broad Federal requirements, States have significant flexibility to design and implement their Medicaid programs based on their unique needs, resulting in 56 distinct programs. Medicaid programs are administered by the 50 States, the District of Columbia, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. These programs are administered at the State level and overseen at the Federal level by CMS.

[5] See GAO, *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others,* GAO–17–317 (Washington, DC: Feb. 15, 2017).

[6] Department of Health and Human Services Office of Inspector General, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing,* OE–02–17–00250 (July 2017).

[7] See GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs,* GAO–11–699 (Washington, DC: Sept. 6, 2011); and *Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse,* GAO–15–66 (Washington, DC: Oct. 24, 2014). See also Department of Health and Human Services, Office of Inspector General,

The Medicaid program also covers opioid prescriptions for its beneficiaries. In our prior work, we have reported on potentially inappropriate activities involving Medicaid's prescription drug coverage. In 2017, for example, we reported on prescriptions for opioid pain medication among Medicaid beneficiaries. In that report, we noted that while opioid pain medication can constitute proper medical care for beneficiaries suffering from painful conditions, the use of these medications among Medicaid beneficiaries with diagnosed opioid abuse or dependence raises concerns about potential inappropriate prescribing.[8] In addition, in a July 2015 report, we found indicators of potential Medicaid prescription-drug fraud and abuse, such as doctor shopping.[9]

In March 2015, HHS announced plans to make addressing opioid abuse a high priority through two broad goals: (1) decreasing opioid overdoses and overall overdose deaths, and (2) decreasing the prevalence of opioid use disorder.[10] In 2016, CDC issued guidelines with recommendations for prescribing opioids in outpatient settings for chronic pain.[11] The guidelines recommended that providers use caution when prescribing opioids at any dose, carefully reassess evidence of individual benefits and risks when increasing opioid dosage to 50 mg morphine-equivalent dose (MED) per day or more, and avoid or carefully justify dosage at 90 mg MED or more.

CDC guidelines also noted that providers should use additional caution in prescribing opioids to patients aged 65 and older, because the drugs can accumulate in the body to toxic levels. Further, in January 2017, CMS issued its Opioid Misuse Strategy for the Medicare and Medicaid programs, including Medicare Part D.[12] The strategy includes the agency's plans to address concerns about beneficiary use of opioids and the prescribing of opioids by providers.

My remarks today discuss the findings and recommendations from our 2017 report on CMS efforts to oversee prescription opioids in Medicare.[13] Accordingly, this testimony focuses on how:

(1) CMS oversees beneficiaries who receive opioid prescriptions under Medicare Part D, and

(2) CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries.

For our report, we reviewed CMS opioid utilization and prescriber data, CMS guidance for plan sponsors—private organizations, such as health insurance companies, contracted by CMS to provide outpatient drug benefit plans to Medicare beneficiaries—and CMS's strategy to prevent opioid misuse. We also interviewed officials from CMS, the six largest Part D plan sponsors, and 12 national associations selected to represent insurance plans, pharmacy benefit managers, physicians, patients, and regulatory and law enforcement agencies. More detailed information on our objectives, scope, and methodology for that work can be found in the issued report. We conducted the work on which this statement is based 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.

High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns, OEI–02–16–0029 (June 2016).

[8] GAO, *Medicaid Expansion: Behavioral Health Treatment Use in Selected States in 2014,* GAO–17–529 (Washington, DC: June 22, 2017).

[9] GAO, *Medicaid: Additional Reporting May Help CMS Oversee Prescription-Drug Fraud Controls*, GAO–15–390 (Washington, DC: July 8, 2015).

[10] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Death* (Mar. 26, 2015). Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress as indicated by at least 2 of 11 criteria occurring within a 12-month period. The criteria include taking opioids in larger amounts or over a longer period of time than was intended, persistent desire or unsuccessful efforts to cut down or control opioid use, or a strong desire or urge to use opioids.

[11] Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016,* Morbidity and Mortality Weekly Report, vol. 65, no. 1 (Atlanta, GA.: Mar. 18, 2016).

[12] Centers for Medicare and Medicaid Services, *Centers for Medicare and Medicaid Services (CMS) Opioid Misuse Strategy 2016* (Jan. 5, 2017).

[13] See GAO–18–15.

CMS DELEGATED MONITORING OF BENEFICIARIES WHO RECEIVE OPIOID PRESCRIPTIONS TO PLAN SPONSORS, BUT DID NOT HAVE SUFFICIENT INFORMATION ON THOSE MOST AT RISK FOR HARM

CMS Delegated Monitoring of Individual Beneficiaries' Opioid Prescriptions to Plan Sponsors

Our October 2017 report found that CMS provided guidance to Medicare Part D plan sponsors on how they should monitor opioid overutilization problems among Part D beneficiaries. The agency included this guidance in its annual letters to plan sponsors, known as call letters; it also provided a supplemental memo to plan sponsors in 2012.[14] Among other things, these guidance documents instructed plan sponsors to implement a retrospective drug utilization review (DUR) system to monitor beneficiary utilization starting in 2013.[15] As part of the DUR systems, CMS required plan sponsors to have methods to identify beneficiaries who were potentially overusing specific drugs or groups of drugs, including opioids.

Also in 2013, CMS created the Overutilization Monitoring System (OMS), which outlined criteria to identify beneficiaries with high-risk use of opioids, and to oversee sponsors' compliance with CMS's opioid overutilization policy. Plan sponsors may use the OMS criteria for their DUR systems, but they had some flexibility to develop their own targeting criteria within CMS guidance. At the time of our review, the OMS considered beneficiaries to be at a high risk of opioid overuse when they met all three of the following criteria:

1. received a total daily MED greater than 120 mg for 90 consecutive days,
2. received opioid prescriptions from four or more health care providers in the previous 12 months, and
3. received opioids from four or more pharmacies in the previous 12 months.[16]

The criteria excluded beneficiaries with a cancer diagnosis and those in hospice care, for whom higher doses of opioids may be appropriate.

We found that through the OMS, CMS generated quarterly reports that list beneficiaries who met all of the criteria and who were identified as high-risk, and then distributed the reports to the plan sponsors. Plan sponsors were expected to review the list of identified beneficiaries, determine appropriate action, and then respond to CMS with information on their actions within 30 days. According to CMS officials, the agency also expected plan sponsors to share any information with CMS on beneficiaries that they identified through their own DUR systems. We found that some actions plan sponsors may take included the following:

- **Case management.** Case management may include an attempt to improve coordination issues, and often involves provider outreach, whereby the plan sponsor will contact the providers associated with the beneficiary to let them know that the beneficiary is receiving high levels of opioids and may be at risk of harm.
- **Beneficiary-specific point-of-sale (POS) edits.** Beneficiary-specific POS edits are restrictions that limit these beneficiaries to certain opioids and amounts. Pharmacists receive a message when a beneficiary attempts to fill a prescription that exceeds the limit in place for that beneficiary.

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[14] Centers for Medicare and Medicaid Services, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,* accessed December 21, 2016, *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf;* and Centers for Medicare and Medicaid Services, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,* accessed April 25, 2017, *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf.*

[15] In addition to instructing plan sponsors to implement retrospective DUR systems, the guidance in the 2013 call letter includes information on other mechanisms to control overutilization. See *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf.*

[16] These criteria were in effect through 2017. CMS announced in its April 3, 2017 call letter the revisions to the OMS criteria that will take effect in 2018. See *Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information,* accessed April 4, 2017, *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf.* Some of the beneficiaries that meet the OMS criteria may not be using the opioids themselves, but rather diverting them by either giving or selling them to others.

- **Formulary-level POS edits.** These edits alert providers who may not have been aware that their patients are receiving high levels of opioids from other doctors.
- **Referrals for investigation.** According to the six plan sponsors we interviewed, the referrals can be made to CMS's National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), which was responsible for identifying and investigating potential Part D fraud, waste, and abuse, or to the plan sponsor's own internal investigative unit, if they have one. After investigating a particular case, they may refer the case to the HHS-OIG or a law enforcement agency, according to CMS, NBI MEDIC, and one plan sponsor.

Based on CMS's use of the OMS and the actions taken by plan sponsors, CMS reported a 61 percent decrease from calendar years 2011 through 2016 in the number of beneficiaries meeting the OMS criteria of high risk—from 29,404 to 11,594 beneficiaries—which agency officials considered an indication of success toward its goal of decreasing opioid use disorder.

In addition, we found that CMS relied on separate patient safety measures developed and maintained by the Pharmacy Quality Alliance to assess how well Part D plan sponsors were monitoring beneficiaries and taking appropriate actions.[17] In 2016, CMS started tracking plan sponsors' performance on three patient safety measures that were directly related to opioids. The three measures were similar to the OMS criteria in that they identified beneficiaries with high dosages of opioids (120 mg MED), beneficiaries that use opioids from multiple providers and pharmacies, and beneficiaries that do both. However, one difference between these approaches was that the patient safety measures separately identified beneficiaries who fulfill each criterion individually.

CMS DID NOT HAVE SUFFICIENT INFORMATION ON MOST BENEFICIARIES POTENTIALLY AT RISK FOR HARM

Our October 2017 report also found that CMS tracked the total number of beneficiaries who met all three OMS criteria as part of its opioid overutilization oversight across the Part D program. However, the agency did not have comparable information on most beneficiaries who receive high doses of opioids—regardless of the number of providers and pharmacies used—and who therefore may be at risk for harm, according to CDC's 2016 guidelines. These guidelines noted that long-term use of high doses of opioids—those above a MED of 90 mg per day—are associated with significant risk of harm and should be avoided if possible.

Based on the CDC guidelines, outreach to Part D plan sponsors, and CMS analyses of Part D data, CMS has revised its current OMS criteria to include more at-risk beneficiaries beginning in 2018. The new OMS criteria define a high user as an individual:

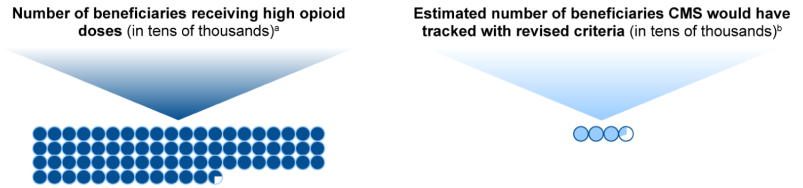
- Having an average daily MED greater than 90 mg for any duration; and
- Receiving opioids from four or more providers and four or more pharmacies, or from six or more providers regardless of the number of pharmacies, for the prior 6 months.[18]

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[17] The Pharmacy Quality Alliance is a consensus-based, multi-stakeholder membership organization that collaboratively promotes appropriate medication use and develops strategies for measuring and reporting performance information related to medications. The alliance developed all but one of CMS's Part D patient safety measures, and that one measure is not related to opioid safety.

[18] According to CMS officials, the changes are partially in response to CDC's 2016 guidelines. The CDC guidelines noted that patients are at risk of harm above 50 mg MED and that providers should generally avoid increasing dosage to more than 90 mg MED of opioids, regardless the number of providers or pharmacies.

Figure 1: CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-585T

[a]This number includes beneficiaries with an average opioid morphine equivalent dose of 90 milligrams or more within a 6-month measurement period.

[b]This number is an estimate of how many beneficiaries would have met CMS's revised Overutilization Monitoring System (OMS) criteria. CMS calculated these totals by applying the revised OMS criteria to 2015 Part D data.

Based on 2015 data, CMS found that 33,223 beneficiaries would have met these revised criteria. While the revised criteria would help identify beneficiaries who CMS determined are at the highest risk of opioid misuse and therefore may need case management by plan sponsors, they did not provide information on the total number of Part D beneficiaries who may be at risk of harm. In developing the revised criteria, CMS conducted a one-time analysis that estimated there were 727,016 beneficiaries with an average MED of 90 mg or more, for any length of time during a 6 month measurement period in 2015, regardless of the number of providers or pharmacies used. According to the CDC guidelines, these beneficiaries may be at risk of harm from opioids, and therefore tracking the total number of these beneficiaries over time could help CMS to determine whether it is making progress toward meeting the goals specified in its Opioid Misuse Strategy to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion. However, CMS officials told us that the agency did not keep track of the total number of these beneficiaries, and did not have plans to do so as part of OMS (see Fig. 1).

We also found that in 2016, CMS began to gather information from its patient safety measures on the number of beneficiaries who use more than 120 mg MED of opioids for 90 days or longer, regardless of the number of providers and pharmacies. The patient safety measures identified 285,119 such beneficiaries—counted as member-years—in 2016.[19] However, this information did not include all at-risk beneficiaries, because the threshold was more lenient than indicated in CDC guidelines and CMS's new OMS criteria. Because neither the OMS criteria nor the patient safety measures included all beneficiaries potentially at risk of harm from high opioid doses, we recommended that CMS should gather information over time on the total number of beneficiaries who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use. HHS concurred with our recommendation.

CMS OVERSEES PROVIDERS THROUGH ITS CONTRACTOR AND PLAN SPONSORS, BUT EFFORTS DID NOT SPECIFICALLY MONITOR OPIOID PRESCRIPTIONS

Our October 2017 report found that CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries through its contractor, NBI MEDIC, and the Part D plan sponsors.

- **NBI MEDIC's data analyses to identify outlier providers.** CMS required NBI MEDIC to identify providers who prescribe high amounts of Schedule II drugs, which include but are not limited to opioids.[20] Using prescription drug

[19] Patient safety measures count member-years, which account for beneficiaries who are enrolled in a Part D plan for only part of a year.

[20] Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and risk of dependence. Schedule II drugs have the highest potential for abuse of any drugs approved for medical use.

data, NBI MEDIC conducted a peer comparison of providers' prescribing practices to identify outlier providers—the highest prescribers of Schedule II drugs—and reported the results to CMS.

- **NBI MEDIC's other projects.** NBI MEDIC gathered and analyzed data on Medicare Part C and Part D, including projects using the Predictive Learning Analytics Tracking Outcome (PLATO) system. According to NBI MEDIC officials, these PLATO projects sought to identify potential fraud by examining data on provider behaviors.
- **NBI MEDIC's investigations to identify fraud, waste, and abuse.** NBI MEDIC officials conducted investigations to assist CMS in identifying cases of potential fraud, waste, and abuse among providers for Medicare Part C and Part D. The investigations were prompted by complaints from plan sponsors; suspected fraud, waste, or abuse reported to NBI MEDIC's call center; NBI MEDIC's analysis of outlier providers; or from one of its other data analysis projects.
- **NBI MEDIC's referrals.** After identifying providers engaged in potential fraudulent overprescribing, NBI MEDIC officials said they may refer cases to law enforcement agencies or the HHS–OIG for further investigation and potential prosecution.
- **Plan sponsors' monitoring of providers.** CMS required all plan sponsors to adopt and implement an effective compliance program, which must include measures to prevent, detect, and correct Part C or Part D program noncompliance, as well as fraud, waste, and abuse. CMS's guidance focused broadly on prescription drugs, and did not specifically address opioids.

Our report concluded that although these efforts provided valuable information, CMS lacked information necessary to adequately oversee opioid prescribing. CMS's oversight actions focused broadly on Schedule II drugs rather than specifically on opioids. For example, NBI MEDIC's analyses to identify outlier providers did not indicate the extent to which they may be overprescribing opioids specifically. According to CMS officials, they directed NBI MEDIC to focus on Schedule II drugs, because these drugs have a high potential for abuse, whether they are opioids or other drugs. However, without specifically identifying opioids in these analyses—or an alternate source of data—CMS lacked data on providers who prescribe high amounts of opioids, and therefore cannot assess progress toward meeting its goals related to reducing opioid use, which would be consistent with Federal internal control standards. Federal internal control standards require agencies to conduct monitoring activities and to use quality information to achieve objectives and address risks.[21] As a result, we recommended that CMS require NBI MEDIC to gather separate data on providers who prescribe high amounts of opioids. This would allow CMS to better identify those providers who are inappropriately and potentially fraudulently overprescribing opioids. HHS agreed, and in April 2018 reported that it is working with NBI MEDIC to separately identify outlier prescribers of opioids.

In addition, our 2017 report found that CMS also lacked key information necessary for oversight of opioid prescribing, because it did not require plan sponsors to report to NBI MEDIC or CMS cases of fraud, waste, and abuse; cases of overprescribing; or any actions taken against providers.[22] Plan sponsors collected information on cases of fraud, waste, and abuse, and could choose to report this information to NBI MEDIC or CMS. While CMS receives information from plan sponsors who voluntarily reported their actions, it did not know the full extent to which plan sponsors had identified providers who prescribed high amounts of opioids, or the full extent to which sponsors had taken action to reduce overprescribing. We concluded that without this information, it was difficult for CMS to assess progress in this area, which would be consistent with Federal internal control standards. In our report, we recommended that CMS require plan sponsors to report on investigations and other actions taken related to providers who prescribe high amounts of opioids. HHS did not concur with this recommendation. HHS noted that plan sponsors have the responsibility to detect and prevent fraud, waste, and abuse, and that CMS re-

[21] GAO, *Standards for Internal Control in the Federal Government,* GAO–14–704G (Washington, DC: Sept. 10, 2014). Internal controls is a process affected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

[22] According to CMS officials, the agency's regulations currently make reporting inappropriate prescribing and any actions against providers voluntary for plan sponsors. See 42 CFR § 423.504(b)(4)(vi)(G)(3).

views cases when it conducts audits. HHS also stated that it seeks to balance requirements on plan sponsors when considering new regulatory requirements. However, without complete reporting—such as reporting from all plan sponsors on the actions they take to reduce overprescribing—we believe that CMS is missing key information that could help assess progress in this area. Due to the importance of this information for achieving the agency's goals, we continue to believe that CMS should require plan sponsors to report on the actions they take to reduce overprescribing.

CONCLUSIONS

In conclusion, a large number of Medicare Part D beneficiaries use potentially harmful levels of prescription opioids, and reducing the inappropriate prescribing of these drugs has been a key part of CMS's strategy to decrease the risk of opioid use disorder, overdoses, and deaths. Despite working to identify and decrease egregious opioid use behavior—such as doctor shopping—among Medicare Part D beneficiaries, CMS lacked the necessary information to effectively determine the full number of beneficiaries at risk of harm, as well as other information that could help CMS assess whether its efforts to reduce opioid overprescribing are effective. It is important that health care providers help patients to receive appropriate pain treatment, including opioids, based on the consideration of benefits and risks. Access to information on the risks that Medicare patients face from inappropriate or poorly monitored prescriptions, as well as information on providers who may be inappropriately prescribing opioids, could help CMS as it works to improve care.

Chairman Toomey, Ranking Member Stabenow, and members of the subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

PREPARED STATEMENT OF MAUREEN DIXON, SPECIAL AGENT IN CHARGE, PHILADELPHIA REGIONAL OFFICE, OFFICE OF INVESTIGATIONS, OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good afternoon, Chairman Toomey. I am Maureen Dixon, Special Agent in Charge of the Philadelphia Regional Office, Office of Investigations with the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG).

I appreciate the opportunity to appear before you to discuss how OIG is combating the opioid crisis in Federal health care programs.

OIG's mission is to protect the integrity of HHS programs and the health and welfare of the people they serve through prevention, detection, and enforcement. To accomplish our mission, OIG uses data analytics and real-time field intelligence to detect and investigate program fraud and to focus our resources for maximum impact. We are a multidisciplinary organization comprised of investigators, auditors, evaluators, analysts, clinicians, and attorneys. In addition, we depend on strong public and private partnerships to ensure coordinated enforcement success. OIG has for several years, identified curbing the opioid epidemic as one of the Department's Top Management and Performance Challenges. Key components of that challenge include addressing inappropriate prescribing of opioids, inadequate access to treatment, and misuse of grant funds. In addition, combatting fraud issues, such as drug diversion and fraud committed by providers, presents a significant challenge for the Department.

OIG has a longstanding and extensive history of enforcement and oversight work focused on prescription drug fraud, drug diversion, pill mills,[1] medical identity theft, and other schemes that put people at risk of harm. Several years ago, OIG detected—and began taking action to address—a rise in fraud schemes involving opioids, as well as associated potentiator drugs.[2] In addition to increasing our investigative efforts to combat prescription drug abuse, we have responded to the growing severity of the opioid epidemic by focusing on work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries. OIG uses advanced data analytics tools to put timely, actionable data about prescribing, billing, and utilization trends and patterns in the hands of investigators, auditors, evaluators, and

[1] A pill mill is a doctor's office, clinic, or health care facility that routinely prescribes controlled substances—such as oxycodone—outside the scope of professional practice and without a legitimate medical purpose.

[2] Drugs that enhance the high or euphoria when combined with controlled substances.

government partners. Our goal is to identify opportunities to improve HHS prescription drug programs to reduce opioid addiction, share data and educate the public, and identify and hold accountable perpetrators of opioid-related fraud.

In my testimony today, I will highlight law enforcement activities led by the Office of Investigations and discuss OIG projects currently underway to combat opioid-related fraud, waste, and abuse. I also will highlight key OIG recommendations that would, if implemented, have a positive impact on the opioid problem.

OIG'S OFFICE OF INVESTIGATIONS TARGETS FRAUD, WASTE, AND ABUSE

OIG's Office of Investigations has investigators covering every State, the District of Columbia, Puerto Rico, and other U.S. territories. We collaborate with other Federal, State, and local law enforcement authorities to maximize our impact. Special Agents in our Office of Investigations have full law enforcement authority and use a broad range of investigative actions, including the execution of search and arrest warrants, to accomplish our mission. OIG and its law enforcement partners combine resources to detect and prevent health care fraud, waste, and abuse. During the last 3 fiscal years (FYs 2015 to 2017), OIG investigations have resulted in more than $10.8 billion in investigative receivables (dollars ordered or agreed to be paid to Government programs as a result of criminal, civil, or administrative judgments or settlements); 2,650 criminal actions; 2,211 civil actions; and 10,991 program exclusions.[3]

Much of OIG's investigative work involves the Medicare and Medicaid programs and is funded by the Health Care Fraud and Abuse Control Program (HCFAC). The HCFAC provides funding resources to the Department of Justice (DOJ), HHS, and OIG, which are often used collaboratively to fight health care fraud, waste, and abuse. Since its inception in 1997, the HCFAC has returned more than $31 billion to the Medicare trust fund. OIG is a lead participant in the Medicare Fraud Strike Force, which combines the resources of Federal, State, and local law enforcement entities to fight health care fraud across the country. Finally, OIG collaborates with State Medicaid Fraud Control Units (MFCUs) to detect and investigate fraud, waste, and abuse in State Medicaid programs.

THE OPIOID CRISIS

Opioid use is a rapidly growing national health care problem, and our Nation is in the midst of an unprecedented opioid epidemic.[4] More than 60,000 Americans died from drug overdoses in 2016, of which 66 percent reportedly involved opioids.[5] Deaths from prescription pain medication remain far too high, and in 2016, there was a sharp increase in deaths involving synthetic opioids such as fentanyl and an increase in heroin-involved deaths.[6] According to the Centers for Disease Control and Prevention (CDC), approximately three out of four new heroin users report having abused prescription opioids prior to using heroin. Prescription drug diversion—the redirection of prescription drugs for an illegal purpose—is a serious component of this epidemic.

OIG'S OPIOID FRAUD ENFORCEMENT EFFORTS

Opioid fraud encompasses a broad range of criminal activity from prescription drug diversion to addiction treatment schemes. Many of these schemes can be elaborate, involving complicit patients or beneficiaries who are not ill, kickbacks, medical identity theft, money laundering, and other criminal enterprises. Some schemes also involve multiple co-conspirators and health care professionals such as physicians, nonphysician providers, and pharmacists. These investigations can be complex and often involve the use of informants, undercover operations, and surveillance.

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[3] OIG has the authority to exclude individuals and entities from federally funded health care programs. The effect of an exclusion is that no payment will be made by any Federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. No program payment will be made for anything that an excluded person furnishes, orders, or prescribes.

[4] Centers for Disease Control and Prevention, *Prescription Painkiller Overdoses at Epidemic Levels* [press release], Nov. 1, 2011.

[5] Centers for Disease Control and Prevention, Data Brief 294, *Drug Overdose Deaths in the United States, 1999–2016,* December 2017, and supplement tables.

[6] Ibid.

2017 National Health Care Fraud Takedown

OIG and our Medicare Strike Force partners led the 2017 National Health Care Fraud Takedown. The Takedown was the largest ever health care fraud enforcement action, resulting in 412 charged defendants across 41 Federal districts, including 115 doctors, nurses, and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately $1.3 billion in false billings. Over 120 defendants, including doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.[7] OIG also announced 295 opioid-related exclusions. The enforcement operation brought together more than 1,000 Federal and State law enforcement personnel, including 350 OIG Special Agents and 30 MFCUs.

Case Examples

OIG agents have investigated the following cases. These examples highlight opioid schemes involving patient harm and prescription and treatment fraud:

Patient Harm

- In Philadelphia, Dr. Norman Werther was sentenced to 25 years in prison for distribution of a controlled substance resulting in death and more than 300 counts stemming from his operation of a pill mill. Werther was part of a multimillion-dollar drug conspiracy involving illegal prescriptions, phony patients, and multiple drug trafficking organizations. The drug traffickers recruited large numbers of pseudo-patients who were transported to Werther's medical office for cursory examinations. The "patients" paid an office visit fee, usually $150, by cash, check, or money order, and Werther wrote prescriptions for them to obtain oxycodone-based drugs without a legitimate medical purpose and outside the usual course of professional practice. The phony patients were then driven to various pharmacies to have their prescriptions filled. The drugs were then turned over to drug traffickers so their organizations could sell them to numerous drug dealers who resold them on the street. At one point, Werther knowingly dispensed approximately 150 pills containing 30 milligrams each of oxycodone, and 30 pills containing 15 milligrams each of oxycodone, to a patient for no legitimate medical purpose, ultimately resulting in the individual's death from overdose.

Prescription Fraud

- In Williamsport, Dr. John Terry was sentenced to 20 months in prison for writing fraudulent prescriptions for oxycodone. Along with Terry, Thomas Ray was sentenced to 71 months in prison on charges of possession with intent to distribute a controlled substance. Terry wrote prescriptions for oxycodone and other narcotics for Ray in reckless disregard of the fact that the drugs were not being used by Ray for legitimate medical purposes, but being diverted and sold on the street. Medicaid paid for the fraudulent prescriptions written for Ray. Terry also wrote prescriptions for oxycodone in Stephen Heffner's name knowing that Heffner was not his patient and the drugs would later be diverted to another individual, David Hatch. Because Medicare paid for these drugs, Heffner and Hatch were both sentenced to 6 months of probation for theft from the Medicare Program.
- In Pittsburgh, Dr. Brent Clark was sentenced to 60 months in prison on charges of distribution of oxycodone and amphetamine outside the usual course of professional practice and health care fraud. He was also ordered to pay more than $225,000 in restitution and forfeit $131,000, the building he owned where he conducted his medical practice and where the offenses were committed, his Drug Enforcement Administration prescribing number, his Pennsylvania State medical license, and a vehicle he owned. Clark distributed oxycodone on 13 occasions and amphetamine on 3 occasions outside the usual course of professional practice.

Treatment Related Fraud

- In Philadelphia, Dr. Alan Summers was sentenced to 48 months in prison and ordered to pay over $4.6 million in restitution after pleading guilty to charges of conspiracy to distribute controlled substances, distribution of controlled substances, health care fraud, and money laundering. Dr. Summers ran a clinic that sometimes operated under the business name NASAPT (National Association for Substance Abuse-Prevention and Treatment). Co-defendants

[7] Department of Justice, *National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for $1.3 Billion in Fraud Losses,* July 2017.

Dr. Azad Khan and Dr. Keyhosrow Parsia were employed by Dr. Summers. The defendants executed a scheme in which they sold prescriptions for large doses of Suboxone and Klonopin in exchange for cash payments. Experts testified at trial that Suboxone and Klonopin should never be prescribed together except in rare cases when absolutely necessary. At the clinic, virtually all customers received prescriptions for both Suboxone and Klonopin regardless of their medical need. During the duration of the conspiracy, Dr. Khan and other doctors at the clinic illegally sold more than $5 million worth of these controlled substances. Almost all of the prescriptions for Suboxone and Klonopin were preprinted before the customer met with a doctor. Khan and the other doctors working at the clinic failed to conduct medical examinations or mental health examinations as required by law to legally prescribe these controlled substances. Several customers who frequented the clinic testified that they were, in fact, drug dealers or drug addicts who sold the prescribed medications. Three other doctors involved in the scheme have pleaded guilty and have either already been sentenced or await sentencing.

- In Johnstown, Dr. John Johnson was sentenced to 84 months in prison and ordered to pay more than $3 million in restitution after pleading guilty to charges of paying kickbacks and tax fraud. Johnson owned and operated a group of pain management clinics and entered into an agreement with Universal Oral Fluid Labs (UOFL) and its owner, William Hughes, to refer patients to UOFL in exchange for kickback payments. UOFL was a clinical drug testing and drug screening lab located in Greensburg, Pennsylvania. Johnson received cash payments and monthly checks from Hughes and UOFL in exchange for referring patients, including Medicare and Medicaid beneficiaries, to UOFL. Johnson referred all of his patients to UOFL for drug testing and related services. He received more than $2,300,000 in kickbacks from Hughes and UOFL for these referrals. As a result of Johnson's referrals, UOFL received millions of dollars from third-party payors, including approximately $3,443,528 from Medicare and $1,147,768 from Pennsylvania Medicaid.

OIG'S EFFORTS TO COMBAT THE OPIOID EPIDEMIC GO BEYOND ENFORCEMENT

Data analysis to identify questionable prescribing, dispensing, and utilization of opioids

OIG uses data analytics to detect and investigate health care fraud, waste, and abuse. We analyze billions of data points and claims information to identify trends that may indicate fraud, geographical hot spots, emerging schemes, and individual providers of concern. At the macro level, OIG analyzes data patterns to assess fraud risks across Medicare services, provider types, and geographic locations to prioritize and deploy our resources. At the micro level, OIG uses data analytics, including near-real-time data, to identify potential fraud suspects for a more in-depth analysis and efficiently target investigations.

In July 2017, OIG released a data brief entitled *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing*[8] in conjunction with the 2017 National Health Care Fraud Takedown. We found the following:

- One in three Medicare Part D beneficiaries received opioids in 2016. In total, 14.4 million beneficiaries received an opioid prescription that year.
- Approximately 500,000 beneficiaries received high amounts of opioids. Beneficiaries with a cancer diagnosis and those enrolled in hospice were excluded from the analysis. To identify these beneficiaries, OIG looked at the morphine equivalent dose (MED) received by each beneficiary, which equates all of the various opioids and strengths into one standard value. Beneficiaries who received high amounts of opioids had an average daily MED greater than 120 mg for at least 3 months in 2016. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg. These dosages far exceed the amounts that the manufacturers recommend. Although beneficiaries may receive opioids for legitimate purposes, these high amounts raise concern due to the health risks associated with opioids.
- Within that group, OIG identified nearly 90,000 beneficiaries at serious risk of opioid misuse or overdose. OIG identified two groups of beneficiaries at se-

[8] OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing,* OEI–02–17–00250, July 2017.

rious risk of opioid misuse or overdose: (1) beneficiaries who received extreme amounts of opioids, and (2) beneficiaries who appeared to be "doctor shopping."[9]

- OIG identified 69,563 beneficiaries who received extreme amounts of opioids. They each had an average daily MED of more than 240 mg for the entire year.
- OIG also identified 22,308 beneficiaries who appeared to be doctor shopping. They each received high amounts of opioids and had four or more prescribers and four or more pharmacies for opioids. While some of these beneficiaries may not have been doctor shopping, receiving opioids from multiple prescribers and multiple pharmacies may still pose dangers from lack of coordinated care. Typically, beneficiaries who receive opioids have just one prescriber and one pharmacy.

- OIG identified about 400 prescribers with questionable opioid prescribing for beneficiaries at serious risk. In the data brief, a total of 401 prescribers stood out as having questionable prescribing because they ordered opioids for higher numbers of beneficiaries at serious risk (*i.e.,* those who received extreme amounts of opioids or appeared to be doctor shopping). In total, prescribers with questionable billing wrote 265,260 opioid prescriptions for beneficiaries at serious risk, costing Part D a total of $66.5 million.

Although some patients may legitimately need high amounts of opioids, questionable prescribing can indicate that prescribers are not checking State databases that monitor prescription drugs, or that they are ordering medically unnecessary drugs that may be diverted for resale or recreational use. Another possibility is that the prescriber's identification was sold or stolen and is being used for illegal purposes. Questionable levels of prescribing also raise significant concern that prescribers may be operating pill mills.

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. Prescribers play a key role in combating opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids when medically necessary. States' prescription-drug-monitoring programs can provide invaluable information to prescribers about a patient's opioid prescription history. Prescribers must be vigilant about checking the State monitoring databases to ensure that their patients are receiving appropriate doses of opioids and to better coordinate patient care. At the same time, the Department must address prescribers with questionable prescribing patterns for opioids to ensure that Medicare Part D is not paying for unnecessary drugs that are being diverted for resale or recreational use.

Identify Opportunities to Improve HHS Programs

Across multiple operating divisions and programs, HHS has many opportunities to help curb this epidemic. Medicare provides prescription drug coverage for 41 million Part D beneficiaries and Medicaid for almost 69 million beneficiaries. The U.S. Food and Drug Administration (FDA) oversees the approval and safe use of prescription drugs. Agencies such as the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), and the CDC award grants to support health care providers, researchers, and States in their efforts to combat the epidemic.

OIG audits and evaluations address opioid issues by identifying opportunities to strengthen program integrity and protect at-risk beneficiaries across HHS programs. OIG currently has numerous opioid-related audits or evaluations underway. They address the following issues:

- Questionable prescribing patterns in Medicaid;
- Medicaid program integrity controls;
- Medicare program integrity controls in the prescription drug benefit;
- CDC's oversight of grants to support programs to monitor prescription drugs;
- FDA's oversight of opioid prescribing through its risk management programs;
- SAMHSA's oversight of opioid treatment program grants;
- Beneficiary access to buprenorphine medication-assisted treatment; and
- Opioid prescribing practices in the Indian Health Service.

[9] Other beneficiaries may also be at serious risk of opioid misuse or overdose, but they were not the focus of this data brief.

In addition, as part of its strategy to fight the opioid crisis and protect beneficiaries, OIG will soon release a new data brief on opioid use in Medicare Part D.[10] It is a follow-up to a previous data brief, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing* (OEI–02–17–00250), which was based on 2016 data. The new data brief is based on 2017 data and, like the previous one, will (1) determine the extent to which Medicare Part D beneficiaries received high amounts of opioids, (2) identify beneficiaries who are at serious risk of opioid misuse or overdose, and (3) identify prescribers with questionable opioid prescribing patterns for these beneficiaries.

In conjunction with the new data brief, OIG will also release an analysis toolkit.[11] It is based on the methodology that OIG has developed in our extensive work on opioids. The toolkit provides detailed steps for using prescription drug data to analyze patients' opioid levels and identify those at risk of opioid misuse or overdose, such as those who receive extreme amounts of opioids or appear to be doctor shopping. The purpose of the toolkit is to assist our public and private sector partners with analyzing their own prescription drug claims data to help combat the opioid crisis.

OIG is also focused on effective public health approaches to prevention and treatment. Currently, we are conducting an evaluation to examine access to Medication-Assisted Treatment (MAT) for opioid use disorder. MAT, including buprenorphine, is a key component of effective treatment for opioid use disorder. Congress has taken sustained action to support MAT services through broadened prescribing authorities and increased Federal funding. However, a treatment gap continues to exist where an estimated 10 percent of the people in the United States who need treatment receive it.

To address this treatment gap, we are examining access to MAT through the SAMHSA buprenorphine waiver program, which permits providers to prescribe buprenorphine to patients in office settings rather than traditional opioid treatment facilities. We are determining the number, location, and patient capacity of providers who have obtained buprenorphine waivers from SAMHSA. We will also determine the extent to which waivered providers are located in areas with high indicators of opioid misuse and abuse (*i.e.,* areas that likely have large numbers of residents in need of treatment services), including whether any of these areas are without waivered providers. We anticipate that this report, when finalized, will highlight counties in need of MAT services that do not now have adequate access.

OIG MAXIMIZES IMPACT THROUGH STRONG COLLABORATION WITH PUBLIC AND PRIVATE PARTNERS

In addition to Strike Force operations and other government collaborations, OIG engages with private sector stakeholders to enhance the relevance and impact of our work to combat health care fraud, as demonstrated by our leadership in the Healthcare Fraud Prevention Partnership (HFPP) and collaboration with the National Health Care Anti-Fraud Association (NHCAA). OIG strives to cultivate a culture of compliance in the health care industry through various educational efforts, such as Pharmacy Diversion Awareness Conferences, public outreach, and consumer education.

Medicare Fraud Strike Force

The Strike Force effort began in Miami in March 2007 and has expanded operations to eight additional cities. Strike Force teams effectively harness the efforts of OIG and DOJ, including Main Justice, U.S. Attorneys' Offices, and the Federal Bureau of Investigation (FBI), as well as State and local law enforcement, to fight health care fraud in geographic hot spots.

The Strike Force teams use near-real-time data to pinpoint potential fraud hot spots and identify aberrant billing. This coordinated and data-driven approach to identify, investigate, and prosecute fraud has produced significant results, highlighted by the July 2017 National Health Care Fraud Takedown. Since its inception in March 2007, the Strike Force has charged more than 3,000 defendants who collectively billed the Medicare program more than $10.8 billion.

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[10] OIG, *Opioid Use in Medicare Part D,* OEI–02–18–00220, forthcoming.
[11] OIG, *Toolkit to Identify Patients at Risk of Opioid Misuse,* OEI–07–00560, forthcoming.

Collaboration With the Department

OIG collaborates with a number of HHS agencies, including the Centers for Medicare and Medicaid Services (CMS) and the Agency for Community Living (ACL), on fraud and opioid-related initiatives. OIG collaborates with CMS and ACL to educate providers, the industry, and beneficiaries on the role each one plays in the prevention of prescription drug and opioid-related fraud and abuse. We share our analytic methods and data analysis with CMS and work together to identify mitigation strategies and develop follow-up approaches to deal with the prescribers and at-risk beneficiaries identified. OIG engages ACL's Senior Medicare Patrol and State Health Insurance Assistance Program through presentations on the prevention of fraud, waste, and abuse.

Opioid Fraud and Abuse Detection Unit

OIG provided critical support in the establishment of the new Opioid Fraud and Abuse Detection Unit established by the Attorney General in collaboration with OIG, FBI, and Drug Enforcement Administration (DEA). The unit focuses specifically on opioid-related health care fraud using data to identify and prosecute individuals who are contributing to the opioid epidemic. This collaboration led to the selection of 12 judicial districts around the country where OIG has assigned Special Agents to support 12 prosecutors identified by DOJ to focus solely on investigating and prosecuting opioid-related health care fraud cases. Each of the 12 districts is supported by OIG, FBI, and DEA.

The Healthcare Fraud Prevention Partnership and the National Healthcare Anti-Fraud Association

The HFPP and NHCAA are public-private partnerships that address health care fraud by sharing data and information for the purposes of detecting and combatting fraud and abuse in health care programs. OIG is an active partner in these organizations and frequently shares information about prescription-drug fraud schemes, trends, and other matters related to health care fraud.

Pharmacy Diversion Awareness Conferences

OIG has collaborated with the DEA to provide anti-fraud education at numerous Pharmacy Diversion Awareness Conferences held across the United States. The conferences were designed to assist pharmacy personnel with identifying and preventing diversion activity. Since 2013, OIG has presented at conferences in 50 States and Puerto Rico.

TOP OIG RECOMMENDATIONS FOR CMS RELATED TO THE OPIOID CRISIS

OIG has made numerous recommendations to improve HHS programs to better protect beneficiaries at risk of opioid misuse or overdose. Specifically, ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Medicare Part D.

As a result of OIG recommendations, Part D has strengthened its monitoring of beneficiaries at risk of opioid misuse. CMS has expanded drug utilization review programs to include non-opioid "potentiator" drugs. These euphoria-enhancing potentiator drugs are often abused in conjunction with opioids and increase the risk of negative outcomes including overdose. CMS now identifies beneficiaries with concurrent opioid and benzodiazepine prescription drug use and will, beginning in 2019, identify beneficiaries who receive high doses of gabapentin in addition to opioids. CMS also expects that when plan sponsors perform case management they would consider the use of these potentiator drugs in their own review processes. Further, CMS has committed to perform analyses to proactively identify other potentiator drugs, meet biannually with OIG to discuss emerging issues, and consider additional enhancements to drug utilization review programs in the future.

Despite the progress made, there are other improvements OIG recommends to protect Medicare beneficiaries.

(1) Restrict certain beneficiaries to a limited number of pharmacies or prescribers.

OIG recommends that CMS encourage implementation of the new Medicare Part D beneficiary lock-in authority under the Comprehensive Addiction and Recovery Act of 2016 (CARA). Lock-in would restrict certain beneficiaries to a limited number of pharmacies or prescribers when warranted and reduce inappropriate use of opioids among Medicare beneficiaries and Part D fraud. This policy would provide coordination of care for beneficiaries being harmed by overprescribing and address beneficiaries who are doctor shopping or intentionally seeking unnecessary prescriptions.

In 2018, CMS promulgated regulations that govern how Part D sponsors should implement the new lock-in authority under CARA, beginning in 2019. However, the decision of whether to implement this program rests with the Part D sponsors.

(2) Require plan sponsors to report to CMS all potential fraud and abuse and any corrective actions they take in response.

CMS should collect comprehensive data from Part D plan sponsors to improve its oversight of their program integrity efforts, including the diversion of opioids for illegitimate use. Sponsors serve as the first line of defense against opioid fraud, waste, and abuse in Part D as they are responsible for paying claims and monitoring billing patterns. However, there is currently a lack of transparency on how Part D sponsors identify and investigate these matters.

(3) Improve Medicaid data.

CMS does not have complete and accurate data needed to effectively oversee the Medicaid program, including opioids. Without accurate claims data, adequate oversight of the Medicaid program is compromised. OIG has a history of work that points to the incompleteness and inaccuracy of CMS's national Medicaid database, the Transformed Medicaid Statistical Information System (T–MSIS). Without a national dataset, CMS, States, and OIG are unable to identify nation-wide trends and vulnerabilities. This hampers program integrity efforts because fraud does not respect State boundaries. OIG recommends that CMS establish a deadline for when national T–MSIS data will be available for multistate program integrity efforts.

CONCLUSION

OIG has made combating the opioid crisis a top enforcement and oversight priority. We will continue to leverage our analytic, investigative, and oversight tools, as well as our partnerships in the law enforcement and program integrity communities and with the Department to maximize our efforts. OIG will remain vigilant in following and investigating emerging opioid fraud trends, especially schemes involving patient harm and abuse.

PREPARED STATEMENT OF HEATHER MALONE,
PERSON IN RECOVERY

They say you shouldn't judge a book by its cover. This is true for me, as many would be shocked if they read the pages in my book.

My name is Heather Malone, and almost six months ago, I finally made the decision to make a better life for myself. For so long, I lived a life of fear, darkness and chaos. I was using heroin on a daily basis. At the end, I was lost and alone. My family wanted nothing to do with me and my own children didn't know their mother.

I was living in North Philadelphia with a person who was physically, mentally, and emotionally abusive. I accepted this because I didn't believe I deserved anything better. Every day I asked myself, "How did I end up here?"

Looking back, it used to be easy to blame my past as for how I turned out. I never learned any kind of coping mechanisms to deal with pain and would keep my emotions deep inside me.

My mother was an addict who always had live-in babysitters look over my sister and me. She eventually moved my aunt and her boyfriend in with us for this purpose. I was four years old when he molested me for the first time. This continued for five years until he left my aunt. I vividly remember the day he left. My aunt ended up going into the bathroom and never coming out. It was hours before I had finally went to check on my aunt. When I did, I found her hanging from the ceiling. All I could do was make sure my little sister who, was five at the time, did not see her.

When my aunt took her life, my mother was not home. And she didn't come at any point during the following three days. I was left, watching my sister, while my aunt hung from the ceiling in our bathroom. Eventually, the neighbors called the authorities. At this point, my father stepped in and took custody of my sister and me. I thought this was my chance to finally be a happy and free kid, something I did not have a chance to experience to that point. Unfortunately it didn't turn out that way, as my father was very abusive. All I wanted was my father to love me, I guess he had his own ways of showing it.

I was fourteen when I tried to escape reality for the first time by taking my own life. I was so lost, alone, hurt, and scared. Obviously I was not successful, but self-harm, more attempts at suicide, and self-destruction continued to play a big part in my life.

My mother came back into my life at eighteen, and this is where demise began. I always longed to be mommy's little girl. But when I moved in with her, she didn't want to be my mother. All she wanted was to have someone to get high with. Like I said, she was an addict and after I got into a minor car accident, she brought me to a doctor she was seeing who prescribed me medication. All I had to do was tell the doctor I had serious back pain and he wrote me a prescription. That fist time taking a pill was a memory I will never forget. I thought I found the answers to all my pain and problems, it gave me a numbing effect that I fell in love with. As time progressed the strength of medications increased as did my addiction. Pills were so easily accessible and they were legal so I did not see the problem with it all at the time.

Time went on, and eventually prescriptions ran out and pills became too expensive and I graduated to heroin, and that became my new best friend. This took me down a very deep dark path, with more pain and suffering and all my never came true. I was a person that was hurting and hurt people. I was raped on numerous occasion; selling my body was an easy way to pay for my next fix. Jails, institutions, running, and using was my life. There were bouts of sobriety with the help of methadone and Suboxone maintenance. And yes, it helped periodically, but there was so much pain that I never dealt with which always led me back to relapse. I didn't know how to live life on life's terms without a substance.

I tried to be and do better. I even went back to school to work with people who were in a similar situation as me at Harcum University. In May of 2012, I was inducted into the honors society for receiving one of the highest GPA's in the tri-state area. As part of this recognition, I was scheduled to give a speech at a ceremony. This is where self-sabotage, which is re-occurring thing for me, took place. It should have been one of the best nights of my life. My father was so proud of me and my family was going to be attending the ceremony. I should have been proud and happy, but I wasn't.

I remember thinking back to how envious I was of my aunt who was able to escape reality when she took her own life. I never made it to that ceremony. The last thing I remember was walking upstairs to my room and getting two scarves, tying them together, and fastening either end to my ceiling fan and myself. Days later, I woke up in ICU at Crozer Hospital with tubes down my throat hooked up to machines that were breathing for me. I was so angry when I woke up—I couldn't even successfully kill myself.

As years went on, things got worse. Addiction became my full-time job. I was consumed with the numbing effect. I didn't want to live. But if I had to, I didn't want to feel anything. I felt like a soulless, empty shell of a person. I used to live and lived to use.

I eventually got back into a relationship with a person who was also in active addiction. I really thought we loved each other. To me, pain equaled love because all the people that were supposed to love me hurt me, so that is all that I thought I deserved. Physical abuse was something I allowed because if someone hurt me physically on the outside I didn't have to feel my internal pain.

Last year, on Friday, December 8th, the abuse went to a whole new level. I remember being woken up by my girlfriend choking me. I begged her to please just end my life. She proceeded to cut my throat, hit me with a bat, and had me hanging over the balcony. I wanted her to drop me. My father showed up and stopped her, he carried me to his car and took me far away from there. I should've went right to the hospital. I was bloody and couldn't walk. I later found out that I had a fractured hip, eyes blackened and finger print bruises on my neck.

But all I could do was beg him to take me to Kensington to get my next fix to feel numb once again. After a lot of persuading, he took me but he made me promise if he did I would then go into treatment. I agreed. I was at my all-time low. I showed up to rehab badly physically beaten. Worse though, I was emotionally and spiritually bankrupt and broken.

Detox was not easy, and insanity set in. I started missing my girlfriend because, again, pain equals love to me. After the third day, I finally found enough courage

to look at myself in the mirror and I almost fainted. Before bruises get better they get worse. This made me take a long look at myself and the life I was living.

I didn't want to live this way anymore, I needed to figure out how to escape the nightmare I had been living for so long. At that moment, I truly surrendered and prayed for a new way of life and guidance.

At Keystone, they had me in a dialectical behavioral therapy (DBT) group for people who have experienced trauma and I am so grateful for that opportunity. In past treatments, I would act as if I used drugs only for the effect and that there was no underlying issues. I never shared that I had a very traumatic past which made me feel like my only answer was addiction. With the help of DBT, I was able to scratch the surface of all my pain. I spoke about my past and secrets that had kept me sick for so long.

As my projected discharge date was approached, my counselors suggested I move to a recovery house. At first I was resistant due to previous stays at recovery houses that were not conducive to my recovery. My counselors explained their suggested recovery house was not your average facility. And the more positive things I heard the more intrigued I became. I thought maybe this is my chance to actually get my act together and live a real life and not just exist.

I made the decision to go, and it has not been easy by any means. I live in a therapeutic community of women that help build me up to be the person I can and want so much to be.

I came through the doors of MVP with so many defects of character. I was so used to living a chaotic lifestyle. This program is helping me recognize when my defects come out and how to work through them so that I can change them and become a better person. Perfecting this process is unrealistic and I fall short all the time. However, because of MVP, I am able to work on being a productive member of society. Today, I am accountable for my actions. I am able to be a daughter, a friend, and most of all, a mother. Trust was always a hard thing for me, but today, I can trust in others, others can trust in me, and most of all I trust in myself.

I am still in a lot of pain on a daily basis due to my fractured hip. I need surgery to get a partial hip replacement and I fear the aftermath because to recover, a doctor will just write me a prescription for pain medication to help ease the physical pain. If I do not notify them ahead of time that I am a person in recovery, it's almost automatic for them to prescribe opiates.

Like I said, that does help with the pain temporarily but this is how my demise of addiction all began with a simple script written from a doctor. I do not want that to be the way my life has to end, but it will because I truly believe I may have another run in me but I do not have another recovery. I want to recover. I don't want to be defined as a statistic and hopefully things can change to help implement changes to avoid over prescribing or prescribing people who are at risk.

In treatment, they asked us what our five year goal was in life. People wanted houses, families, and cars. When it was my turn to share, all I wished for was genuine happiness. I honestly thought pure happiness was unattainable for a person like me, and I definitely didn't think I would be able to achieve it within five years. But today, I can truly say that I am so grateful to be exactly where I need to be.

PREPARED STATEMENT OF RICHARD SNYDER, M.D., SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, INDEPENDENCE BLUE CROSS

Senator Toomey, members of the subcommittee, good afternoon and thank you for the invitation to testify at today's field hearing examining efforts to prevent opioid overutilization and misuse in government health care programs. My name is Dr. Richard Snyder, and I am the Senior Vice President and Chief Medical Officer for Independence Blue Cross (Independence), based in Philadelphia. Through our parent company, Independence Health Group, we serve over 8.4 million people in 24 states and the District of Columbia, including more than 2.5 million people in Southeast Pennsylvania. For almost 80 years, we have been enhancing the health and well-being of the people and communities we serve.

We appreciate the opportunity to provide information regarding our efforts to address the ongoing opioid crisis. This national epidemic is widespread, affecting the American public with no regard for age, income, education, or geography. The overprescribing and abuse of prescription opioids in the United States has reached epi-

demic proportions and Philadelphia's unfortunate status as the city with the cheapest and purest heroin in the country further exacerbates the problem in our region.

According to local health officials, approximately 1,700 people in southeastern Pennsylvania died in 2016 from an opioid overdose. While all 2017 data is not yet available, the Centers for Disease Control and Prevention (CDC) reports that Pennsylvania had the fastest growing rate of drug overdose deaths nationwide from July 2016 to July 2017.

Independence is not new to this fight. We have been working for years with the doctors, hospitals, and community partners in our region to refine our medical policies to reduce overprescribing, to protect appropriate access to therapy for those who are in need and to work collaboratively to make treatment options available for those trapped in a cycle of abuse or misuse.

COMMERCIAL EFFORTS TO REDUCE OVERPRESCRIBING

Before discussing overprescribing patterns and policies in Medicare, it may be helpful to first walk through our efforts in the commercial health insurance space, where we have more discretion to implement medical policies that are consistent with the most recent and relevant clinical evidence.

- **Limiting High-Dose Opioid Prescriptions:** Since the beginning of 2015, Independence has required doctors to provide additional clinical documentation to prescribe our members high doses of opioids. In 2016, we updated these policies to reflect the most recent CDC prescribing guidelines.
- **Outreach to Outlier Prescribers:** We share the CDC's guidelines with our network providers and have specifically focused on the 1,250 prescribers who have exceeded them, providing member-level detail to enable prescriber review and modification. This outreach has resulted in nearly 60 percent changing or decreasing their prescribing habits.
- **Systems to Prevent Doctor Shopping and Improper Prescribing:** Our ongoing dialogue with local, regional, State, and Federal law enforcement agencies, including the U.S. Attorney's Office for the Eastern District and the Pennsylvania Attorney General's Office, encourages valuable information sharing that can help prevent and deter fraud, such as doctor shopping or inappropriate prescribing practices. In 2017, our Investigations Division used tips and data analysis to review 141 cases of improper prescribing and dispensing, resulting in 14 individuals being convicted of insurance or prescription fraud.
- **Cumulative Five-Day Supply Limit:** In 2017, Independence became one of the first insurers in the country to restrict first-time, low-dose opioid prescriptions to a five-day supply limit, with an exemption for patients with cancer or terminal illnesses. During the last six months of 2017, the number of members using opioids dropped 22 percent and the number of prescriptions dropped 26 percent.

The results are promising. Since 2014, Independence has seen a major reduction in members using opioids, opioid prescription claims processed, and opioid dosages prescribed. This includes a 45-percent reduction in opioid users (45,000 fewer members), a 35-percent reduction in opioid prescriptions (100,000 total), and an 18-percent reduction in morphine equivalent dose.

ACCESS TO EFFECTIVE TREATMENTS

Beyond prescribing guidelines, we know many of our members need access to effective treatment services for opioid use disorder (OUD). Independence plan designs offer coverage for a range of services, including detoxification, rehabilitation, outpatient programs, and counseling, as well as medication-assisted treatments (MATs), to treat substance use disorder.

We know that in addition to it being the right thing to do, getting our members with OUD into evidence-based treatment is a sound strategy for containing health care costs. We have done the analysis and know that an Independence member with unaddressed OUD utilizes about $10,000 more in healthcare services than a member with OUD who is being treated with an MAT, like buprenorphine or naltrexone. In other words, for every 100 members we can guide into effective treatment, Independence can save our members $1 million in claims costs.

This is why we have become one of the few commercial insurers that covers methadone and why we have removed initial prior authorization restrictions for common

MATs. Our provider network includes 100 different substance abuse rehabilitation facilities and more than 5,000 behavioral health providers. We were also the first commercial insurer accepted by Caron Treatment Centers, one of the country's premier addiction treatment programs located in Pennsylvania.

HOW MEDICARE PRESCRIBING GUIDELINES WORK AND RECOMMENDATIONS FOR FUTURE IMPROVEMENTS

In the Medicare Advantage (MA) market, we are proud to be the most popular plan in Southeast Pennsylvania, including here in Bucks County. We share your concerns with the recent Department of Health and Human Services (HHS) Office of the Inspector General report that noted that one in three Medicare Part D beneficiaries received an opioid in 2016, including roughly 500,000 individuals who received opioid scripts of greater than 120 mg per day for at least three months.

Within Independence's MA membership, approximately 11.5 percent of beneficiaries utilized opioids in 2017, compared to less than 4.5 percent in our commercial membership. Approximately 400 members were designated as "at-risk" for an OUD due to a high daily dose use over an extended period of time. A total of 120 Medicare members participated in an addiction treatment program in 2017.

Within the Medicare population, there are differences in how Independence and other insurers can address and prevent OUD. It is important to keep in mind that HHS, specifically the Centers for Medicare and Medicaid (CMS), has established very specific and detailed rules that must be followed within the sphere of traditional Medicare and MA offerings. At times, this has meant that CMS has prevented Independence from putting reasonable limitations on prescribing.

For example, we recently experienced such a challenge when CMS rejected our initial 2018 High Dose Opioid Policy. As part of the criteria, Independence wanted the provider community to evaluate patients for non-pharmacologic treatment, such as physical and/or psychological therapy. In response to that recommendation, CMS stated that: "Criteria cannot require treatment parameters that are not managed by Part D. Delete the PA element or remove evaluation for non-pharmacologic treatment including but not limited to physical and/or psychological therapy requirements. Criteria appear too restrictive or overly burdensome."

While this was unfortunate for the 2018 plan year, CMS made great strides in improving prescribing guidelines in the 2019 Final Call Letter, which sets annual program policies for MA. Starting in January; plans will have to limit initial opioid prescriptions to no more than a seven day supply. In addition, for all other MA members previously prescribed opioids, CMS will now require a care coordination edit when daily prescribing guidelines have been exceeded, forcing plans and/or network pharmacists to engage with the prescribing physician. With these changes, Independence anticipates further prescribing decreases as the 2019 Medicare enhancements are operationalized.

As CMS works with plans to begin transitioning more MA members off of opioids if they do not fit the criteria for initial fills, the agency will need to allow and encourage additional flexibility for plans. Having seniors evaluated and transitioned to Part B benefits, such as physical therapy, is clinically appropriate in many instances and the agency should embrace these options as a potential non-pharmaceutical solution. Other non-opioid pain management therapies, such as acupuncture, which the FDA has included in its ″blueprint″ for non medication based therapies, will need to be considered as a covered service under Medicare as the next phase of prescribing adjustments begin. Along with this greater flexibility in therapy, CMS should also consider integrating Pharmacy Quality Alliance performance measures (such as the proportion of beneficiaries prescribed more than 120mg for 90 days or longer) into the Star Rating program. Doing so will tie financial incentives to how well plans work with their provider partners to reduce unnecessary opioid prescribing, which is beneficial for patients, for providers, and for plans.

Additionally, the future expansion of MA care coordination efforts may require updates to Federal privacy statutes. Alerting the primary care physicians of Independence members who have been treated for OUD at a separate facility is currently prohibited under Federal law by 42 CFR Part 2. This is not the case for a member who has been treated for a heart attack or diabetes in the ER. Care coordination parity, or treating OUD records the same way other health records are treated under the Health Insurance Portability and Accountability Act (HIPAA), is essential in the battle against the opioid epidemic. We all recognize the vital need to appropriately share important health factors across the provider spectrum, while main-

taining a patient's right to privacy. Aligning Part 2 with HIPAA is a necessary and integral piece of the regulatory framework that we believe will ensure providers have the full and accurate understanding of a patient's medical history that is necessary for appropriate care at the appropriate time at the appropriate level.

OVERUTILIZATION MONITORING AND AT-RISK BENEFICIARIES IN MEDICARE

Independence regularly communicates with CMS on opioid overutilization. This is done through the agency's Overutilization Monitoring System (OMS) to identify members who may be at-risk of diverting and abusing opioids. In the current Level 3 retrospective opioid overutilization program, members are identified on a monthly basis using a rolling six-month look-back period based on the following criteria: (1) use of opioids with an average daily dose greater than or equal to 90mg, and (2) either four or more prescribers and pharmacies, or six or more prescribers, regardless of pharmacies. Under these criteria, very few Independence members are identified annually and when they are, the situation is evaluated immediately.

The prescribers of the identified members are reviewed according to specialty to determine appropriate targeting for case management communications and interventions. Independence schedules a telephonic conversation with the prescribers and the corresponding pharmacists, either together or separately.

The process will result in either prescriber verification of the appropriateness of the member's opioid therapy or, more likely, we will implement a point-of-sale benefit edit for the member to prevent them from continuing to access that level of opioids. The member is notified in writing and they are reminded of their ability to appeal the limit. CMS requires plans to report back on the outcome of these incidences. When necessary, Independence refers cases to our internal Criminal Investigations division for potential referral to law enforcement.

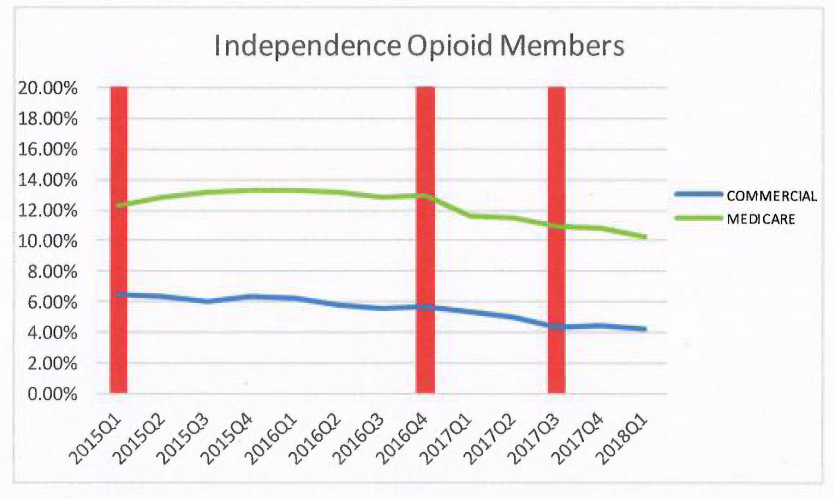
Independence supports CMS's efforts to expand these criteria in 2019 to include other potentiator drugs (such as benzodiazepines) and agrees that these criteria and reporting requirements could be expanded further still. We look forward to working with CMS on this endeavor and we will be submitting our comprehensive feedback to the agency in the coming weeks.

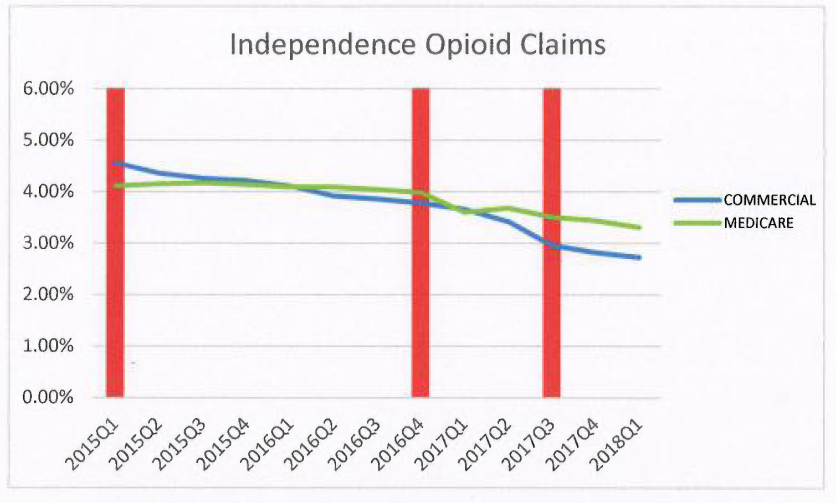
TREATMENT GAPS IN MEDICARE

In terms of services and treatments that are covered for those who have been diagnosed with an OUD, we follow the requirements defined by CMS. As a MA plan, we are required to cover the same benefits as original Medicare. These are not inclusive of all options made available to our commercial members.

One of the Medicare treatment gaps is the lack of coverage for methadone when it is administered in an outpatient setting as part of MAT. While not many of our commercial members have utilized our coverage for this MAT, it can be suitable and effective for certain members. The lack of coverage for sub-acute inpatient services at residential treatment centers (RTCs), which can be an appropriate setting after detoxification, is another current treatment gap. Currently, Medicare members are discharged to a partial hospitalization program, an intensive outpatient program, or professional outpatient services following their initial detoxification. Beneficiaries may be more successful in treatment with the introduction of an interim stage, such as a step-down to a RTC, for a discrete period of time.

On behalf of Independence and our CEO Dan Hilferty, I want to thank you for the opportunity to share my thoughts with you today. We are committed to finding solutions that will curtail overprescribing, protect the appropriate use of opioids, and enable access to effective treatment of OUD. We all want to end this epidemic that is ravaging our communities and our Nation. We are losing too many of our friends, family members, and community to this disease. While we are making significant progress, there is much more work to be done. We look forward to working with CMS and Congress on finding sensible policy solutions to aid in this fight.





Q1 2015—Q1 2018	Commercial	Medicare
Reduction in Opioid Utilizers	−35%	−16%
Reduction in Opioid Claims	−40%	−19%

*The red bars in the first two graphs indicate the implementation of new prior authorization policies on commercial market opioid prescribing in 2015 and 2016 as well as the 5-day initial limit instituted in 2017.

PREPARED STATEMENT OF HON. PATRICK J. TOOMEY,
A U.S. SENATOR FROM PENNSYLVANIA

Thank you to the Bensalem Township Council for hosting this field hearing of the Senate Finance Subcommittee on Health Care, to the witnesses for making themselves available for what I hope to be an illuminating discussion, to the public officials here for dedicating your attention to this important issue, and to the public for your interest.

There are many lessons relevant to our current times buried within the annals of history. Today's opioid and heroin epidemic is no different. Sadly, this is not the first time even our own Nation has found itself in the depths of a public health crisis precipitated by the overuse of opium and its derivatives. In the 19th and early 20th centuries, medical advances like the development of morphine and the adoption of the hypodermic syringe made a powerful reliever of pain readily available to the masses. The addictive qualities and negative effects of opium and morphine use were not fully appreciated until it was too late for too many.

It is unfortunate that we find ourselves today in a predicament with such a clear precedent, but it is not too late to learn from the experience. There was no simple solution to that public health crisis and there will be no simple solution today. Then, the transition away from dependence on opiates was enabled in part by developing ways to resolve underlying diseases, such as by improving sanitation. It was enabled in part by embracing alternative treatments for pain, such as the adoption of aspirin as an analgesic beginning in 1899. It was enabled in part by improving pharmaceutical controls and restricting the importation of opium and its derivatives. Finally, there was a significant shift in medical practice to appreciate that in many, though not all, cases the dangers associated with this line of treatment outweighed the benefits.

Then and now, the correlation between an increased availability of opioids and negative societal repercussions such as substance use disorder and overdose cannot be ignored. Opium became the most commonly dispensed medical item by 1834. From that time until the tide was finally turned in the late 1890s, the number of individuals struggling with opiate-related substance misuse would grow six-fold.[1] Fast forward to the 21st century and opioids are once again among the most popularly prescribed class of medications.[2] From 1999 to 2016, opioid-related overdoses quintupled.[3] When we look at this issue in the present day by region, the trends are even clearer. High prescribing and high overdose rates have gone hand-in-hand in Appalachia, while significantly lower prescribing rates and significantly lower overdose rates have been the norm in places like Texas and the upper Midwest.[4]

Another useful point of comparison is opioid consumption internationally. Data compiled from the United Nations International Narcotics Control Board shows that from 2012–2014 the United States, after adjusting for population size, still utilized eight times as many opioids as Italy, six times as many opioids as France, four times as many opioids as Great Britain, and over one and one half times as many opioids as Canada.[5] This is despite having a population with an average age lower than each of those nations.[6]

This is not to say we have not made some significant progress in recent years. Since 2011, the total volume of opioid analgesics dispensed has fallen by 29 percent.[7] Increased awareness both throughout the medical profession and the public as a whole, coupled with developments such as the endorsement of guidelines for prescribing opioids for chronic pain by the Centers for Disease Control and Prevention,[8] have had a profound impact. The adoption of prescription drug monitoring programs, such as the one recently implemented by the Commonwealth of Pennsyl-

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[1] David T. Courtwright, *Dark Paradise: A History of Opiate Addiction in America,* Harvard University Press, 1982, *http://www.hup.harvard.edu/catalog.php?isbn=9780674005853&content=reviews.*

[2] Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., "Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies," *The New England Journal of Medicine,* March 31, 2016, *https://www.nejm.org/doi/full/10.1056/NEJMra1507771.*

[3] "Opioid Overdose," Centers for Disease Control and Prevention, accessed May 24, 2018, *https://www.cdc.gov/drugoverdose/index.html.*

[4] Grant Baldwin, Ph.D., MPH, "Overview of the Public Health Burden of Prescription Drug and Heroin Overdoses," Centers for Disease Control and Prevention, July 1, 2015, *https://www.fda.gov/downloads/drugs/newsevents/ucm454826.pdf.*

[5] Dr. Keith Humphreys, "Americans use far more opioids than anyone else in the world," *The Washington Post,* March 15, 2017, *https://www.washingtonpost.com/news/wonk/wp/2017/03/15/americans-use-far-more-opioids-than-anyone-else-in-the-world/?utm_term=.ee4e2a669229.*

[6] The World Factbook: Median Age, Central Intelligence Agency, accessed May 24, 2018 *https://www.cia.gov/library/publications/the-world-factbook/fields/2177.html.*

[7] "Medicine Use and Spending in the U.S.: A review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science, April 19, 2018, *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.*

[8] "CDC Guideline for Prescribing Opioids for Chronic Pain," Centers for Disease Control and Prevention, accessed May 24, 2018, *https://www.cdc.gov/drugoverdose/prescribing/guideline.html.*

vania,[9] have given health care providers a powerful new tool to help inform the best course of treatment.

Despite this progress, the amount of opioids being dispensed today is still roughly five times the level we saw in 1992. In 2016, there were still 215 million opioid prescriptions written across the country.[10] In our Commonwealth of Pennsylvania, there were still counties with more prescriptions than people, such as Fayette (129 prescriptions per 100 people), Lackawanna (112 per 100), and Mercer (109 per 100).[11] Let me reiterate, that is more than one opioid prescription for every man, woman, and child within those counties.

The question we are going to explore today is what are our Nation's largest payers of health care—Medicare and Medicaid—doing to prevent opioid overutilization and misuse.

With the implementation of the Medicare prescription drug benefit in 2006, commonly referred to as Medicare Part D, the Federal Government became the single largest purchaser of opioid analgesics.[12] Studies suggest that while Medicaid does not spend as much money on opioids as its Federal counterpart for the aged and disabled, Medicaid beneficiaries receive average annual doses twice as high as those who are privately insured.[13] Furthermore, Medicaid beneficiaries are much more likely than the general population to be diagnosed with substance use disorder[14] or suffer an overdose.[15]

The approaches of the Medicare and Medicaid programs to prevent opioid overutilization and misuse have been, appropriately, multi-faceted. Some examples include:

- Congress worked with the previous administration[16] to decouple questions related to pain management in patient surveys from Medicare hospital reimbursement,[17] a system that created a harmful financial incentive to prescribe more opioids;[18]
- The Centers for Medicare and Medicaid Services (CMS), plan sponsors, States, health systems, medical professional societies, and other stakeholders have undergone a noteworthy campaign of prescriber education;
- CMS is implementing a 7-day initial fill limit for opioid-naïve patients in the Medicare program starting in 2019;
- Medicare, State Medicaid programs, and plan sponsors have utilized drug management programs that incorporate tools like prior authorization, point-of-sale edits, and patient review and restriction (often referred to as "lock-in") programs to encourage more appropriate prescribing; and

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[9] David Wenner, "'Doctor shopping' for opioids declines in Pa.; new monitoring program gets credit," *Harrisburg Patriot News,* April 26, 2017, *http://www.pennlive.com/news/2017/04/doctor_shopping_for_opioids_sh.html.*

[10] "U.S. Prescribing Rate Maps," Centers for Disease Control and Prevention, accessed May 24, 2018, *https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.*

[11] "U.S. County Prescribing Rates, 2016," Centers for Disease Control and Prevention, accessed May 24, 2018, *https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html.*

[12] C. Zhou, C.S. Florence, and D. Dowell, "Payments for Opioids Shifted Substantially to Public and Private Insurers While Consumer Spending Declined, 1999–2012," *Health Affairs* (Project Hope), May 2016, *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1103.*

[13] M.J. Edlund, B.C. Martin, M.-Y. Fan, J.B. Braden, A. Devries, and M.D. Sullivan, "An Analysis of Heavy Utilizers of Opioids for Chronic Non-Cancer Pain in the TROUP Study," *Journal of Pain and Symptom Management,* 2010, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2921474/.*

[14] "Medicaid and the Opioid Epidemic," Medicaid and CHIP Payment and Access Commission, June 2017, *https://www.macpac.gov/wp-content/uploads/2017/06/Medicaid-and-the-Opioid-Epidemic.pdf.*

[15] Mark J. Sharp, Ph.D., Thomas A. Melnik, DrPH, "Poisoning Deaths Involving Opioid Analgesics," Morbidity and Mortality Weekly Report, April 17, 2015, *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6414a2.htm.*

[16] Tracie Mauriello, "Toomey backs change in ACA that ties reimbursements to patient satisfaction," *Pittsburgh Post-Gazette,* April 21, 2016, *http://www.post-gazette.com/news/politics-nation/2016/04/21/Toomey-backs-change-in-ACA-that-ties-reimbursements-to-patient-satisfaction/stories/201604210119.*

[17] "CMS Finalizes Hospital Outpatient Prospective Payment System Changes to Better Support Hospitals and Physicians and Improve Patient Care," Centers for Medicare and Medicaid Services, November 1, 2016, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-11-01.html.*

[18] Sean Gregory, "How Obamacare Is Fueling America's Opioid Epidemic," *Time,* April 13, 2016, *http://time.com/4292290/how-obamacare-is-fueling-americas-opioid-epidemic/.*

- Law enforcement has aggressively worked to crack down on those working to defraud the Medicare and Medicaid programs for monetary gain.

Today we will hear from witnesses who should give us insight into the effectiveness of these efforts and how we may improve them. Joining us are Dr. Mary Denigan-Macauley, Acting Director of Health Care at the United States Government Accountability Office (GAO); Ms. Maureen Dixon, Special Agent in Charge at the Philadelphia Regional Office of the Office of the Inspector General for the United States Department of Health and Human Services (HHS–OIG); Dr. Richard Snyder, senior vice president and chief medical officer of Independence Blue Cross; Ms. Heather Malone, a constituent in recovery; and Mr. Matthew Weintraub, District Attorney for Bucks County.

Some of the specific questions that will be explored:

- **Do these efforts focus on a large enough portion of the total beneficiaries who are at risk of harm?** When CMS adopted an opioid overutilization policy to reduce the inappropriate use of opioids in 2013, it established the Overutilization Monitoring System (OMS) to monitor plan sponsor compliance and provide quarterly reports on high-risk beneficiaries. The Government Accountability Office (GAO) last year found the OMS only includes a small subset of the population that is at-risk according to CDC guidelines (individuals receiving a daily dose at or above 90 milligrams morphine equivalent dose).[19] Furthermore, recent research by the University of Pittsburgh showed that even beneficiaries that have suffered a nonfatal opioid-related overdose often continue to receive legal opioid prescriptions following this life-threatening event.[20] Currently, our Medicare and Medicaid systems do not alert health-care providers or plans to this potentially dangerous situation.
- **Are we doing enough to ensure that when potential fraud is identified appropriate action is taken?** Both the GAO and the HHS OIG have recommended improving communication between CMS, its contractors, and insurance plans on when potential fraud has been identified and what corrective action has been taken.
- **Are we doing enough to equip providers with the information they need?** The adoption of electronic prescribing for controlled substances, which would provide real time information and reduce fraud associated with forgeries, has been slow. Additionally, Congress is considering adopting legislation that would require CMS to alert providers when their opioid prescribing patterns differ significantly from their peers.
- **Are the efforts currently underway in the Medicare and Medicaid programs having any noticeable impact on the local level?** Despite a discernable drop in the amount of opioid prescriptions being written, initiatives like the highly successful Bucks County Medication Takeback Program are still seeing record amounts of unused medications taken in.[21]

I thank you all for being here today. I look forward to the discussion, and remain confident that by working together at the Federal, State, and local levels, we can continue to make substantial progress in our efforts to prevent and overcome opioid and substance misuse.

PREPARED STATEMENT OF MATTHEW WEINTRAUB,
DISTRICT ATTORNEY, BUCKS COUNTY

Good afternoon, and thank you, Senator Toomey, for the opportunity to provide testimony to this committee. As Bucks County District Attorney, I will try to focus my remarks on the challenges of the opioid epidemic as I see them, with a specific focus on why prevention is so important.

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[19] GAO–18–15, "Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm," Government Accountability Office, October 6, 2017, *https://www.gao.gov/products/GAO-18-15.*

[20] W. Frazier, G. Cochran, W. Lo-Ciganic, et al., "Medication-Assisted Treatment and Opioid Use Before and After Overdose in Pennsylvania Medicaid," *JAMA,* 2017;318(8):750–752. doi:10.1001/jama.2017.7818, *https://jamanetwork.com/journals/jama/fullarticle/2649173.*

[21] Christian Menno, "Record amounts collected at drug take-back events in Bucks, Montgomery Counties," *Bucks County Intelligencer,* November 2, 2017, *http://www.theintell.com/news/20171102/record-amounts-collected-at-drug-take-back-events-in-bucks-montgomery-counties/1.*

Bucks County is particularly challenged in its battle against the opioid epidemic due to our proximity to Philadelphia (Kensington specifically), Allentown, and Trenton which makes it easy for those suffering from addiction to obtain drugs. We strive to prevent heroin and other drugs from infiltrating our county, but they are easy to obtain with a short drive. That is why a regional or national response is vital. No one county or entity within the county can do it alone. We in Bucks County do work well as a team across systems such as law enforcement and health and human services, but we do need more help. The following is a great example of a case where cross-county collaboration thwarted a pill-dealing drug ring. In 2018, members of the Bucks County Drug Strike Force conducted an investigation in which ten people were arrested in Berks County for making and passing fraudulent prescriptions. Over 106 fraudulent prescriptions were filled in the Bucks County/Philadelphia area which resulted in these individuals obtaining 12,500 Oxycodone pills. These pills were then distributed on the street in Bucks County and Philadelphia.

Victims of this epidemic not only include the users themselves, but the emotional, and often criminal, toll taken on family and loved ones. Additionally, in 2017 we had 217 babies born diagnosed with Neonatal Abstinence Syndrome (NAS). These innocent newborns are a startling reminder that the opioid epidemic does not only affect those who are addicted.

Our medication take-back program demonstrates the overprescribing problem we face as illustrated by the amount of unneeded medication in our community. In a good news, bad news scenario, we are the number one county in the State in medication take-back, having collected over 100,000 pounds of unused, old, or expired medication since this program's inception. That is a lot of medication that can no longer be diverted to hurt or kill someone ever again. But, that is a lot of unnecessary medication, period. Medicare and Medicaid are two of the largest payers for prescription opioids and therefore hold a critical role in making sure we reduce the amount of excess opioids in circulation in the first place.

Congress has recently dedicated an unprecedented $4.6 billion to combat the opioid crisis in fiscal year 2018, and it is important to make sure that funding reaches the places where it is needed most through the programs that will be most effective. Such programs that could benefit from such funding in Bucks County include drug recovery programs in jails that can educate and successfully begin to treat our inmates so that they never return. Another innovative program we are looking to expand is the Bucks Police Aiding in Recovery, modeled off of a similar effort by the Bensalem Police Department, which helps increase treatment access to those who seek it voluntarily.

While Medicaid and Medicare may have responded slowly to implement controls aimed at curbing overutilization of opioids in the first place, the Behavioral Health (drug/alcohol treatment) Medicaid providers have been strong partners in providing treatment supports. Unfortunately, part of the challenge we face is that no one wants these providers to open up facilities or increase services in their community. We must combat this community stigma against those with substance use disorders, and we need our elected officials to be leaders in this effort.

Those in recovery cannot be looked at as needing only treatment supports. Physical health, housing, nutrition, employment and other social determinants of health need to be addressed to help people in recovery. That is another part of the challenge that all single county authorities must strive to address. Finally, we have spent so much time focused on heroin, that we have turned our attention away from other substances. Our current concern is a "twin epidemic" which pairs stimulants (*i.e.,* methamphetamine) and opiates (*i.e.,* oxy or heroin). We are now finding that many opioid abusers are also abusing meth in order to ease their painful physical withdrawal symptoms experienced as they seek their next opioid fix. We must also continue to focus on underage drinking and marijuana use which continue to be issues for our communities.

Thank you for the opportunity to address the committee today to talk about the challenges of the opioid epidemic as I see them, with a specific focus on why prevention is so important in this battle against the opioid epidemic.

