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EXAMINING THE POLICIES AND PRIORITIES OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEARING

BEFORE THE

COMMITTEE ON EDUCATION AND THE WORKFORCE U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

HEARING HELD IN WASHINGTON, DC, MARCH 15, 2016

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EXAMINING THE POLICIES AND PRIORITIES OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Tuesday, March 15, 2016
U.S. House of Representatives
Committee on Education and the Workforce
Washington, D.C.

The Committee met, pursuant to call, at 10:00 a.m., in room 2176 Rayburn House Office Building. Hon. John Kline [chairman of the committee] presiding.

Present: Representatives Kline, Foxx, Roe, Thompson, Salmon, Rokita, Barletta, Messer, Byrne, Carter, Bishop, Russell, Curbelo, Stefanik, Allen, Scott, Hinojosa, Davis, Courtney, Fudge, Polis, Sablan, Wilson, Bonamici, Pocan, Takano, Jeffries, Clark, Adams, and DeSaulnier.

Staff Present: Andrew Banducci, Workforce Policy Counsel; Janelle Belland, Coalitions and Members Services Coordinator; Kathlyn Ehl, Professional Staff Member; Ed Gilroy, Director of Workforce Policy; Callie Harman, Legislative Assistant; Christie Herman, Professional Staff Member; Tyler Hernandez, Press Secretary; Amy Raaf Jones, Director of Education and Human Resources Policy; Nancy Locke, Chief Clerk; Michelle Neblett, Professional Staff Member; Brian Newell, Communications Director; Krisann Pearce, General Counsel; Alexandra Pena, Staff Assistant; Lauren Reddington, Deputy Press Secretary; Alissa Strawcutter, Deputy Clerk; Juliane Sullivan, Staff Director; Leslie Tatum, Professional Staff Member; Olivia Voslow, Staff Assistant; Tylease Alli, Minority Clerk/Intern and Fellow Coordinator; Pierce Blue, Minority Labor Detailee; Jacque Chevalier, Minority Senior Education Policy Advisor; Denise Forte, Minority Staff Director; Christine Godinez, Minority Staff Assistant; Carolyn Hughes, Minority Senior Labor Policy Advisor; Eunice Ikene, Minority Labor Policy Associate; Brian Kennedy, Minority General Counsel; Richard Miller, Minority Senior Labor Policy Advisor; Alexander Payne, Minority Education Policy Advisor; Veronique Pluviose, Minority Civil Rights Counsel; and Marni von Wilpert, Minority Labor Detailee.

Chairman KLINE. A quorum being present, the Committee on Education and the Workforce will come to order. Good morning, everyone, and welcome, Secretary Burwell. We appreciate you joining us to discuss the policies and priorities of the Department of Health and Human Services.

From welfare and health care to early childhood development and support services for older Americans, the policies your department oversees affect the lives of millions of Americans.

Conversations like this one are vitally important as we work to ensure that the Department is acting in the best interest of the taxpayers and those in need.

As we examine what programs and policies are working and which ones are in need of improvement, I hope there are a number of areas where we can find common ground.

Of course, there are also areas where we will ultimately agree to disagree, and perhaps the most prominent example is the President's health care law. As has been the case for nearly six years, this flawed law continues to hurt working families, students, and small businesses. It is still depressing hours and wages for low-income workers, still making it harder for individuals to receive the care they need, and still driving up health care costs.

One Emory University professor recently wrote that his family's health insurance premium is now their biggest expense, even greater than their mortgage. Before the health care law went into effect, this man was able to cover his entire family of four for less than $13,000. Now, the cost of insuring just him and his wife is nearly $28,000. Twice the cost to cover half as many people. In fact, paying more for less is becoming a hallmark of the health care law.

Over the years, Republicans have put forward a number of health care reform ideas, ones that would expand access to affordable care and lead to a more patient-centered health care system. We will continue to do so, because we firmly believe the President's health care law is fatally flawed and unsustainable, and more importantly, because we believe the American people deserve better.

Again, I suspect we will have to agree to disagree, but as I mentioned, there are areas where I am hopeful we can find common ground.

Head Start, for example, currently supports nearly 1 million children at a cost of more than $9 billion annually. It is an important program for many low-income families. However, concerns persist that it is not providing children with long-term results.

We both agree, I am sure, changes need to be made, but so far we have different ideas of what reform should look like. The Department is in the process of fundamentally transforming Head Start through regulations that will have serious consequences for the vulnerable families this important program serves.

We, on the other hand, have outlined a number of key principles that we believe will strengthen the program based on feedback we collected from parents and providers.

I look forward to discussing where we might be able to find middle ground and work together so that these children can have the solid foundation they need to succeed in school and in life.

I am also hopeful that we can work together to ensure changes to the Preschool Development Grants program are implemented as Congress intended. The *Every Student Succeeds Act* reformed the program to help States streamline and strengthen early learning efforts.

To accomplish this goal, Congress moved the program from the Department of Education to HHS, which already oversees the bulk of early learning programs. As you take on this responsibility, Madam Secretary, please know we intend to stay engaged with the Department to ensure a successful transition.

Finally, the Department is also responsible for helping States to prevent and respond to child abuse and neglect, specifically those outlined in the *Child Abuse Prevention and Treatment Act* or CAPTA. As I am sure you are aware, this law provides States with resources to improve their child protective service systems, if they make a number of assurances concerning their child welfare policies.

It has come to our attention that some States are making these assurances without putting the necessary policies in place. Yet, not a single State is being denied Federal funds.

A Reuters' investigation recently revealed the shocking and deadly consequences of this neglect and cast serious doubts as to whether basic requirements of the law are being met and enforced.

In light of this tragic report, we wrote to you to better understand the Department's process in reviewing and approving State plans under CAPTA, and I would like to continue that discussion here today.

It is clear that the current system is failing some of our country's most vulnerable children and families, and something has to change.

As you can see, we have quite a bit to cover today. These and other issues are vitally important to the men and women we serve, and we have a responsibility to ensure that we are serving those individuals in the best way possible.

With that, I will now recognize the ranking member, Mr. Scott, for his opening remarks.

[The information follows:]

Prepared Statement of Hon. John Kline, Chairman, Committee on Education and the Workforce

From welfare and health care to early childhood development and support services for older Americans, the policies the Department of Health and Human Services oversees affect the lives of millions of Americans. Conversations like this one are vitally important as we work to ensure the department is acting in the best interests of taxpayers and those in need. As we examine what programs and policies are working, and which ones are in need of improvement, I hope there are a number of areas where we can find common ground.

Of course, there are also areas where we will ultimately agree to disagree, and perhaps the most prominent example is the president's health care law. As has been the case for nearly six years, this flawed law continues to hurt working families, students, and small businesses. It's still depressing hours and wages for low-income workers, still making it harder for individuals to receive the care they need, and still driving up health care costs.

One Emory University professor recently wrote that his family's health-insurance premium is now their biggest expense – even greater than their mortgage. Before the health care law went into effect, this man was able to cover his entire family of four for less than $13,000. Now, the cost of insuring just him and his wife is nearly $28,000. That's right – twice the cost to cover half as many people. In fact, paying more for less is becoming a hallmark of the health care law.

Over the years, Republicans have put forward a number of health care reform ideas, ones that would expand access to affordable care and lead to a more patient-centered health care system. We will continue to do so, because we firmly believe the president's health care law is fatally flawed and unsustainable, and more importantly, because we believe the American people deserve better.

Again, I suspect we will have to agree to disagree, but as I mentioned, there are areas where I am hopeful we can find common ground.

Head Start, for example, currently supports nearly one million children at a cost of more than $9 billion annually. It's an important program for many low-income families. However, concerns persist that it's not providing children with long-term results.

We both agree changes need to be made, but so far, we have different ideas on what reform should look like. The department is in the process of fundamentally transforming Head Start through regulations that will have serious consequences for the vulnerable families this important program serves. We, on the other hand, have outlined a number of key principles that we believe will strengthen the program based on feedback we collected from parents and providers. I look forward to discussing where we might be able to find middle ground and work together so that these children can have the solid foundation they need to succeed in school and in life.

I'm also hopeful that we can work together to ensure changes to the Preschool Development Grants Program are implemented as Congress intended. The Every Student Succeeds Act reformed the program to help states streamline and strengthen early learning efforts. To accomplish this goal, Congress moved the program from the Department of Education to HHS, which already oversees the bulk of early learning programs. As you take on this responsibility, Secretary Burwell, please know we intend to stay engaged with the department to ensure a successful transition.

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A Reuters' investigation recently revealed the shocking and deadly consequences of this neglect and cast serious doubts as to whether basic requirements of the law are being met and enforced. In light of this tragic report, we wrote to you to better understand the department's process in reviewing and approving state plans under CAPTA, and I'd like to continue that discussion today. It's clear that the current system is failing some of our country's most vulnerable children and families, and something has to change.

As you can see, we have quite a bit to cover today. These and other issues are vitally important to the men and women we serve, and we have a responsibility to ensure they are serving those individuals in the best way possible.

Mr. SCOTT. Thank you, Chairman Kline, and welcome, Secretary BURWELL. Thank you for being with us. We look forward to your testimony.

Today, we will hear about the President's Fiscal Year 2017 Health and Human Services' budget proposal and the Department's policy priorities. Once again, I commend the Secretary for her work to ensure that the budget reflects the priorities of this committee, protecting access to health care for all Americans, giving all children the chance to succeed, and making sure that we meet the needs of families and children affected by public health threats when they occur.

In many areas, I believe we have made great progress on these priorities. In the not so distant past, many families were left without affordable health care options and many more could not have access to basic consumer protections in their insurance.

Double digit increases in prices were routine every year. Women routinely charged more for insurance than men. If you lost you lost your job and wanted to start a new business and you had a preexisting condition, you were essentially out of luck. If you were a senior and fell into the Part D doughnut hole, you did not get any

help, and when we consider the *Affordable Care Act*, thousands of people every day were losing their insurance.

Passage of the *Affordable Care Act* has given millions of Americans access to health care coverage, many for the first time in their lives. The ACA has helped slow the growth in health care costs, it is closing the doughnut hole for seniors, and has encouraged and improved access to mental health services and preventive care. Instead of thousands losing their insurance, millions more have gained insurance.

So, I thank Secretary Burwell for her efforts and her Department's hard work in implementing the *Affordable Care Act*. I recognize the challenge your department faces in implementing this law with limited resources and unlimited attacks.

Despite these challenges, the ACA has expanded coverage to millions and given millions more robust consumer protections in their health coverage. The ACA has provided a historic foundation for which we are going to accomplish our ultimate goal, making sure that all Americans have the opportunity to succeed.

I do not believe that we have reached the finish line yet, but I look forward to working with the Department and my congressional colleagues to make meaningful improvements as we strengthen the law.

I also pleased that the President's budget has placed a priority on giving all children a chance to succeed by ensuring robust funding to increase both access to and quality of early learning and child care programs. We must invest in high quality early learning programs because all children deserve to enter kindergarten with the building blocks to success.

Decades of research have shown that properly nurturing children in the first five years of life is essential to supporting enhanced brain development, cognitive functioning, and emotional and physical health.

All too often, low-income working families lack access to high quality affordable child care in their early childhood education, and these children tend to fall behind. Beyond the achievement gap, children that do not participate in high quality early learning programs are more likely to have weaker educational outcomes, lower earnings, increased involvement in the criminal justice system, and affordable high quality child care is, therefore, not just critical for children, it is also critical for working parents.

Child care is a two generation program. Parents of young children need child care to work and go to school, and lack of stable child care is associated with job interruptions and job loss for working parents. Child care ought to be a national priority for America's children and working families.

Just two programs survived the bulk of the Federal role in early education, the Head Start program and the Child Care and Development Block Grant. Unfortunately, because of limited Federal funding, too few children have appropriate access. This unmet need continues to grow. Only four of 10 eligible children have access to a Head Start program, and fewer than one out of six eligible children receive Federal child care assistance.

We have decades of evidence that investing in programs like Head Start and the Child Care and Development Block Grant

works. This is the time to invest in these programs and ensure that we are giving all children the chance to succeed.

I also want to commend the Secretary and her department for their efforts in response to some of the most troubling health crises of our time, the Ebola outbreak, Zika and opioid crisis. The Department has been in the forefront of responding and keeping Americans safe and healthy, particularly when you talk about budgeting, some do not always see the value of investing in prevention or readiness activities so that we are equipped to deal with a public health crisis.

Like many Federal programs, in fact, like health care insurance itself, you often do not miss it until it is gone. It is important now more than ever that we invest in our Nation's current and future health and well-being. The President's proposal does this with the Cancer Moonshot and other long-term investments.

Lastly, I would like to thank the Department and the Secretary for their efforts to respond to the catastrophic situation in Flint, Michigan. The research is clear on the impact of exposure to lead on young children, the adverse effects of lead exposure range from decreased academic attainment to increased needs for special education, and a higher likelihood of behavioral challenges. These impacts can result in a significant decline in earnings, loss of tax revenue, additional burdens to the criminal justice system, and increased stress on our hospital systems.

The opportunity for a strong start to a successful life will be stunted for Flint's children if they are not given the necessary resources, including early intervention and access to high quality early learning programs, such as Head Start, to help them overcome the lifelong effects of exposure to lead.

We need to come up with the money to make that possible, and make no mistake, we should not expect to fix this crisis easy or on the cheap. In fact, it will cost approximately $1.2 billion to provide long-term comprehensive services to all Flint children exposed to lead just in the areas that cover programs under this committee's jurisdiction.

Furthermore, it is imperative that this committee and the Department continue to examine how Federal programs can be responsive and ensure that every Flint youth is receiving the necessary services to mitigate the effects of lead exposure.

The Department's response so far has been commendable. Additional funding for health centers in Flint, Medicaid expansion to provide vital health coverage and important health screenings, $3.6 million onetime emergency funding to help Head Start grantees expand early childhood education, health care and nutritional services.

These are examples of targeted Federal solutions, but this committee and this Congress has to do more. The impact of lead exposure on young children is long-lasting, and a response must have a long-term approach.

We must use all of the tools available to us, starting with prenatal care and screenings of pregnant moms, early literacy resources, early interventions to identify special education needs, Title I and Title II funding from the *Elementary and Secondary*

Education Act, after school programs, at-risk youth prevention programs, even investments in college access efforts.

I know with all the Department's leadership, we can continue to respond to this crisis, and I am hopeful that together we can put forward real solutions and help mitigate the damage from the water crisis in Flint, and make sure young children there get back on track to a prosperous fulfilling life.

So, thank you, Mr. Chairman, and thank you, Secretary Burwell. I look forward to your testimony.

[The information follows:]

Prepared Statement of Hon. Robert C. "Bobby" Scott, Ranking Member, Committee on Education and the Workforce

Thank you Chairman Kline, and welcome Secretary Burwell. Thank you, Secretary, for being with us and I look forward to your testimony.

Today, we will hear about the President's Fiscal Year 2017 Health and Human Services Budget proposal and the Department's policy priorities. Once again, I commend the Secretary for her work to ensure that the budget reflects the priorities of this Committee – protecting access to healthcare for all Americans, giving all children a chance to succeed, and making sure that we meet the needs of families and children affected by public health threats when they occur.

In many areas, I believe we have made great progress in these priorities. In the not so distant past, too many families were left without affordable health care options and many more did not have access to basic consumer protections in their insurance. Women were routinely charged more for insurance than men. If you lost your job or wanted to start a new business and you had a preexisting condition, you were out of luck. If you were a senior and fell into the Part D donut hole, you didn't get any help.

The passage of the Affordable Care Act has given millions of Americans access to health coverage, many for the first time in their lives. The ACA has helped slow the growth in health care costs, is closing the donut hole for seniors, and has encouraged and improved access to mental health services and preventive care.

I thank Secretary Burwell for her efforts and her Department's hard work implementing the Affordable Care Act. As I've said before, I recognize the challenge your Department faces in implementing this law with limited resources and unlimited attacks. Despite these challenges, the ACA has

expanded health coverage to millions and given millions more robust consumer protections in their health coverage. The ACA has provided a historic foundation on which we can work to accomplish our ultimate goal – making sure all Americans have the opportunity to succeed. I do not believe that we have yet reached the finish line and I look forward to working with the Department and my Congressional colleagues to make meaningful improvements to strengthen the law.

I was also pleased that the President's budget request placed priority on giving all children a chance to succeed by ensuring robust funding to increase both access to and the quality of early learning and child care programs. We must invest in high-quality early learning programs because all children deserve to enter kindergarten with the building blocks to success.

Decades of research has shown that properly nurturing children in the first five years of life is instrumental to supporting enhanced brain development, cognitive functioning, and emotional and physical health. But all too often, low-income working families lack access to high-quality, affordable child care

and early childhood education, and these children tend to fall behind. Beyond the achievement gap, children who don't participate in high-quality early education programs are more likely to have weaker educational outcomes, lower earnings, and increased involvement in the criminal justice system. Affordable, high-quality child care is not just critical for children, it is also critical for working parents. Child care is a two-generation program. Parents of young children need child care to work or go to school. And a lack of stable child care is associated with job interruptions and job loss for working parents. Child care ought to be a national priority for America's children and working families.

Just two programs provide for the bulk of the federal role in early education: the Head Start Program and the Child Care and Development Block Grant. Unfortunately, because of limited federal funding, too few young children have access. This unmet need continues to grow – only 4 out of 10 eligible children have access to Head Start, and fewer than 1 out of 6 federally-eligible children receive federal child

care assistance. We have decades of evidence that investing in programs like Head Start and the Child Care and

Development Block Grant works. It is time to invest in these programs and ensure that we are giving ALL children the chance to succeed.

I want also to commend Secretary Burwell and her Department on their efforts to respond to some of the most troubling health crises of our time. From the Ebola outbreak to Zika to the opioid crisis, the Department of Health and Human Services has been at the forefront of responding and keeping Americans safe and healthy. Particularly when you talk about budgeting, some do not always see the value of investing in prevention or readiness activities so that we are equipped to deal with a public health crisis. But like many federal programs and in fact like health care insurance itself, you often don't miss it until it's gone. So it's important, now more than ever, that we invest in our nation's current and future health and well-being. The President's budget proposal does this with the "Cancer Moonshot" and other long-term investments.

Lastly, I sincerely thank the Department's for their efforts to respond to the

catastrophic situation in Flint. The research is clear on the impact of exposure

to lead on young children. The adverse effects of lead exposure range from decreased academic attainment to increased need for special education and a higher likelihood of behavioral challenges. These impacts can result in a significant decline in earnings, loss of tax revenues, additional burdens to the criminal justice system, and increased stress on our hospital systems.

The opportunity for a strong start to a successful life will be stunted for Flint's children if they are not given the necessary resources, including early-intervention and access to high-quality early learning programs, such as Head Start, to help them overcome the life-long effects of exposure to lead.

We need to come up with the money to make that possible. Make no mistake – we should not expect the fix to this crisis to be easy or cheap. In fact, it will cost approximately $1.2 billion to provide long-term, comprehensive services to all Flint children exposed to lead. And that cost only covers the programs that fall under this Committee's jurisdiction. Furthermore, it is a moral imperative for this Committee and the Department to continue to examine

how federal programs can be responsive and ensure every Flint youth is receiving the necessary services to mitigate the effects of lead exposure.

The Department's response has been commendable – additional funding for health centers in Flint, Medicaid expansion that will provide vital health coverage and important health screenings, and $3.6 million in one-time emergency funding to help Head Start grantees expand early childhood education, health, and nutrition services. These are examples of targeted federal solutions. But this Committee and this Congress should do more.

The impact of lead exposure on young children is long lasting and our response must have a long-term approach. We must use all the tools available to us, starting with pre-natal care and screenings for pregnant moms, early literacy resources, early interventions to identify special education needs, Title I and II funding from ESEA, after-school programs, at-risk youth prevention programs, even investments in college access efforts. I know that with the Department's leadership, we can continue to respond to this crisis. I am hopeful that, together, we can put forward real solutions to help mitigate the

damage from the water crisis in Flint and make sure the young children there get back on track to a prosperous, fulfilling life.

Thank you and Secretary Burwell, I look forward to hearing from you today.

Chairman KLINE. I thank the gentleman. Pursuant to Committee Rule 7(c), all members will be permitted to submit written statements to be included in the permanent hearing record. Without objection, the hearing record will remain open for 14 days to allow such statements and other extraneous material referenced during the hearing to be submitted for the official hearing record.

It is now my pleasure to introduce our distinguished witness, welcome back to our new environs here. The Honorable Sylvia Mathews Burwell serves as Secretary of the U.S. Department of Health and Human Services. Prior to joining HHS, she served as director of the Office of Management and Budget under President Obama and in a whole bunch of other positions in the Clinton Administra-

tion. This will be the Secretary's second appearance before the Committee during her tenure at HHS.

Secretary Burwell, I will now ask you to please stand and raise your right hand.

[Witness sworn.]

Chairman KLINE. Let the record reflect she answered in the affirmative. Before I recognize you to provide your testimony, let me remind you of our lighting system. It is pretty straightforward. It is a green, yellow, red system. The lights are right in front of you. As in the past, I have no intention of ever dropping a gavel while you are speaking, but I would ask that you try not to go on too long so that members have a chance to engage in the discussion.

Members will each have five minutes to ask questions, and as my colleagues know, I am not quite as reluctant to drop the gavel if they are exceeding the five minutes, and, I would ask my colleagues, please do not talk for 4.5 minutes and then ask a question that will take her five minutes to respond to.

We do not have time for that today, because I would advise all of you that the Secretary has a hard stop time at noon. We are going to try to give everybody the five minutes, but we may have to curtail that time if we start running short. So, I would appreciate your cooperation.

Madam Secretary, you are recognized.

TESTIMONY OF THE HONORABLE SYLVIA MATHEWS BURWELL, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, D.C.

Secretary BURWELL. Chairman Kline, Ranking Member Scott, and members of the Committee, thank you for the opportunity to discuss the President's budget for the Department of Health and Human Services today.

As many of you know, I believe all of us share common interests and that we can find common ground. In recent legislative sessions, this committee took important steps to strengthen our workforce and open the doors to new early learning opportunities. Thank you for your leadership in passing the *Workforce Innovation and Opportunity Act* and the *Child Care and Development Block Grant Act of 2014*. We look forward to working with you on both of these in the year ahead.

The budget before you today is the final budget for this administration and my final budget as Secretary. It makes critical investments to protect the health and well-being of the American people. It helps ensure that we can do our job to keep people safe and healthy, accelerates our progress in scientific research and medical innovation, expands and strengthens our health care system, and helps us continue to be responsible stewards of the taxpayers' dollars.

For HHS, the budget proposal is $82.8 billion in discretionary budget authority. Our request recognizes the constraints in our budget environment and includes targeted reforms to Medicare, Medicaid, and other programs. Over the next 10 years, these reforms to Medicare would result in net savings of $419 billion.

Let me start with an issue we have been working on here at home and abroad, and as we work aggressively to combat the

spread of Zika. The administration is requesting $1.9 billion in emergency funding, including $1.5 billion for the Department of Health and Human Services. We appreciate Congress' consideration of this important request. This funding will help us implement the essential strategies to prevent, detect, and respond to this virus, with a focus on reducing the risks to pregnant woman.

I know the rise of opioid misuse, abuse, and overdose has affected many of your constituents. Every day in America, 78 people die of opioid related deaths, and that is why this budget proposes significant funding, over $1 billion, to combat the opioid epidemic.

Research shows that early learning programs, as the Chairman mentioned, can set a course for a child's success throughout their life. That is why over the course of this administration, together with congressional support, we have more than doubled access to early Head Start services for infants and toddlers.

Our budget proposes a total of $9.6 billion to the Head Start program and an investment in child care services that would allow us to serve over 2.6 million children. Beyond this budget, for the children in Flint, Michigan, we have already announced $3.6 million, as Mr. Scott mentioned, in one-time emergency for Head Start money.

With these funds, they can expand early childhood education, behavioral health services, and other vital nutrition services. Today, too many of our Nation's children and adults with diagnosable mental health disorders do not receive the treatment they need. So, this budget proposes $780 million in new mandatory and discretionary resources over the next two years to close that gap.

While we invest in the safety and health of Americans today, we must also relentlessly push forward on the frontiers of science and medicine. This budget invests in the Vice President's cancer initiative. Today, we are entering a new era in medical science. With proposed increases of $107 million for the precision medicine initiative and $45 million for the administration's BRAIN initiative; we can continue this progress.

In order for Americans to benefit from our recent breakthroughs in medical science, we need to ensure that all Americans have access to quality affordable health care. The *Affordable Care Act* has helped us make historic progress. Today, more than 90 percent of Americans have health coverage—the first time in our Nation's history that has been true.

The budget seeks to build on that progress by improving the quality of care that patients receive and spending dollars more wisely. It proposes investments to improve the access to care for underserved groups across the United States, including many in rural communities, with $5.1 billion in health center funding and nearly $14 billion over the next decade for our Nation's health care workforce.

By advancing and improving the way we pay doctors, coordinate care, and use health data and information, we build a better, smarter system.

Finally, I want to thank the employees of HHS. In the past year, they fought Ebola in West Africa, helped millions gain health coverage, and have done the quiet day-to-day work that makes our Nation healthier and stronger. I am honored to be a part of the

team, and as members of this committee know, I am personally committed to working closely with you and your staff to find common ground to deliver for the American people.

Thank you.

[The statement of Secretary Burwell follows:]

Statement by
Sylvia M. Burwell
Secretary
U.S. Department of Health and Human Services
on
The President's Fiscal Year 2017 Budget
before
Committee on Education and Workforce

U.S. House of Representatives
March 15, 2016

Chairman Kline, Ranking Member Scott, and Members of the Committee, thank you for the opportunity to discuss the President's FY 2017 Budget for the Department of Health and Human Services (HHS). In recent legislative sessions, this Committee took important steps to pass the Workforce Innovation and Opportunity Act, which strengthens our workforce, and the Child Care and Development Block Grant Act of 2014, which supports high quality early learning programs and builds on our early learning continuum. We thank you for your leadership on these important issues and look forward to working with you on implementation in the year ahead.

The Department has made historic strides towards ensuring that all Americans have access to the building blocks of healthy and productive lives—a priority that I know we share. Thanks to the Affordable Care Act, we have helped millions of Americans find quality, affordable insurance, and slowed the growth in health care costs for families and taxpayers. At the same time, we have worked to improve the quality of coverage—with more protections and benefits, like wellness visits and some cancer screenings now offered at no extra cost—no matter where you get your insurance. Alongside this work, we have responded to a number of national and global health challenges. In coordination with our partners across the federal government, we led a response to the Ebola outbreak in West Africa and prepared our infrastructure here at home, and have

helped to unite global health leaders to prevent and respond to future outbreaks. We continue these efforts to protect the public health in our work responding to the lead crisis in Flint, Michigan and implementing essential strategies to prevent, detect, and respond to the spread of Zika. We convened state leaders in our fight against prescription opioid misuse, abuse, and overdose as part of a nationwide three-pronged strategy to drive progress. And we advanced the frontier of medicine through cutting-edge research in genomics and technology. Through all these efforts, we have worked to ensure the responsible stewardship of taxpayer dollars by taking steps to further strengthen program integrity, saving money for the taxpayer and making sure our programs deliver in the best possible way for those we serve.

The President's FY 2017 Budget for HHS builds on this progress through critical investments in health care, science and innovation, and human services. The Budget proposes $82.8 billion in discretionary budget authority, and additional mandatory funding to further support specific initiatives in the discretionary budget. This includes investments in critical priorities that I know we share—cancer research, opioids abuse prevention and treatment, and behavioral health efforts. The Budget recognizes our continued commitment to balancing priorities within a constrained budget environment through legislative proposals that, taken together, would save on net an estimated $242 billion over 10 years.

Building upon the Successes of the Affordable Care Act

The FY 2017 Budget advances access, affordability, and quality in our nation's health care system—goals that we share with Congress and this Committee. Through targeted investments, the Budget expands access to care, particularly for rural and other underserved populations,

strengthens services for American Indians and Alaska Natives, and supports primary and preventive care.

Expanding Access to Health Insurance Coverage. The Affordable Care Act is expanding access to care for millions of Americans who would otherwise be uninsured, improving quality of care for people no matter how they get their insurance, while slowing the growth in healthcare costs nationwide. To encourage more states to expand Medicaid, the Budget would give any state that chooses to expand Medicaid eligibility three years of full federal support, no matter when the state expands. The Budget also funds the Children's Health Insurance Program through FY 2019 to ensure comprehensive and affordable coverage for beneficiaries as well as budget stability for states. We look forward to working with Congress to extend this program for the millions of children who depend upon it.

Investing in Health Centers. For 50 years, health centers have delivered comprehensive, high-quality, cost-effective primary health care to patients regardless of their ability to pay. Today, more than 1,300 health centers operate over 9,000 sites and provide health care services to 1 in 14 people in the United States, including to nearly 175,000 patients at 81 service delivery sites in Minnesota and 290,000 patients at 145 service delivery sites in Virginia. Health centers also play a role in reducing the use of costlier care through emergency departments and hospitals. The Budget invests $5.1 billion in health centers, including $3.75 billion in mandatory resources, to serve over 27 million patients across the country in FY 2017.

Bolstering the Nation's Health Care Workforce. The Budget includes investments of nearly $14 billion over ten years in our Nation's health care workforce to improve access to healthcare services, particularly in rural and other underserved communities. This includes support for over 10,150 National Health Service Corps clinicians serving the primary care, behavioral health and dental needs of more than 10.7 million patients in areas with limited access to care. The request includes additional funding to place providers in rural areas and other underserved communities in order to expand access to treatment for prescription opioid and heroin abuse and to improve access to crucial behavioral health services.

Strengthening Health Outcomes in Indian Country. The FY 2017 Budget continues the Administration's commitment to support and strengthen services in Indian Country. The Budget funds the Indian Health Service (IHS) at $6.6 billion, an increase of $402 million over FY 2016, to bolster programs that serve over 2 million American Indians and Alaska Natives at over 650 health care facilities across the United States. The Budget includes $67 million in new investments in the critical area of behavioral health to address high rates of mental illness, substance abuse, and suicide in tribal communities. The Budget also fully funds contract support costs, which provides critical overhead funding to tribes who operate facilities under self-determination and self-governance agreements.

Strengthening Health Programs in the Territories. The Budget removes the cap on funding to Medicaid programs in the U.S. territories to better align territory Medicaid programs with those of States and expands eligibility to 100 percent of the Federal poverty level in territories currently below this level. This proposal would gradually increase the share of Medicaid costs

covered by the federal government as territories modernize their Medicaid programs—providing critical healthcare funding to Puerto Rico and helping to mitigate the effects of its fiscal crisis.

Building Blocks for Success at Every Stage of Life

The Budget request supports the Department's efforts to serve Americans at every stage of life, including by promoting the safety and well-being of our nation's children, and helping older Americans live as independently as possible.

Investing in Child Care and Early Learning. Research has shown the significant positive impact that early learning programs can have on a child's development and lifelong well-being. The Budget proposes strategic investments to make affordable, quality child care available to every low- and moderate-income family with young children; to build on investments to expand access to high quality early learning programs including both Head Start and the newly authorized Preschool Development Grant program; and to invest in voluntary, evidence-based home visiting programs that have long-lasting, positive impacts on child development.

The Administration's investment in Head Start services has more than doubled access for infants and toddlers over the course of the Administration, and significant investments have been made to strengthen the quality of services that Head Start provides. The FY 2017 Budget provides a total of $9.6 billion for the Head Start program, which includes the resources necessary to maintain this expansion of services. In addition, the Budget builds on the investments made in FY 2016 to expand the number of children attending Head Start programs that offer a full school

day and year program, which is proven to be more effective than programs of shorter duration and helps meet the needs of working parents. In collaboration with the Department of Education, the Budget includes $350 million for Preschool Development Grants to support states in building and expanding high-quality preschool systems.

The President's Budget continues the historic proposal to provide $82 billion over 10 years in additional mandatory funds for child care to ensure that all low- and moderate-income working families with young children have access to high-quality child care. This proposal will increase the number of children served to a total of 2.6 million by 2026 and raise the quality of care children receive. In addition, the FY 2017 Budget includes almost $3.0 billion in discretionary child care funding, an increase of about $200 million, to support states, tribes, and territories as they implement the new health, safety, and quality requirements of the bipartisan child care reauthorization, and to create pilots that will test and evaluate strategies for addressing the child care needs of working families, including in rural areas and for families working non-traditional hours.

Preventing Child Trafficking. The President's Budget requests almost $44 million for efforts to prevent, identify, and treat child abuse and neglect, an increase of nearly $11 million from the FY 2016 enacted level. With these funds, ACF plans to provide $9.5 million in demonstration grants to help states and tribes implement the Preventing Sex Trafficking and Strengthening Families Act of 2014. This will help develop strategies to prevent, identify, and respond to child trafficking. In addition, grants will also be awarded for the development of comprehensive

services to children and youth who have already been trafficked and are in the care of the child welfare system.

Supporting Child Welfare. The Department plays a critical role in supporting child welfare, particularly among vulnerable populations. The Budget includes $1.8 billion over 10 years to ensure that child welfare professionals have the right training and skills—proven to be linked to better outcomes for children across a range of measures. The Budget also includes a package of investments designed to do more to prevent the need for foster care and assist children and families so that children can either be reunited with their biological parents or placed in a permanent home.

Modernizing the Approach for Addressing Poverty. Finally, the Budget seeks to strengthen the nation's safety net to meet our 21st century poverty challenges. A total of 15.5 million children lived in poverty in 2014, a staggering number that translates into lost opportunity, productivity, quality of life, and lifespan. Twenty years after creating the Temporary Assistance for Needy Families (TANF) program, funds are proposed to reform and strengthen this critical program that serves approximately 3 million children per month. The Budget increases funding for TANF to help offset some of the erosion to the block grant, while laying out the basic principles for reform—including moving towards a stronger accountability framework for states coupled with increased flexibility, ensuring better targeting of TANF funds, and creating a renewed focus on reducing child poverty. We look forward to working with lawmakers to strengthen the program's effectiveness in accomplishing its goals.

Supporting Older Adults. As members of this Committee are aware, the population age 65 and over is projected to more than double to 98 million in 2060. In FY 2017, HHS continues to make investments to address the needs of older Americans, many of whom require some level of assistance to live independently and remain in their homes and communities for as long as possible. The Budget continues to propose reforms that help to protect older Americans from identity theft, to support access to counseling, respite, and nutrition services that will allow states to provide approximately 205 million meals to over 2 million older Americans nationwide. The Budget also continues the Department's commitment to support effective Alzheimer's disease research, education, and outreach, as well as patient, family, and caregiver services.

Healthcare Delivery System Reform

At HHS, we are focused on moving towards a health care system that delivers better quality of care, spends dollars in a smarter way, and keeps people healthy. The Budget advances the Department's work in three critical areas: improving the way providers are paid, finding better ways to deliver care, and creating better access to health care information for providers and patients.

Improving the Way Providers Are Paid. Rather than paying for the quantity of tests and screenings that providers order—a common practice—the Department is moving toward paying for the quality of care given. For patients, this can lead to more frequent communication with their care provider and fewer unnecessary trips back to the hospital. The Budget includes proposals to establish competitive bidding for Medicare Advantage payments and introduce value-based purchasing for certain Medicare providers. The Budget also encourages

participation in alternative payment models through a number of proposals, including creating a bonus payment for hospitals that collaborate with certain alternative payment models. In January 2015, the Department set the goal of tying 30% of Medicare fee-for-service payments to alternative payment models by the end of 2016, and 50% by 2018. We announced earlier this month that we have met the first goal ahead of schedule: as of January 1, 2016, an estimated 30% of Medicare payments are tied to alternative payment models. We look forward to working with Congress to build on this progress.

Improving Care Delivery. To drive progress in the way care is provided, HHS is focused on improving the coordination and integration of health care, engaging patients more fully in decision-making, and improving the health of patients—with an emphasis on prevention and wellness. As part of that, we are focused on improving access to care by investing in and supporting telehealth, especially for rural areas. The Budget proposes to expand the ability of Medicare Advantage plans to deliver services via telehealth, and to enable rural health clinics and federally qualified health centers to qualify as originating telehealth sites under Medicare.

Improving Access to Information. In an effort to promote transparency on price, cost, and billing for consumers, the Budget supports the standardization of billing documents and elimination of surprise out-of-network charges for privately insured patients receiving care at an in-network facility. The Budget also provides continued investments to achieve secure, seamless data interoperability in order to better serve individuals, providers, and payers, including a funding increase and new authorities for the Office of the National Coordinator for Health Information Technology.

Building Evidence to Drive Systemic Improvement. Reforming the delivery system requires an evidence base of effective practices. The Budget proposes an increase of $24 million for health services research at the Agency for Healthcare Research and Quality (AHRQ) to advance and improve the performance of the healthcare system. For example, AHRQ data show that 87,000 fewer patients died in hospitals due to patient harms from 2010 to 2014—saving nearly $20 billion. While we are encouraged by this progress, substantial challenges remain to build a health system that meaningfully involves patients in decision making, and consistently uses high quality evidence to provide safe and high quality care for all.

Reducing the Cost of Prescription Drugs in Medicaid and Medicare. Nationally, prescription drug spending growth has accelerated to its highest rate since 2002 and is projected to drive overall healthcare cost growth. New therapies and cures change lives, but too many Americans struggle to afford the medications they need. The Department is focused on improving patient access to affordable prescription drugs, developing innovative purchasing strategies, and incorporating delivery system reform concepts like value- and outcome-based models into drug purchasing arrangements. The Budget includes a number of proposals, including Medicare Part D negotiation, aimed at improving access to necessary treatments and increasing the value that Americans are getting from their medications, while continuing to encourage important and lifesaving innovations.

Improving Healthcare for Dual Eligible Beneficiaries. As members of this Committee are aware, people enrolled in both Medicaid and Medicare have complex and often costly health care

needs. The Budget includes legislative proposals to improve access to care for dual-eligible beneficiaries, while decreasing overlap and inefficiencies that currently exist between the two payers.

Keeping People Healthy and Safe

The President's Budget builds on the Department's strategy to address prescription opioid and heroin misuse, abuse, and overdose; and invests in crucial behavioral health services, and strengthens our nation's public health infrastructure.

Preventing Prescription Opioid Abuse. Prescription drug abuse impacts the lives of millions of people across the country—with 78 Americans dying of opioid-related causes every single day. The Budget proposes significant new discretionary and mandatory funding totaling nearly $1.1 billion to build on investments funded by Congress in FY 2016 and to execute on the Department's three-pronged evidence-based approach to combat the opioids crisis:

- ***Expanding the Use of Medication-Assisted Treatment.*** The new two-year, $1 billion mandatory funding investment will help ensure that every American who wants to get treatment for an opioid use disorder will be able to. These funding levels will enable individuals with opioid use disorder to get treatment in FY 2017 and FY 2018 by reducing costs, engaging patients, and expanding access to treatment.
- ***Improving Prescribing Practices.*** The Budget invests in programs that support improved prescribing practices, including by supporting improved uptake of CDC's upcoming prescribing guidelines for providers. The Budget also proposes to require states to track

high prescribers and utilizers of prescription drugs in Medicaid—saving $770 million over 10 years—and bolsters other critical efforts to support providers with the tools they need.

- ***Expanding the Development and Use of Naloxone.*** To best prepare communities and first responders, the Budget includes a total of $22 million for programs that support the use of naloxone – a life-saving drug. Among other critical programs, the Budget invests in the Rural Opioid Overdose Reversal Grant program to target rural areas hit hardest by opioid abuse.

Expanding Access to Behavioral Health Care. Despite the expanded behavioral health coverage for millions of Americans by the Affordable Care Act, less than half of children and adults with diagnosable mental health disorders receive the treatment they need. To address this gap, the Budget proposes a total of $999 million, including a new two-year $500 million investment in behavioral health care, to help engage individuals with serious mental illness in care, improve access to care by increasing service and workforce capacity, and ensure that the behavioral health care system works for everyone. A portion of the two-year, $500 million mandatory initiative will allow six additional states to participate in the Certified Community Behavioral Health Clinic Demonstration.

Combating Antibiotics Resistant Bacteria. The emergence of antibiotic-resistant bacteria continues to be a significant public health concern. The FY 2017 Budget includes $877 million to continue expanding the nation's ability to protect patients and communities by implementing interventions that reduce the emergence and spread of antibiotic-resistant pathogens. This

funding will also support ongoing ground-breaking research to aid the development of new drugs and diagnostic products, building the nation's treatment options for these dangerous pathogens.

Investing in Domestic and International Preparedness. The Department leads critical efforts to strengthen our public health infrastructure here at home and bolster the nation's preparedness against chemical, biological, nuclear and radiological attacks. The Budget invests $915 million, an increase of $2 million, for domestic and international public health infrastructure, including funding to expand implementation of the Global Health Security Agenda (GHSA) to strengthen capacity in Phase 2 countries to address public health emergencies. Over the next five years, the United States will work with more than 30 partner countries—representing over four billion people—to help them prevent, detect, and effectively respond to infectious disease threats. I am pleased to share that work with many of these countries has already begun. We appreciate the funding provided by Congress last year for this crucial priority.

As we work aggressively to combat the spread of Zika, the Administration is requesting $1.9 billion in emergency funding, including $1.5 billion for HHS, to enhance our ongoing efforts both domestically and internationally. The requested resources will build on our ongoing preparedness efforts and will support essential strategies to combat this virus, such as rapidly expanding mosquito control programs; accelerating vaccine research and diagnostic development; enabling the testing and procurement of vaccines and diagnostics; educating health care providers, pregnant women and their partners; improving epidemiological capacity and expanding laboratory and diagnostic testing capacity; improving health services and supports for low-income pregnant women, and enhancing the ability of Zika-affected areas to better combat

mosquitoes and control transmission. We appreciate the Congress's consideration of this important request.

Serving Refugees and Unaccompanied Children. In light of a global displacement crisis, the Administration has committed to expanding the Refugee Admissions Program in FY 2016 and FY 2017. All refugees are subject to the highest level of security checks of any category of traveler to the United States. At HHS, the Administration for Children and Families' role is to link newly-arrived humanitarian populations, including refugees as well as asylees, Cuban entrants, and special immigrant visa-holders, to key resources necessary to becoming self-sufficient, integrated members of American society. The Budget provides initial financial and medical assistance for an estimated 213,000 entrants, 100,000 of which are refugees, consistent with the Administration's commitment to admitting at least 100,000 refugees in FY 2017.

HHS is legally required to provide care and custody to all unaccompanied children apprehended by immigration authorities until they are released to an appropriate sponsor to care for them while their immigration cases are processed. Based upon the increase in unaccompanied children apprehended at the Southwest border this fall, ACF has taken prudent steps to identify temporary capacity so that we are adequately prepared if additional shelter space is needed. To ensure that HHS can provide appropriate care for unaccompanied children in FY 2017, the Budget includes the same amount of total base resources available in FY 2016, as well as a contingency fund that would trigger additional resources only if the caseload exceeds levels that could be supported with available funding.

Leading the World in Science and Innovation

The FY 2017 Budget builds on the historic gains the Department has made in medical and scientific research and lays the ground work for scientific and technological breakthroughs for the 21st century. Thanks to biomedical research, including NIH investments, cardiovascular death rates in the United States have fallen by more than 70% in the last 60 years. Cancer death rates are now falling 1-2% per year; each 1% drop saves approximately $500 billion. Breakthroughs in HIV therapies enable people in their 20's to live a full life span. The FY 2017 Budget includes $33.1 billion for the NIH, an increase of $825 million, to build on the funding provided by this Congress in order to advance our shared commitment to support research that promotes economic growth and job creation, and advances public health.

Launching the Cancer Moonshot. Investments in research have led to significant developments in the prevention, screening, and treatment of cancer. To support the Vice President's Cancer Moonshot, the Budget includes a multi-year $755 million initiative that accelerates the nation's fight against cancer by expanding access to clinical trials, pursuing new vaccine technology, and funding exceptional opportunities in cancer research. These investments will drive scientific advances that aim to understand the causes of cancer, discover new prevention strategies, improve early detection and diagnosis, and develop effective treatments.

Advancing Precision Medicine. Recent breakthroughs in genomics, computing, and molecular medicine have ushered in a new era where more treatments are based on the genetic characteristics of each patient. The Budget increases funding for the Precision Medicine Initiative by $107 million to a total of $309 million to support critical new studies on therapies, and to continue to scale a cohort study to gather data on the interplay of environmental exposures, physical parameters, and genetic information.

Investing in the BRAIN Initiative. Despite the advances in neuroscience in recent years, the underlying causes of most neurological and psychiatric conditions remain largely unknown due to the vast complexity of the human brain. To further revolutionize our understanding, the Budget provides an increase of $45 million, for a total of $195 million within NIH, for the BRAIN Initiative. This research has the potential to discover underlying pathologies in a vast array of brain disorders and provide new avenues to treat, cure, and even prevent common conditions, such as Alzheimer's disease, autism, depression, schizophrenia, and addiction.

Making the Department Stronger

One of my top priorities as Secretary is to position the Department to most effectively fulfill its core mission by investing in key management priorities, including program integrity and cybersecurity. I appreciate the Committee's interest in these critical issues.

Strengthening Program Integrity. The Budget continues to make cutting fraud, waste, and abuse a top Administration priority by requesting $199 million in new program integrity investments in FY 17. The Budget fully funds the Health Care Fraud and Abuse Control

(HCFAC) discretionary cap adjustment. In FY 15 alone the HCFAC program returned over $2.3 billion to the Federal government and private citizens. The Budget includes proposals that will expand and strengthen the tools available to CMS and states to combat fraud, waste, and abuse, including in state Medicaid programs. In total, proposed program integrity investments and authorities in the Budget will yield an estimated $25.7 billion in scorable and non-scorable savings to Medicare and Medicaid over ten years.

Focusing on Stewardship. To improve the efficiency of the Medicare appeals system and reduce the backlog of appeals awaiting adjudication at the Office of Medicare Hearings and Appeals (OMHA), HHS has developed a comprehensive strategy that involves additional funding, administrative actions, and legislative proposals. The Budget includes resources at all levels of appeal to increase adjudication capacity and advances new strategies to alleviate the current backlog. The Budget also includes a package of legislative proposals that provide new authority and additional funding to address the backlog.

Conclusion

Members of the Committee, thank you for the opportunity to testify today and for your continued leadership on these important issues. I am grateful to have you as partners as we make the investments critical for today while laying a stronger foundation for tomorrow. I want to conclude by thanking the men and women of our Department, who work tirelessly every day to deliver impact for those we serve—the American people. I welcome your questions.

Chairman KLINE. Thank you, Madam Secretary. That is close to a record, seven seconds over five minutes. Well done. Thank you very much.

I mentioned in my opening remarks that we are concerned about the recent Reuters' investigation into abuse and neglect of children born in families battling drug addiction, and there was a law, CAPTA, that falls under your department's jurisdiction.

We sent a letter to you asking for information. The Department responded, and we thank you for that, but clearly, we still have a problem out there, it seems to me.

Congress has taken steps to streamline the application process, but the application still goes through the Children's Bureau at HHS, where they review States' applications and sign off that it is adequate before Federal funds are dispersed.

So, I know you looked at this. Do you feel like that within the law, the Department is doing everything it can to ensure that States are upholding the law, or is there more that should or could be done?

Secretary BURWELL. So, when these issues were raised, some of the issues raised in the Reuters' articles, we have gone and followed up on the examples that were raised, and right now, the State of South Carolina is being put on a performance improvement plan. So, specific actions are being taken where we have found there is wrongdoing. That is in terms of when things are brought to our attention.

As part of this process of review, we also put in place a different process to review what the States are saying. When they say they have a plan, in this next year's round, we will be asking for more details of those plans, so we can understand that the States actually have something that is a workable plan. So, we have taken steps in terms of where we understand there is something wrong and trying to get in front of it by making sure that we do a different process with regard to review of the plan.

The other thing I would just say is it will be an important part of the Administration for Children and Families as we review their budget.

Chairman KLINE. Okay. That is a change to the practice—

Secretary BURWELL. It is a change.

Chairman KLINE. We will be watching with interest. It does seem to us there needed to be a way for the Department to be able to confirm that the States are doing what they are supposed to be doing, without waiting for somebody to come and complain.

Secretary BURWELL. Which is why we have taken that step to do it in a more proactive fashion with the proposal, so we will look forward to the Committee's support for the Administration for Children and Families as a part of the budget process that we are able to enforce and do, I think, what the Committee rightfully is raising.

Chairman KLINE. Thank you. We just passed and the President signed into law the *Every Student Succeeds Act*. It took six, seven, eight, or 12 years or something to get to it and through it, but it is done, and it is the law. Under the Act, as I mentioned in my opening remarks, the Act now authorizes a preexisting program known as the "Preschool Development Grants Program."

Your department now has the lead under the law, with respect to funding authority and responsibilities. As I mentioned, it seemed to us that was clear because you already have billions of dollars in preschool funding through $9 billion in Head Start alone.

We believe that Congress specifically limited Federal interference in State early childhood systems to maximize State and local control over the improvement or development of the early childhood systems.

So, given the language of the law and what I think are clear protections in the law, what are you doing, where are you in the process in effecting that transition from the appropriated but not authorized program that was in Education and is now authorized and will be appropriated, I am sure, program that is in your jurisdiction?

Secretary BURWELL. So, the transition by statute will occur in 2017, not in this fiscal year. Right now, we are working with our colleagues at the Department of Education to actually formulize the relationship between us. We are going to do an MOU, a Memorandum of Understanding, to formalize the way we incorporate the best practices from Education and their input, as we integrate this program into the continuum.

I think you know at the Department, we have home visiting. We have early childhood. We have early Head Start. We have this program. We will integrate across that continuum, having the Department of Education be a contributor, and we decided to formalize the relationship.

Chairman KLINE. I am very pleased to hear that. It is because you are involved in all of those programs and you have that continuum that made sense to many of us to put this program there so it can be managed altogether.

I am going to try to set the example for my colleagues and yield back the balance of my time. Pay attention, please, all. Mr. Scott, you are recognized.

Mr. SCOTT. Nice try. Thank you. Madam Secretary, much has been made about the increasing cost of health care. Can you tell us briefly how the increases in health care costs now compare to what they were before the *Affordable Care Act*?

Secretary BURWELL. So, we have some of the lowest levels of Medicare growth on record that we have had since the passage of the ACA and the implementation. So, that has been a very important part. We have seen four of the five lowest years of growth in Medicare spending, and that is important for the taxpayer and for the Federal budget.

With regard to employer-based care, and that is the care that the vast majority of Americans have in this country, last year, the increase in employer-based care was around 4.2 percent in terms of the premiums. When we look at the period from 2000 to 2010, that number was 7.6. So, what we see is a decrease in the premium growth costs for those in the employer system.

With regard to the marketplace itself and the individual market, last year in the marketplace, the premium increases averaged in about the 7 percent range, and what we know is before the *Affordable Care Act*, in the individual market, premium increases were regularly in the double digit space.

So, whether one is looking at employer-based care, Medicare, which I know we are all concerned about from a taxpayer perspective, or looking at the marketplace itself, what you see is slowing in the growth of health care costs. It brings us to slowing but still increasing, and that is why I believe we need to spend a lot of time on delivery system reform and reforming the way we provide quality care at more affordable prices. I hope we will be able to talk about that some today.

Mr. SCOTT. How much more do people with preexisting conditions have to pay?

Secretary BURWELL. With regard to the preexisting, and I think this gets to the quality portion of what I was just talking about, in the system today, and I think everyone in this room knows someone who has had cancer or has asthma or some other condition, for all of those individuals, they no longer need to worry that they will either be cut off from their care or not be able to access the care.

I have had the opportunity to travel around the country and meet those people who previously did not have that opportunity. Making sure that those with preexisting conditions can no longer be discriminated against is a very important part of the progress on quality of care that we have seen.

Mr. SCOTT. Do the people with preexisting conditions have to pay any extra?

Secretary BURWELL. No. They are neither kept out nor do they pay extra in terms of what they would pay in their premiums.

Mr. SCOTT. Can you say briefly how the failure to expand Medicaid in some States affects those who have insurance?

Secretary BURWELL. With regard to how that impacts those who have insurance, it comes in the form of uncompensated costs. So, the work that we have done—we have seen about a $7.8 billion reduction in uncompensated costs since the passage of the implementation of the *Affordable Care Act*. The vast majority of those benefits are going to the States that have expanded Medicaid. What that means is that reduction in uncompensated care gets translated through the system, and it gets translated through the system to individuals and to hospitals and communities.

We know that now in terms of rural hospital closures, which are something many are concerned about, we see more of those rural hospital closures in States that have not expanded. This is because of the uncompensated care issue. It flows to individuals. It flows to communities, and it flows to hospitals.

Mr. SCOTT. Thank you. Disasters can happen anywhere. If a disaster were to happen in one of our districts, we could look at how you respond to Flint, Michigan to see how you would respond in our areas. Can you say what you are doing in Flint, Michigan for that disaster, particularly in Head Start?

Secretary BURWELL. So, the President asked that the Department of Health and Human Services lead the Federal response, which we are doing. So, we are coordinating the response of FEMA delivering water, SBA making sure that loans can get through, HUD helping housing get different pipes into public housing, and then the work we are doing.

You mentioned our Medicaid expansion, as well as our Head Start work. The Head Start work, we have done a $3.6 million addition to expand both coverage and services, and that is because a lot of what you do to mitigate lead has to do with education and nutrition.

Our colleagues at USDA are working very closely with us as well on the nutrition component, and put in place an ability for mothers to use WIC money to do formula that was not water based, because obviously that was a problem for those children focused on 0 to 6.

Mr. SCOTT. Does the Zika request include research?

Secretary BURWELL. Yes, it does, and I hope we will have more time to discuss Zika. I just got the report today, and for U.S. citizens, there were over 450 million cases, and I hope we will have an opportunity to discuss that more.

Chairman KLINE. The gentleman's time has expired. Dr. Roe?

Mr. ROE. Thank you, Mr. Chairman. Thank you, Madam Secretary, for your pushing the rule for the end of life counseling. That is a huge thing. I have heard a lot of positives about that. I want to thank you for that.

Just a couple of quick questions.

Stop-loss insurance regulation, as you know, in the private sector, a majority of those plans are basically self-insured plans, like we had in the City of Johnson City when I was the mayor. We used stop-loss insurance to protect our losses if they went above what we calculated they might be.

Would you commit to the Committee not to regulate stop-loss insurance as health insurance because it is clearly not, in the future as Secretary of HHS?

Secretary BURWELL. I want to understand exactly what the regulations and laws are, I apologize, this is one I am not familiar with, I want to look into it, and we will get back to you in terms of how we think about that issue.

Mr. ROE. Okay. Thank you. Just for the record, our increase in the marketplace in Tennessee was over 30 percent this year.

A couple of things on Meaningful Use and electronic health records. As you know, physicians are struggling to meet the Meaningful Use and full disclosure. The primary care group I was in had over 100 physicians, and we have met—1 of the 12 percent in the country—they have met that, and about 40 percent of hospitals in Stage 2.

Why would you go to the penalty phase of Stage 3 this year, which I think you are going to do, when 80 plus percent have not met Stage 2 yet? So, you know that the doctors, providers, hospitals, and physicians are going to be cut; why not just put it on pause for a year until they can get the systems to help? They are trying. They are out there trying to do this day and night, so why not do that? Why not pause for a year?

Secretary BURWELL. I think what we have tried to do is hear the concerns that have been expressed, and I think you know in the rulemaking that we recently put out, we were working to also include the legislation you all recently gave us on MACRA, and transferring to that system that we have been given legislatively to work through.

So, working to make sure that we can get to the place where we are listening to providers—

Mr. ROE. That is what I am hearing out in the real world, that you are not listening. That is a concern because they are going to get the penalty phase this year. So, I appreciate you are working on that, but what I think I am hearing out there in the real world is we are trying the best we can to comply with these things, but there are so many things with electronic health records and so forth, and I say this jokingly, but an electronic health record, I think, made me a congressman not a doctor any more.

A couple of other things I want to go through very quickly, and I wrote you a letter about the breast cancer screening guidelines. I appreciate you putting that on hold for two years. One of my partners in practice, if he had followed the guidelines, one doctor in one practice, 24 patients would have fallen through the cracks and not been picked up early: 24 breast cancers, one doctor.

The other I want to mention is the PSA screening. The United States Preventive Task Force Services, which had no urologists and no oncologists, made a recommendation that absolutely should not be done, and you, as the Secretary, are going to penalize the primary care doctor if they order a PSA regardless of the patient's family history, regardless of their race, and regardless of their symptoms, essentially.

So, I want to know—last night, I got a call from someone who had a PSA of two, a 59-year-old man, got up to go to the bathroom one time at night, went to his doctor. His primary doctor had ordered one previously, ordered another one, ignoring these guidelines, it was three. He said we better check it again in 90 days. It was five point something then. Sent to an urologist. This man has prostate cancer at 59. He would have been missed by these guidelines and might have died.

I think these guidelines are going to cost people their lives. I think we need to seriously step back and take a look at them, at least let the science get worked out before you penalize a primary care doctor for ordering a PSA, a test that is not perfect, but it is an adjunct to clinical history and other things. I would strongly encourage you to do that.

This was last night. I do not know how you would answer that patient's family when that patient would very likely have died had they followed these guidelines.

Another issue I want to just bring up briefly: affordability of health insurance. I am in a billion dollar health care system at home where I practiced, 60 percent of the uncollectible debt in that hospital are people with insurance. To make these plans affordable, we have increased the out-of-the-pockets and co-pays so high, that people cannot pay those, just average, normal people, rural America, where I live.

The last comment, we mentioned this last year. In rural America, where I live, what is killing our hospitals in Medicare is the Medicare Wage Index, which is very unfair to rural areas. We get 0.74 cents to what another place might get $1.50. I would like to hear from you on that. I want to work with you on that.

With that, Mr. Chairman, I yield back.

Chairman KLINE. I thank the gentleman. Mr. Hinojosa?

Mr. HINOJOSA. Thank you, Chairman Kline and Ranking Member Scott. I support President Obama's Fiscal Year 2017 budget for the Department of Health and Human Services because the administration's priorities for HHS support the well-being of all Americans, and are closely aligned with the needs of my congressional district.

Madam Secretary, it is a pleasure to have you testify before this committee, and I want to ask the chairman as a member of this committee for unanimous consent that the three pages of my opening remarks be included in today's report.

Chairman KLINE. Without objection. I am sorry. I am blaming it all on the ranking member here.

Mr. HINOJOSA. Thank you, Mr. Chairman. Madam Secretary, as you know, the State of Texas did not expand Medicaid, and that has hurt us a great deal. I am pleased to hear of your efforts to incentivize these vital programs. In your view, why is it important for States to expand Medicaid?

Secretary BURWELL. So, the Medicaid expansion issue, I think, has two different elements to it. It has the element of the individual, and it is about providing financial and health security for the individual.

In the State of Texas, over 40 percent of those who would be eligible are working folks, so for many working people, making sure they can have both that financial and health security is a very important thing to their individual well-being.

Separately, there is the issue of what it means economically to hospitals and to the States. We know that in the State of Kentucky, what we have seen in terms of an analysis by Deloitte as well as the University of Louisville, that until 2021, 40,000 new jobs would be created in Kentucky, and $30 billion would flow into the State of Kentucky.

So, it is an economic issue in a broader sense, but it is also about the individuals and how their lives can be changed, and certainly as you reflect, we have a budget proposal to try and keep encouraging States to come in.

Mr. HINOJOSA. Thank you. Parental engagement and involvement has been one of the most critical if not the most critical part of a Head Start program over the last 50 years. This holistic approach ensures that children are ready for school. How does this proposed rule for Head Start strengthen parental involvement?

Secretary BURWELL. So, Head Start, and I think you know I am a Head Start kid, it has been a successful program for many years, and certainly not just my professional opinion but my personal opinion, but the issue of the intergenerational part of this, and Mr. Scott referenced it in his opening testimony, is an essential part, and it is essential both to get the full benefit of the program, and as we work forward, that is some of the changes in the proposed rule.

It is everything from making it easier—in the current rule that is there, one-third of some of the requirements are cut out, in trying to get to simplification, to make things easier for parents and easier for providers, so they can engage and participate.

As a parent of a 6 and 8 year old, I am very clear about the engagement and what it means in terms of children's well-being, and

also having quality places for your children to be in terms of your ability to focus on your work.

So, it is about—

Mr. HINOJOSA. Thank you for that clarification. Thank you, Madam Secretary. Helping children and young people who qualify for help through DACA, Deferred Action for Childhood Arrivals, is very important to my region because I have such a large number of students, K–12, who qualify.

How do the priorities in your proposal help them?

Secretary BURWELL. With regard to the DACA issues, I am afraid I will most likely need to defer to my colleagues at Justice and DHS, who are much more engaged in those issues.

With regard to the programs that are available, I think you know that the health centers throughout the Department are an important part of health care for people who do not have coverage or coverage access any other way.

Mr. HINOJOSA. Thank you. Madam Secretary, the ACA has been instrumental in increasing access to health care for residents in my district and across the Nation. What can communities such as mine do to increase participation in ACA's health insurance marketplace? What are some of the best practices that you can share?

Secretary BURWELL. So, open enrollment, I would just remind everyone, November 1 through the end of January next year, and preparing for that open enrollment is a very important thing because it is about the communities' engagement.

Having visited communities all over the country, what I see are stakeholder groups and groups that have come together. The hospitals, the insurers, all kinds of local community groups come together and make sure that the information is there, and that people have a place to go.

I have visited in the State of Texas. There is some great United Way 2-1-1, you just dial 2-1-1 and you are able to get that kind of access.

Mr. HINOJOSA. Madam Secretary, in my district, the uninsured was 40 percent before ACA. Today, it is only 18 percent. So, we have made great progress. Thank you.

Secretary BURWELL. Thank you.

Chairman KLINE. The gentleman's time has expired. Mr. Byrne?

Mr. BYRNE. Thank you. Madam Secretary, I want to talk to you about the transitional reinsurance program and some current concerns that I and others have about the legality of the way these funds have been used.

We are going to put on the screen the actual text of the law, that you see there now. I also have here the same legal memorandum that my colleague, Chairman Pitts, showed you two weeks ago when you testified before the Energy and Commerce Committee.

The nonpartisan Congressional Research Service, which put out this memo, analyzed this issue and stated, and I am going to quote them, "Insofar as CMS' interpretation allows the entire contribution of an issue in any given year to be used only for reinsurance payments such that no part of it is allocated for the U.S. Treasury contribution, and that would appear to be a conflict with a plain reading of Section 1341(b)4," that is the language up there.

"Because the statute unambiguously states that each issuer's contribution contain an amount that reflects its proportionate share of the U.S. Treasury contribution, and that these amounts should be deposited in the General Fund of the U.S. Treasury, a contrary agency interpretation would not be entitled to deference under the Chevron decision."

We have that second piece of language up there now. So, you have had two weeks since Chairman Pitts brought this to your attention. You had the legal memorandum. I assume you have had a chance to go over this with your staff and your counsel.

[Additional submission by Mr. Byrne follows:]

Rep. Byrne (R-AL) PowerPoint Slides

"The [assessment] **shall be designed** so that . . . each issuer's contribution amount for any calendar year under clause (iii) **reflects its proportionate share** of an additional $2,000,000,000 for 2014, an additional $2,000,000,000 for 2015, and an additional $1,000,000,000 for 2016."

ACA § 1341(b)(3)(B)(iv)

"Notwithstanding the preceding sentence, any contribution amounts described in paragraph (3)(B)(iv) **shall be deposited into the general fund of the Treasury of the United States and may not be used for [the reinsurance program]**."

ACA § 1341(b)(4)

You would agree that you did not put $5 billion in the Treasury that you were required to. My question now is do you know not agree that you violated the law in not putting the $5 billion with Treasury?

Secretary BURWELL. We believe that our reading of the law is accurate and correct. As we put out—

Mr. BYRNE. Can you give me some authorization for that?

Secretary BURWELL. Yes. What we did was we actually put out our reading of the law in a Notice of Proposed Rulemaking for public comment. We put out our logic. We put out our reasoning to the public to review our proposal, not in an interim final rule, but in a Notice of Proposed Rulemaking, so we could have comments.

A wide range of groups commented on our rule, as is regular practice. No one raised any concerns—

Mr. BYRNE. Madam Secretary, let me take my time back on that. Whether they commented or not, the law is plain on its face. It does not matter what you think or somebody outside of your department thinks if the law is plain, you do not get to interpret it any other way, and the nonpartisan Congressional Research Service says you directly contradicted the law in the way you actually carried it out.

So, are you saying now that because you put it out in comment that you get to interpret it any way you want to, despite the plain wording of the statute?

Secretary BURWELL. What I am suggesting is that we believe our reading is accurate. The public had an opportunity to point out if they thought it was inaccurate. That was not done. We believe that our reading of the law is accurate.

Mr. BYRNE. Well, Madam Secretary, let me just say this, the nonpartisan Congressional Research Service directly contradicts you. They say you read it completely wrong and that you clearly violated the law.

Now, there is a lot of concern in America right now about the anger among the electorate. I just came through a primary a few weeks ago. The electorate is angry. They are angry because people in positions of responsibility like you violate the law. You violated the law. The nonpartisan Congressional Research Service has said you violated the law.

Here we are today with some excuse that you put it out for comment. The fact that you put it out for comment does not relieve you of the responsibility to enforce the law as it is plainly written. It is plainly written. There is no wriggle room around this.

The fact that you have had two weeks to look at this and you cannot offer me any legal authority for what you did tells me that you just decided or your staff decided we are not going to put the $5 billion in the Treasury as we are required to do by law.

I can tell you my constituents and the people across the United States of America are sick and tired of that. So, if you want to provide to this committee at a later date whatever your legal staff wants to provide as whatever legal basis for their interpretation, that is fine, but telling me you put it out for notice and comment does not answer the question as to how you get around the clear requirements of this law, and it is not just my interpretation that

I am going on here, I am going on the interpretation of the nonpartisan Congressional Research Service.

I appreciate you telling us what you have told us here today, but it is not an answer. I hope you and your legal staff after this is over will put something together and send it back to us. I yield back.

Secretary BURWELL. Congressman, I would like to reflect that what I said was we have put out our legal argument. I understand and respect there is a disagreement in the interpretation of the law.

What I was saying is we have articulated why we believe our reading of the law is correct, not only have we articulated that through communication, we did it in a very public way. We believe our reading of the law is correct, and I would also reflect that with regard to this, and this particular issue, there have been 71 IG and GAO investigations in terms of the question that you are raising.

We are working hard to implement the law. There are thirty open, there have been over 100 examinations. With regard to what I am hopeful for is that we can get to the place where we can have the conversations about how to control costs and improve quality in this country in our health care system. That is what we are working to do.

Chairman KLINE. Madam Secretary, the gentleman's time really has expired. We will not get to any of that if we do not try to stay within the five minutes. Mrs. Davis?

Mrs. DAVIS. Thank you, Mr. Chairman, and good to have you with us, Madam Secretary. I wanted to really go to one of the areas where as you said we are trying to create a smarter system.

In that regard, I think there has been some early success of the diabetes prevention program. We have seen evidence that really is common sense, I think, that if you speak to the need for providing better nutrition, exercise training, that you are going to see a reduce on the onset of diabetes. We have seen that particularly in seniors.

I just wanted to mention that there is bipartisan legislation to expand the diabetes prevention program to Medicare. There have been numerous pilots to demonstrate that really can have a demonstrable effect on saving lives, as well as cutting costs.

I am hoping that you can take a look at that as well, how can we work to expand that. I would love to see all my colleagues come together on that legislation, but there may be some other tools that we have as well. I hope you will take a look at that.

I want to shift quickly to early childhood, because that is an area that you are going to be working heavily in as we go forward, and certainly reflected in the legislation, the transition is in 2017.

I know that within that legislation, there is a call to expand the length of the school day among other requirements. I am wondering what you are doing, what the staff is looking at now, how are we going to move forward with that while at the same time being certain we are keeping the quality the same or at least better, maintaining quality, and certainly finding ways that we hit the bar of lengthening but we are not losing some of the other ingredients that make up such a successful program.

Secretary BURWELL. So, as part of our Head Start rulemaking right now, it is an open rulemaking, so with regard to what the conclusion will be, it is not something I can comment on. At this point in time, we are reviewing a number of comments in different places.

It does get, I think, to a little bit of the chairman's comment at the beginning, about making sure we are continuing to make strides, so that the benefits of these programs are known for the children in the short-term as well as the long-term, in terms of that third grade level and some of the research that we have seen.

One of the suggestions out of that research that had some questions was the question of lengthening of time, that time there makes a difference to the child's ability to gain and retain what they need in order to build the building blocks, especially at that critical point in the third grade where we really need them reading in a way that it will take off, because then they are using the reading for learning when they get to the third grade.

So, the time issue is related to the quality issue that the Chairman had raised earlier.

Mrs. DAVIS. I appreciate that. I know that what we do not want to see is enrollment have to drop as a result of that. That is a big concern.

The other one is regarding homeless children. In San Diego, we certainly have a number of children who come in and out of the school year. As you are working on the rulemaking, how can we provide for spaces for children who may be in and out of the program and be sure we guarantee they have a spot when in fact they are present and they need to be part of that program?

Secretary BURWELL. I think it has two elements to it, as we continue to think about the issue of making sure there is flexibility for those children, but also working deeply on the issue of homelessness as well, so that you are addressing the problem for those that are, but taking on that issue.

At the beginning of this year, I became the chair of the United States Government's Interagency Council on Homelessness, and because of the work that we actually share, this committee and the Department, we will be focusing on youth homelessness as one of the main priorities.

We will continue the work on veterans' homelessness because great progress has been made, but we want to take that next step. So, working on flexibility within the programs but also trying to get to the root of the issue, we will engage in.

Mrs. DAVIS. Yes, thank you so much. I know in terms of stability of young children's lives, it is key they are in a program and they can count on that when their families are moving and not stable. That is so important to them.

Very quickly, just on one other issue. In the Administration for Children and Families, the plan is to provide about $9.5 million in demonstration grants to help prevent youth sex trafficking. I am wondering if you could just speak briefly to how you expect different States to utilize these funds.

Secretary BURWELL. You know, I think this is a place where different States are going to use different tools based on their problems and their approach to those problems. This is also a place

where our regional offices are engaging directly with the communities.

Mrs. DAVIS. Thank you.

Chairman KLINE. The gentlelady's time has expired. Mr. Curbelo?

Mr. CURBELO. Thank you, Mr. Chairman. Madam Secretary, more than 4,000 foreign children and adolescents have resettled in Miami, Dade County, in Fiscal Year 2015, and 937 more in the first quarter of Fiscal Year 2016. Foreign born students add an average of $2,720 in extraordinary costs to local school districts, above and beyond the per pupil State reimbursements.

The numbers of refugees, especially Cuban refugees, has increased substantially in our community. The estimated number was over 4,000 last year and is expected to be on a similar pace in the current year. However, this could be an understated number because many parents are immigrating without their children, and their children join them later once they have adjusted their status.

This presents a problem because the later arriving children of refugee parents do not count under refugee data, but they still represent major costs to local communities.

Since school districts are barred from inquiring into immigration status, is there a proxy measure for school-wide services that can be used to determine the actual impact of the significant influx on affected school districts?

Secretary BURWELL. You know, I apologize, but I am going to need to defer to my colleague at the Department of Education with regard to how those measures would be done in schools. I apologize.

Our role, I think you know, is with the parents as they come in terms of the Office of Refugee Resettlement. So, I apologize, but we can get that to my colleague.

Mr. CURBELO. Okay. Let me ask you, what is HHS doing, if anything, to address the recent increase in foreign born students that are challenging communities like ours? How can we help school districts like Miami, Dade County, serve these students?

Secretary BURWELL. You know, with regard to our role, I think one of the things that we can do is make sure that those transitions of the individuals—the Office of Refugee Resettlement, which is a part of HHS—the thing that I think we can do is make those resettlements as successful as possible.

Part of that success, I think, is making sure they become employed members of communities. At that point, our contribution can be making sure they are engaged, employed, and contributing members of the community in terms of employment and taxes, so that then is a part of the regular system.

With regard to other issues, again, I will defer to my colleague at Education.

Mr. CURBELO. So, let me ask you also, because this is a critical issue for our community, and as you know in the past, we have seen over 50,000 or close to 50,000 Cubans resettle in the United States, and the Miami, Dade County School District and Monroe County Schools, for that matter, obviously carry a heavy burden.

Do you know if funding from the Cuban Haitians Social Services Set-Aside—can school districts draw from those funds to mitigate some of the impacts on these school districts?

Secretary BURWELL. I am not familiar that they can, but why do we not go back and check, and I am happy to get back to you on that issue.

Mr. CURBELO. Well, this is just a critical issue for our community, Madam Secretary. I hope to work with you and with your department to find ways, to find more support for Miami, Dade County. This is another case where a local community faces the results or the consequences of what I believe is a flawed Federal immigration policy, a flawed Federal refugee policy in this case, and I think it is incumbent on the Federal Government to help communities like ours solve these problems because it is unfair for all of these costs, for all of the burden, to fall on local school districts and on local municipalities.

Thank you, Mr. Chairman. I yield back.

Chairman KLINE. I thank the gentleman. Mr. Courtney?

Mr. COURTNEY. Thank you, Mr. Chairman, and thank you, Madam Secretary, for your outstanding service. Your portfolio is about as complex and broad as any in government, and I think you are doing an outstanding job. Thank you.

Secretary BURWELL. Thank you.

Mr. COURTNEY. In your testimony on page 11 you talked about the heroin and opioid component in the President's budget, $1.1 billion. Again, it is allocated to help law enforcement, treatment, prevention, and education, which is what I am hearing back home in my district, 28,000 people lost their lives to accidental overdoses, as you pointed out, in 2014.

That is a 14 percent increase from the year before. The 2015 numbers are not going to be any better, and I know that because in Connecticut we saw a 20 percent increase since 2015 numbers by the Office of the Medical Examiner just a few weeks ago.

Director Botticelli was up in Eastern Connecticut talking to folks who are on the front lines on this, and you know, what is striking is police and law enforcement are totally engaged in doing their job, but they are the first to say you cannot arrest your way out of this problem.

Emergency room providers who are saving lives with Narcan are frustrated because there is not enough detox beds and treatment beds, so there is a revolving door for a lot of these folks who are addicted and have no place to go after they have been revived.

The medical provider community is ready, I think, to talk about reforming the prescription overprescribing of pain killers.

What I think is of concern is that again, you just released new funding to HRSA, to community health centers, which is much appreciated, but there is no request for emergency funding this year.

When you look at Zika and you look at OCO, what Mr. Kline and I are going to be voting on, billions in emergency funding for our overseas military operations on the Armed Services Committee, but when you look at a problem where we are losing 28,000 people a year—Senator Shaheen and myself have a bill to sort of move that push to get resources into this year, which is so obviously needed.

I just wondered if you could just sort of talk about your perspective on that, you know, the administration's willingness to work with us, who really want to get folks who are on standby ready to help with a solution.

Secretary BURWELL. So, the issue of the treatment and treatment opportunities, that is the biggest part of the money, the $1 billion that we have asked for. It is about treatment.

I think all of you know in your communities as you visit, behavioral health is something that was paid for at the community level, and so it has never been built up, and now we have a very acute problem with people dying but as your law enforcement reflect, every law enforcement I talk to, they tell you I am not a social worker or a health worker, so that is why it is so critically important that we get funds to move, because those funds move to the States and the communities—

Mr. COURTNEY. Right.

Secretary BURWELL. To get that treatment. The other parts are very important, but without the treatment, we now have a bolus of people who are addicted, sadly. I wish that was not the case. We need to prevent any more, but we have to take care of that which we have.

Right now, Narcan or preventing an overdose death is not the only solution. If people are in medication assisted treatment, we can make progress. That is why we are pushing hard. We appreciate your leadership and others in terms of trying to make sure we get that funding for the treatment. Funding will also go to other issues, as to Naloxone, getting access to people, because not all—I am sure you hear this in your communities—not everybody in terms of first responders have access.

We also have work at FDA. They have approved a nasal approach which will be easier for others to use that do not have to be a trained first responder to do that.

So, we will work across, but the money for treatment, which I think is what you are focused on right now, is an essential part of getting to another place in this crisis.

Mr. COURTNEY. So, again, the Senate sort of went partway there last week in terms of the Comprehensive Addiction Recovery Act, but again, it is authorizing legislation without resources, and as Congressman Kildee used to say, "An unfunded authorization is kind of like a get well card to somebody who is sick, it does not really fix the problem."

Again, that is where I think the HRSA funding that was put out last week is getting to the house on fire that is happening out there, but again, the budget priorities are totally on target, as you said, but the question right now is on timing, because this issue is accelerating and intensifying.

I hope all of us are going to work together because it affects every district, rural, suburban, urban. It is hitting veterans again because of Service connected injuries. This should be an easy one for us to work together on.

Secretary BURWELL. Yes. The fire alarm, this is a seven alarm fire and we sent one department. We need seven or eight others to get to the real issues and the problem.

Mr. COURTNEY. Thank you. I yield back.

Chairman KLINE. The gentleman yields back, without mentioning basketball. Ms. Stefanik?

Ms. STEFANIK. Thank you, Mr. Chairman. First, I want to echo my friend and colleague, Mr. Courtney's, statements that the heroin and opioid epidemic is an issue that I have been focused on in my district, and I look forward to working with you on that issue.

Thank you, Madam Secretary, for being here today. Shifting gears, I think we can all agree here that we need to make sure that our seniors receive the best care possible, and in order to do that, we must accept there are differing needs across this country.

The *Older Americans Act* is an important law that helps seniors remain in their homes and out of expensive institutional care. As you know, what may work for seniors receiving meals or care in urban areas is likely to be inadequate to the unique challenges facing rural areas such as the district I represent in New York's North country, where we have one of the highest concentrations of seniors in New York State.

One of the hallmarks of the *Older Americans Act* is the State and local control provided through the structure of the aging network. This is a great example of legislation that understands one-size-fits-all does not always work.

Can you speak to how this structure is important to meeting the needs of this Nation's elderly and what we will do to continue the successful model?

Secretary BURWELL. Yes, and thank you for your leadership in terms of the reauthorization, we think it is important to continue. I think what you are reflecting is we need to make sure we maintain the flexibility for States because it is in very wide variance in terms of what it means to serve that community and serve that community well.

So, we want to continue. We think the reauthorization does not need major changes, but some small changes that can help us with making sure we are using the best data and evidence that we have, which is based on some of our learnings that different things are working in different places, and keep that flexibility in place.

I think you know in this budget that is before us, even without the reauthorization, we have some funding increases in particularized areas, and whether that is protecting against elder abuse and how that is done in rural areas versus urban areas, protecting in that space as well as some of the food programs that you mentioned, but we want to work across the spectrum of needs and work with those communities on what their priorities are.

Ms. STEFANIK. Great. Thank you for that, and I yield back.

Chairman KLINE. The gentlelady yields back. Mr. Polis?

Mr. POLIS. Thank you, Mr. Chairman. I want to thank the Secretary for joining the committee today, and I want to thank her and the administration for putting forward a budget that reduces our deficit, makes important investments in health and education that our country needs.

I applaud the work of the Department of Health and Human Services for working to implement the *Affordable Care Act*. I congratulate on the especially successful 2016 third quarter enrollment period and 4.9 million new customers in the Federal Exchange.

Madam Secretary, you have seen firsthand, of course, the positive effects of the *Affordable Care Act*. I know in my home State of Colorado, 16.5 percent of people lacked health care insurance before the *Affordable Care Act*, and last year, the number fell to 6.7 percent, a historic low.

I am concerned, however, about how the geographic rating areas for each State can skew the cost of health care. My constituents in Grand County, for example, face among the very highest premium increases in the country. Their premiums went up at least 25 percent this year. They pay, by the way, nearly twice as much as other Coloradoans for insurance.

How is the Department helping States to guarantee that families and individuals who live in rural mountain communities are able to access high quality care at a reasonable cost the way the Affordable Care Act intended?

Secretary BURWELL. So, one of the things that is important in both the employer-based market as well as the individual market is the fact that the *Affordable Care Act* actually put out-of-pocket caps in terms of what people will spend, and that is another important benefit getting to quality and affordability that we have not touched on, and I think that is important.

With regard to the other issues in terms of the *Affordable Care Act* and the steps it is taking to work on places where I think it is fair to say that in our country there are pockets, such as that you have described, and in some cases, States, such as the State of Alaska, where a market is not working in terms of creating the amount of competition either in providers or insurance companies to put downward pressure on price.

I think a part of that is why some of the changes that came in the *Affordable Care Act* that help us with delivery system reform and some of the work we are doing in the innovation centers to create models that people can use to have that downward pressure.

So, there are two parts to it. It is focusing on specific markets themselves where the problems exist, but then overall, as a Nation, figuring out the steps we need to take to put that downward pressure, and our Accountable Care Organizations, we have already seen hundreds of millions of dollars of savings, and while the statutory level that you all gave us is very high to meet success before one can replicate, we have met that, and are now in a phase two of that.

So, it is about regional and retail strategy, and then a strategy across the Nation.

Mr. POLIS. Are there are some States that have rolled out single geographic rating areas for their entire State?

Secretary BURWELL. I will have to go and check. I think—I will check.

Mr. POLIS. Thank you.

Secretary BURWELL. I do not want to give you an incorrect answer, so we will come back on that.

Mr. POLIS. Sure. To transition to Head Start, of course, I am a firm believer in the benefits of Head Start for kids and communities, and in my district and my State, we also have many high quality charter schools that serve at risk kids. Public charter schools have the autonomy to offer a unique curriculum, many stu-

dents and parents take advantage of that. In Denver Public Schools, about a quarter of the kids attend public charter schools.

You know Head Start grants are given to non-profits, community centers, sometimes traditional public schools, but to my knowledge, no charter school has received Head Start grants and few have applied.

Can you talk about what your agency is doing to clarify guidance and do outreach so that high quality charter schools know they are eligible for Head Start grants and understand how to meet the Head Start requirements so they can offer those services for families?

Secretary BURWELL. Out of our conversation last year, this is something that we have followed up on, and are issuing hopefully clearer guidance. I think we believe it is possible and people can do it, but clearly, I think as you reflect, people do not understand that charters can do it, so we are issuing guidance to make that clearer, and then we will work to implement that so people can know what process they need to do to do it, because we think it is quite possible and people can do it.

Mr. POLIS. Thank you. I also wanted to briefly address transgender health. I have worked closely with my colleagues in the Equality Caucus, Representative Takano, Representative Pocan, also on this committee.

HHS proposed a rule to implement the non-discrimination provisions of the *Affordable Care Act* that would prohibit discrimination on the basis of gender identity. When can we expect a final rule, and are there improvements to the proposed form to the final rule, which is so important to the LGBT community?

Secretary BURWELL. Because it is an open rulemaking process, we will not be able to talk about the specifics of the final rule, but a rule that is very important. I think you probably know that 1557 we were implementing before, but it had been five years.

Mr. POLIS. You will have time to complete that rule, correct?

Secretary BURWELL. Yes.

Mr. POLIS. Okay. Thank you. I will have some other questions for the record, and I will yield back.

Chairman KLINE. The gentleman yields back. I need to advise my colleagues that we are going to restrict the time now to four minutes and hope we do not have to go to three minutes. The math shows we have too many people and not enough time.

Mr. Russell, you are recognized for four minutes.

Mr. RUSSELL. Thank you, Mr. Chairman, and thank you, Madam Secretary, for being here today.

As a returning combat veteran, I had some firsthand experience with prescription pain killers. In my case, Percocet, but, while it did reduce the pain, it left me with a clouded mind. I became concerned about that. I did not like not having my faculties, so I quit taking them.

However, pain management, and not just among our veterans, has resulted in perhaps a lot of what is categorized as suicides, it might have been accidental death. On a broader scale nationally, at least 18 States now have more deaths due to prescription opioids than car fatalities.

Secretary BURWELL. Correct.

Mr. RUSSELL. The fatality rates have increased five-fold since 1990. Accidental overdoses are up 360 percent since 1999. In 2004, prescription and other over-the-counter drugs were responsible for more years of lost potential life than all accidents from falls, firearms, drownings, fires, and non-medication poisonings combined.

Opioid pain killer prescriptions have increased 800 percent from 1997 to 2006, and the data for the next decade will probably exceed even further.

America now has had an increase in these, but I cannot imagine they have had an 800 percent increase in pain. Instead, America now has seen a health science environment that allowed law makers to pass these laws in the first place, and I think America has been sold faulty health science and a bill of goods.

So, my question to you, Madam Secretary, in the $1.1 billion spending program to provide treatment to those exposed and suffering this abuse, we have been exposed to prescription heroin nationwide, what actions will you be taking to curtail the science that suggested these laws be passed in the first place?

Secretary BURWELL. The research on pain and pain treatment, I think, is an important part of the solution. I think when we look at the steps that we need to take to push back on many of the statistics you articulated, number one, we need to change prescribing practices, because that is how many folks are getting the prescription, and then that is sometimes a transfer to heroin itself. I think you were referring to both. We need to work on the medication assisted treatment, and we need to get access to Naloxone.

With regard to the research issues, at NIH, there are two parts to this, and one part is making sure that we are researching pain issues as well as the treatment of pain, and this is a space where I actually work with my colleague at the Department of VA, because they have much of the research and are doing some of the advances. As you articulated, it is a pool of people, sadly, who have these issues in terms of pain.

So, we are working on it there. We are working on it at NIH, and with regard to FDA, what we are trying to do is speed along the process for those that can find drugs that are not opioid based in terms of pain, as well as those that are tamper-resistant. Those are some of the changes we most recently made at FDA.

Mr. RUSSELL. I would hope rather than chase more money after bad practices that we would take these things off the market. I think we existed for a long time as a country, we fought world wars, we did a lot of other things. America has not had an 800 percent increase in pain.

I would hope that you would devote more effort towards the faulty science that has allowed these laws to pass. We are creating an epidemic that we are not likely to recover from. I do appreciate your efforts thus far. Thank you. Mr. Chairman, I yield back.

Chairman KLINE. The gentleman yields back. Mr. Sablan?

Mr. SABLAN. Thank you very much, Mr. Chairman. Madam Secretary, you mentioned this would be your last budget hearing. I think you should be proud. There are so many things in the proposal that would serve Americans greatly.

I am the only member here who is not representing a State. I am going to limit my conversation to one issue. The President pro-

posed in his fiscal 2017 budget that the National Medicaid program be available to the 4 million Americans who live in the insular areas, including my constituents, in the Northern Mariana Islands, and thank you, this is a very welcomed proposal.

The people of the Mariana Islands are not as well off as the rest of Americans. Our median household income is about $20,000, and the national median income is $50,000. Because we have so many who are poor, we have many who qualify for Medicaid, 15,036 of our total population of 53,000 receive medical care through the Medicaid program.

As you know, Medicaid in the Mariana Islands and the other insular areas is not the same as Medicaid elsewhere. There is a cap on the amount of Federal Medicaid money that goes to our islands, only about $5 million per year to the Marianas.

The local cost-share of Medicaid is not computed on overall income as it is with the rest of America. So our Commonwealth, our local government has to pay 45 percent of the cost more like one of the richer US states would pay. We are not rich, however.

So, we welcome the additional Medicaid money provided by the *Affordable Care Act* beginning in 2011, about $13 million per year. That new money kept our only hospital open when the local government had to stop its annual funding for our hospital because of the Great Recession and loss of tax revenues.

That Affordable Care Act money is only available through 2019. What happens then? Does our hospital close? What about those now on Medicaid, do they lose coverage? I would like to give you the time to please explain to the committee about the President's proposal and how we are going to make sure that Americans in my district get the same access to health care as Americans elsewhere, everywhere else in our Nation?

Secretary BURWELL. So, our proposal is a proposal that we hope will address the issue of a cliff and not create further cliffs with regard to putting in place a proposal that will transfer away from a cap and create matches that are more aligned with the matches that other Americans receive, at the same time, the proposal includes steps to make sure that there are reforms and governance is put in place.

So, it would happen over a period of time where steps would have to be met in order for the changes to occur. It is a proposal both about getting out of where we have a cliff and the problems that you have described in terms of the need, but do it in a way that is also encouraging high quality Medicaid performance and program integrity.

So, the proposal combines those two things. We believe it is a reasonable and a very needed proposal, and we should get ahead of this issue, and that is why we have it in our budget.

Mr. SABLAN. Thank you very much. It is very needed, not just for the Northern Marianas but for Puerto Rico, American Samoa, Guam, and the U.S. Virgin Islands. I yield back my time. Thank you.

Chairman KLINE. I thank the gentleman. He yields back. Mr. Barletta?

Mr. BARLETTA. Thank you, Mr. Chairman, and thank you, Secretary Burwell, for being here today.

I was deeply disturbed by a recent Senate report that found the Centers for Medicare and Medicaid Services, which is part of your department, had billed out roughly $750 million in Obamacare subsidies to half a million people who were unable to prove their citizenship or lawful presence in our country.

These tax credits are solely to be used to purchase health insurance by United States citizens and those lawfully residing here. Instead, they were improperly distributed, and the Federal Government will likely never see a cent returned.

This report was just one of many reports that have recently come to light detailing the rapid fraud and waste under Obamacare mismanagement that hard working Americans have had to foot the bill for.

I have been working to fight illegal immigration for more than a decade now, and I find it extremely troubling that, at a time when our national debt is $19 trillion and counting, the Federal Government continues to throw money away with no regard for the consequences.

I would have a hard time explaining to families in my district, many of whom are struggling to put food on the table, as to why they should be helping to pay for the health expenses of someone who broke the law to get here and has no right to those Federal dollars.

Secretary Burwell, whose decision was it to prioritize illegal immigrants over American citizens?

Secretary BURWELL. So, with regard to the Senate report —I take the issues of program integrity and budgets very seriously. You probably know, it was during the years that I was at OMB that we actually had balanced budgets, close to the only time during my lifetime. So I take these issues of program integrity very seriously.

With regard to the Senate report, I think what the Senate report reflects and says is that they were not able to provide—they did not provide—the documentation, we do not know whether they did or did not.

I think with regard to the program integrity that you raised, as one looks at what happened in the first year of the *Affordable Care Act*, and there were about 250,000 people who were taken off last year, in terms of changes, both immigration and income, 1.6 million people in terms of when we reviewed and we were not able to receive the documentation, not knowing whether they could or could not, and that was both for immigration, the immigration number is about 500, and the other number is about—

Mr. BARLETTA. Am I correct in that the tax credits are used, if somebody cannot produce legal documents at the time, the tax credits are used until they can come back, it gives them an opportunity to come back and prove their legal status?

Secretary BURWELL. It is a 90-day period which is given by statute.

Mr. BARLETTA. Right. So, my question is after the 90 days, why then did the Federal Government not go back, why did we not go back to those people after we gave them the tax credits to get the money back of the tax credits that could have been used for someone else?

As the head of an agency that knows what it is like to scratch for every penny, please explain to me how the administration is going to make up to my constituents and ensure that three-quarters of a billion dollars is returned to the American taxpayers?

Secretary BURWELL. With regard to that, that is the regular tax process. For any of these individuals, what will happen is they will owe those in taxes, in terms of reconciling, so the IRS in its processes—

Mr. BARLETTA. We can count on that money coming back?

Secretary BURWELL. So, what will happen is when they go in, this will be reconciled through the IRS process. That is the way the enforcement will occur because it is a tax matter, so it occurs on the IRS side of the house.

Mr. BARLETTA. Thank you, Mr. Chairman.

Chairman KLINE. The gentleman yields back. Ms. Bonamici?

Ms. BONAMICI. Thank you, Mr. Chairman. Thank you, Secretary Burwell. Your work covers so many areas that affect the daily lives of Oregonians and Americans. I appreciate that.

I want to thank my colleague and friend, Representative Stefanik, for bringing up the *Older Americans Act*. I want to ask you about the Home & Community-Based Supportive Services program that funds services like legal assistance, elder abuse and prevention, transportation and meal sites, medical appointments, referral assistance for seniors and their caregivers.

Now, I am supporting the additional $10 million in the President's request as well as many of my colleagues. Why is it important to increase funding for the *Older Americans Act* programs, especially the Home & Community-Based Supportive Services, given the rapidly rising population of older Americans? I do want to save time for another.

Secretary BURWELL. I will just quickly say I think there are two elements. It is about what it means for the individuals in terms of these programs we know are making a difference in terms of supporting people to be able to have care at home, if that is what is appropriate for them. So, it is about the individual.

It is also about the economics as well, in terms of the success of these programs contributes economically.

Ms. BONAMICI. Keeping seniors in their homes, it is less expensive. Thank you. The Oregon Health Science University has been working in collaboration with Intel on genome mapping. That is especially useful in cancer research. The goal is to make personalized genomic analysis faster, less costly, more routine.

What are some of the challenges that research institutions face regarding the collection and sharing of information, and what opportunities might the Cancer Moonshot provide to overcome some of these obstacles in advanced precision medicine?

Secretary BURWELL. Some of the limitations are the fact that the areas of science do not work together, and you actually need an engineer to help deliver through the system. A biologist figures out what it needs, but an engineer actually delivers the delivery mechanism, and we have not broken down those silos as we think about the science. I think it can help with that.

The other thing I think it can help with is data and information, because one of the things, and this is part of what precision medi-

cine is about, making sure data and information can be widely accessed in safe, secure ways. That is both about privacy and cybersecurity. That information can be used widely and broadly to discover and understand more quickly.

It also in the end will save costs because how one accesses information for trials will become easier and less costly, which is a very important cost element to drugs.

Ms. BONAMICI. Thank you. I look forward to working with my colleagues on those important issues. Finally, I think my colleagues brought up the issues with opioid overdose and abuse and all the resulting deaths, and we have had an explosion in my State as well as the country.

I applaud your three-pronged evidence-based approach. Can you talk a little bit about the prong of improving prescribing practices?

Secretary BURWELL. An extremely important part, and the Center for Disease Control and Prevention will be issuing new prescriber guidelines in terms of the issue of how we can talk about these issues and think about these issues.

One of the problems is many physicians say I do not know, I was not trained in this way. We want to get those out and make sure people are using those. When you think that over 250 million prescriptions a year for opioids, we know we do not need that many as a country, so prescribing is an issue, so we are going to target that as an issue, get out new guidelines, and then we need to probably work with the Congress to make sure those guidelines are used.

Ms. BONAMICI. Thank you. I know my State just received about $2.7 million to expand substance abuse services, particularly focused on treating opioid abuse. I know that is not enough. We still have more work to do.

I had a fourth question but the Chairman asked already about preschool development grants, and I look forward to watching that and hope the transition is seamless as the HHS continues to manage those grants.

I yield back. Thank you, Mr. Chairman.

Chairman KLINE. The gentlelady yields back. Dr. Foxx?

Ms. FOXX. Thank you, Mr. Chairman. Secretary Burwell, I want to follow up somewhat on what my colleague, Mr. Byrne, was talking about in his line of questioning, but first I want to say I have heard from employers who self-insure that this transitional reinsurance fee is particularly burdensome to them, depriving them of resources that could be used instead to create jobs.

You asserted that HHS interpreted the law accurately and appropriately. You claim that the comment period for the NPRM resulted in no objections to the Department's interpretation of the law.

However, most of us believe that the NPRM was drafted in such a complicated way that no one could interpret it in the way your department did, where you used convoluted language to create a loophole to justify your reasoning. Given your dubious interpretation of the law thus far—you have heard members of this committee, and you will hear us say we think you have interpreted it wrong. I agree with Mr. Byrne, you have interpreted it wrong. You

are hearing directly from members of Congress that you have interpreted it wrong.

I am now concerned that you are going to find a way to extend the transitional reinsurance program even though the law clearly states that it expires this year. So, could you expand in greater detail your legal interpretation of implementing the transitional reinsurance program contrary to the letter of the law?

Can you commit to this committee that you will follow the letter of the law which states the program must cease collections for the program at the end of this year? Do you plan to distribute funds after 2016?

Secretary BURWELL. With regard to the question of the reinsurance program, I think it is actually important to focus on what the substance of this program is about, and the substance of this is an issue that we have actually talked about in a number of places, which is pressure on costs, and you were indicating another space, in terms of this is about putting downward pressure on costs by creating an ability for the issuers in a new market.

This is one of the transitional programs, and there are no plans to extend it beyond.

Ms. FOXX. Okay. So, you consider the transition period time is over?

Secretary BURWELL. We have no plans to change our reinsurance time table that was set out. Risk adjustment is the only program that will continue beyond right now.

Ms. FOXX. Okay. When you say "we have no plans," would you be a little more explicit, you will or you will not?

Secretary BURWELL. I am being very clear, we have no plans. We just issued our rulemakings - our Proposed Notice, a Payment Notice—there is nothing that indicates anything that we do other than where we are.

Ms. FOXX. Alright. Madam Secretary, I have some other questions, but Mr. Chairman, in the interest of time and my colleagues, I will yield back the balance of my time.

Chairman KLINE. I thank the gentlelady. Mr. Pocan?

Mr. POCAN. Thank you, Mr. Chairman. Thank you, Madam Secretary, for being here today. I am trying to get to three subjects in four minutes. I am going to try to go fast.

Does the name Brent Brown from Wisconsin ring a bell to you? This is a gentleman who wrote a letter to the President, and I would like to ask unanimous consent to enter this letter into the record.

Chairman KLINE. Without objection.

Secretary BURWELL. I do know.

Mr. POCAN. Yes. A gentleman who had spent his entire life savings on health care, he was literally a dead man walking, could not get health insurance because he had a preexisting condition, and because of the *Affordable Care Act*, he is alive today.

What is unique about the letter, and I just want to read two or three of the paragraphs, this is in his letter, "I probably wore pins and planted banners to display my Republican loyalty. I was vocal in my opposition to you, particularly the ACA. Before I briefly explain my story, allow me to say this, I am very sorry. I understand written content cannot convey emotions very well, but my level of

conviction has me in tears as I write this. I was so very wrong, so very wrong." He goes on to explain about his preexisting condition and had it not been for the *Affordable Care Act*, he would not be alive today.

So, I just think that is a wonderful example and story, and more importantly, part of his appeal was to try to tell people maybe on the other side of the aisle who have been trying to repeal this for 63–64 times, you know, maybe it is time to move on. I just wanted to mention that.

One of the issues that came up was about the *Affordable Care Act* when it first came out, that on the employer rolls you were going to reduce employees because of the part-time hour commitment, do you very quickly have any updates on that, how we're doing?

Secretary BURWELL. We have seen no evidence, and we have continued the recovery in terms of involuntary part-time employment. The involuntary part-time employment increased as part of the recession, but we continue to see progress and a normal recovery, so there are no analytics that show there has been an impact in terms of part-time work.

Mr. POCAN. Great. Thank you. I know a number of us talked about opioid abuse. I would like to talk about something different than behavioral health, mental health issues.

I know that while the opioid issue is really getting a lot of attention right now, I think mental health issues, especially as someone who is a former legislator, 25 to 30 percent of the people in the prison system in Wisconsin are there for mental health. If they were there because they had cancer, people would be in the streets, but that is not how we are dealing with this issue and the amount of costs that go into it, very supportive of the President's budget and the increases he is trying to do.

I just want to make sure we are keeping the focus on mental health as we do this because not just the State government, in Wisconsin, that is $250 to $300 million a year just for the people who have mental health in the corrections system, but in the local jails, local government, et cetera.

I think it is really sad commentary on how we treat the disease and not have enough efforts there, and anything we can do would be much appreciated.

Secretary BURWELL. I think the *Affordable Care Act* together with the *Mental Health Parity Act* are the two most important steps we can make as a Nation to get parity in this space.

Mr. POCAN. Great. The final issue I just want to raise in the last minute I have, prescription drugs. One of the issues that we have seen is prices are rising again, going up. I recently was at our VA, and he was telling me about what he had to do for one of his patients, a drug that was $125,000 a dose.

We know that recently companies like Pfizer are trying to do tax inversions so they do not have to pay taxes here and go to Ireland, by buying a smaller company, yet at the same time, they are not going to charge us the prescription prices that they pay in Ireland, which is considerably less than they are paying here.

I would just like to advocate for anything we can do and you can do within your department to help us look at that issue because I

think we may need to work with those folks working on inversions, because I think it is a real tragedy that we are paying more and more for prescription drugs, including 27 percent, I think, of mental health is on prescription drugs, and we need to do something more.

Secretary BURWELL. High cost drugs is a priority, and there are a number of elements in the budget we think would help address it.

Mr. POCAN. Thank you. I yield back.

Chairman KLINE. The gentleman's time has expired. Mr. Bishop?

Mr. BISHOP. Thank you, Mr. Chairman. Thank you, Madam Secretary, for your testimony this morning.

On February 19, as part of the Fiscal Year 2017 Medicare Advantage Rate Notice, CMS proposed a cut to Medicare Advantage employer group waiver plans, otherwise known as Medicare Advantage retiree coverage, 3.3 million seniors received their Medicare Advantage coverage through this plan.

In fact, in Michigan alone, there are more than 300,000 retirees, including labor unions, State and local government, and private employer retirees who rely on Medicare Advantage retiree coverage.

These proposed cuts would jeopardize the high quality care that they depend on for their health and financial security. That is why, last week, my colleague, Representative Debbie Dingell, and I, led a bipartisan Michigan delegation letter that included 11 of our colleagues in Michigan, to raise concerns with regard to the impact these proposed cuts would have on our constituents, and we also urged the agency to remove the cut to the Medicare Advantage retiree coverage from the final rate notice.

Earlier this month, the UAW Retiree Medical Benefits Trust, which provides health coverage to retirees and their dependents of the United Auto Workers Union, who formerly worked for the Michigan Big Three (GM, Ford, and Chrysler) submitted comments to CMS expressing concerns with CMS' proposed cuts to Medicare Advantage retiree coverage and the impact these cuts would have on their retirees.

The Trust currently provides coverage to 719,000 people. Of this population, 534,000 are covered by Medicare. The Trust offers their retirees a choice of plans in which they can enroll. At the present time, 161,000 of these retirees have selected and are covered by Medicare Advantage plans.

In comments submitted to CMS, the UAW Retiree Medical Benefits Trust expressed concerns that the proposed cuts to Medicare Advantage retiree coverage might result in diminishing the quality of care available to retirees and the proposal would lead to substantial reduction in payment to employer group waiver plans, thereby resulting in premium increases and/or benefit reductions.

This leads me to my question. I did send you this letter, and I appreciate the fact that you have acknowledged receipt of that letter. Thank you very much for that.

Having said what I just said, and the grave concerns they represent to in particular my constituents in the State of Michigan, can you tell me whether or not CMS considered the impact the cuts to the Medicare Advantage retiree coverage would have on the 3.3

million seniors who depend on this form of coverage when developing the Advanced Notice?

Secretary BURWELL. So, we did, and appreciate that, and appreciate the letter you have sent. We are in an open comment period, so welcome the comments and the concerns. We did consider this issue.

We actually looked to our experience when we did this change in Part D. We did not see the impact that folks are saying could happen. We did not see that impact occur. We, like you, want to make sure affordability is an important part of it in our work, but we try to balance affordability for the individual as well as affordability for the taxpayer with the Medicare dollars, and feel it is a proposal that meets those, but we want to continue to hear the comments and see if there is something that would distinguish it from the experience we previously had.

Mr. BISHOP. Have you responded to the UAW's concerns?

Secretary BURWELL. Probably because it is a part of the comment and the rulemaking process, most likely we took it in as a formal comment, but I am not sure how they did it, whether it was in the form of a letter or a comment. I do not know specifically, but it will most likely be a part of the record for the comment period.

Mr. BISHOP. Thank you, Madam Secretary. I yield back.

Chairman KLINE. The gentleman yields back. Mr. Takano?

Mr. TAKANO. Thank you, Mr. Chairman. Madam Secretary, it is truly a pleasure to hear from you this morning about your department's priorities. I am glad to hear about the administration's continuing commitment to programs that support working families, educate our children, and keep Americans healthy.

First, I would like to ask you about the Department's work to support LGBT seniors. As you may know, the Congressional LGBT Equality Caucus, of which I am co-chair, has formed an LGBT Aging Issues Task Force. We sent a letter to Administrator Greenlee asking for ACL to require each State plan to assess whether State units on aging are meeting the needs of the LGBT community in their area.

As you know, LGBT elders have poorer physical health, worse mental health, lower income, and fewer close ties on average than other seniors.

Can you speak to whether ACL will be rolling out a guidance focused on LGBT older Americans, and if not, what will they be doing to assist this aging population?

Secretary BURWELL. With regard to this population, which as you articulated has a higher level of challenges than other parts of our elderly populations as a nation, there have been a number of steps that we as an entire department have taken in this space.

I think you are familiar with our LGBT Coordinating Committee, which is a part of what has led to another thing that will be coming to fruition, which I think is a very important part of understanding the problem better, which is data collection, a five-year data collection, that will be targeted, so we can better understand the specifics of both what is happening in terms of the results, but what is causing many of the things you talked about in terms of the discrepancies that we see among the elderly.

The third piece that I would actually mention is we have created a National Resource Center, specifically focused on LGBT issues, for communities to access so they can find out information and better serve the community.

So, we are going to continue to work on these issues, appreciate your leadership, and look forward to continuing with the things you think we can do more in this space.

Mr. TAKANO. Well, thank you, Madam Secretary. I wonder if you would be willing to have a meeting with the members of the LGBT Caucus to discuss these important issues?

Secretary BURWELL. I am sure that we and our team can figure out how we can do that and the best way to get action taken.

Mr. TAKANO. Wonderful. Madam Secretary, in your testimony you mentioned the administration's commitment to growing our health care workforce by making continued investments in the National Health Service Corps, and graduate medical education.

Ensuring that we have a robust health care workforce is one of my top priorities. In Riverside County, which I represent, there are only 34 primary care physicians for every 100,000 people. Half the number of doctors needed to provide adequate access to care.

Can you share more about the administration's efforts to guarantee we have the health care workforce that we are going to need?

Secretary BURWELL. So, it has a number of different elements. You mentioned one in terms of the National Health Service Corps and our emphasis on the National Health Service Corps, and building that up, and continuing to add members to the Corps.

In addition, the funding that we do for HRSA, our Health Resources Services Administration, is another important part of making sure that we are building up a Corps.

I think the other thing is how we do the policies. Our graduate medical education funding proposal, we actually shifted to the mandatory side because we believe that funding should be a dependable, continual part of funding, so we are encouraging people to go into these fields and know they will have an ability to have help with their loans.

The other thing that I would mention is the focus on primary care, because we believe that is at the center and core of transitioning our system to where people have primary care homes.

So, it is both in policy and funding across the Department that we are working on the issue of making sure we have enough health providers.

The other thing is people at the top of their licenses, right now, we want to make sure there is more access for nurses and others to be able to do certain types of functions, and lastly, telemedicine. There are three proposals on that.

Mr. TAKANO. Mr. Chairman, I almost made it. I am sorry.

Chairman KLINE. The gentleman's time has expired. Mr. Rokita?

Secretary BURWELL. I am sorry. That was me, sorry.

Mr. ROKITA. I thank the Chairman. Thank you for coming, it is good to see you. On behalf of the Governor of the State of Indiana, Mike Pence, and many of us in the State, thanks for working with us on what we call "HIP 2.0," consumer driven health care, that I think will be a model to help the Department and others around

the country really get at cost constraints while serving more people. Thank you for your cooperation and leadership in that regard.

Secretary BURWELL. Thank you.

Mr. ROKITA. I wanted to talk to you a little bit about the budget this morning. I thought I heard in your opening statement that you were able to get savings from Medicare and Medicaid, or did I misunderstand that?

Secretary BURWELL. There are Medicaid proposals as well as Medicare proposals.

Mr. ROKITA. I heard Medicaid and Medicare reforms.

Secretary BURWELL. Yes.

Mr. ROKITA. You did not mean spending reforms or did you mean spending reforms? What is the effect of the reforms?

Secretary BURWELL. Savings. The effect is savings, $419 billion for Medicare, Medicaid, and other areas.

Mr. ROKITA. Over the 10 year window?

Secretary BURWELL. That is right.

Mr. ROKITA. Thank you. In your written statement on page two, you say that taken together, there is an estimated savings of $242 billion over 10 years. What is the difference in those numbers?

Secretary BURWELL. We pay for our child care. We pay for the other mandatory issues, so we pay for. That is the savings in that space, the entitlement space. We use some of that for savings and we use some of that to do things like fund child care.

Mr. ROKITA. Thank you. How do you save, in terms of Medicaid particularly, how do you save money when I thought CBO's January report said Medicare spending will grow by $200 billion in 10 years, what is your—

Secretary BURWELL. Medicare or Medicaid?

Mr. ROKITA. Medicaid.

Secretary BURWELL. Medicaid spending. With regard to some of the proposals in the Medicaid space, one of the proposals, and I will have to see if this is one of the ones that scores into those numbers, but what we want to do is work with States so they can do purchasing for drugs together, help States do combined purchasing, which can drive down Medicaid costs for them and for us. That one, I have to check to see if it is one of the scorable ones, but those are the types of things that we are looking at.

Mr. ROKITA. Okay. What do you think about flexibility grants or block grants or making finite—instead of an open-ending fee for service kind of structure—what about taking a finite amount of money and saying look, this is what you have to spend, State X, find out who really is poor, what the poor really need, and how the poor should get it?

Secretary BURWELL. So, I think the question of capping Medicaid—the concerns we have with it are front and center right now in Puerto Rico, where we have almost 250 cases of Zika, we have over 10 cases of pregnant women who have tested for Zika, and you have a situation where you have a population whose needs were not being met before this started, and then you have a situation like Zika layered on top.

So, having a program that is about the ability to be flexible with the needs of the people, to meet the needs, what—

Mr. ROKITA. That example is a little extreme. That is what a supplemental funding measure could be for, something like that. We do not have to—

Secretary BURWELL. I hope that is an expression of support for our Zika sup——

Mr. ROKITA. Well, it is an expression that Congress can act in emergencies, and you are describing an emergency. You are not describing day-to-day, in Puerto Rico. I am running out of time, so thank you.

This is not meant to be a political "gotcha" in any way, but I clearly remember and see evidence where the President in 2008 when he was running for office the first time said he would be able to lower insurance premiums with his *Affordable Care Act* at $2,500 per family on average.

Your testimony describes the fact that we have slowed the growth in health care costs. What happened? What is different?

Secretary BURWELL. I think in terms of that number, that is the projected growth, the amount of the projected growth, the—

Mr. ROKITA. He said lower premiums.

Secretary BURWELL. With regard to the specifics, I apologize, I am just—

Chairman KLINE. I am sorry, the gentleman's time has expired, and we are rapidly approaching—Ms. Clark?

Ms. CLARK. Thank you, Mr. Chairman, and thank you, Secretary Burwell, for not only your testimony today but the incredible work that you are doing. I especially want to highlight your commitment to addressing the opioid crisis, coming from a State like Massachusetts where it has just been a devastating effect, we so appreciate your partnership and your commitment.

I specifically want to ask you about adolescents and young adults. I have spoken with many experts who treat this population. They have been clear that this population needs special protocols to be able to tailor the treatment to their unique social and biological needs. They are also clear there has not been enough emphasis on programming or research in this area.

Can you discuss any efforts that are underway to target action towards young adults and adolescents, and if you see this as an important area for fighting the opioid crisis?

Secretary BURWELL. So, with regard to the fighting it in the here and now, a couple of elements and steps. One is you are right, because what happens is—I heard a story this past week of a young person at Cornell, an athlete injury, got on the opioids, overdosed and is dead.

So, there is special need especially because of these athletic injuries, this gets to the prescribing guidelines, and making sure there are alternative approaches to helping these students and young people through their pain and their athletic injuries. That is one whole category.

There is another category that we know sadly that while I think people think alcohol is an okay alternative for these young people, it is not, because I think what we know is that is a gateway often to the prescription. Those that are participating in those activities are more likely as they get older to participate in other activities.

That is the here and now and things we need to focus on. The research that we need to do with regard to the question of opioids across the board is a broad part of the research. The questions of does it help for long-term pain and acute pain, that sort of thing, and making sure we are thinking about young people as we do the research is a more longer term issue but one we need to focus on.

Ms. CLARK. And one we would love to work with you on. I want to quickly get back to Zika. You spoke about some startling numbers, even here in the United States. Every day we are seeing more of the connection being verified by research about the connection and danger for pregnant women. We are also seeing countries around the globe that have very restricted access to family planning for women saying do not become pregnant at this time.

Can you elaborate on what is being done both here at home and abroad to make sure that women have access to a full range of health care options?

Secretary BURWELL. So, three fundamental things as part of the strategy. Number one, a deep focus on pregnant women because of the concerns around microcephaly, and the very extreme birth defects that can occur with women who have Zika while they are pregnant.

Number two, communication, making sure we are reaching as many people as possible who are either traveling to that region or have a partner who has traveled to the region, because we know sexual transmission is possible. So, communicating about the guidelines as much as we know as quickly as we know.

And number three is making sure that we are focused on the research that we need to do to understand more about the disease, including how to do better vector control. This is a disease that is spread by a mosquito that can bite four people in one setting. It is an indoor mosquito. It can breed in a capful of water. It is a very difficult mosquito to control.

We are continuing to use best practices, but more research on the disease, on the vaccine, and the vector need to be done.

Ms. CLARK. Great. Thank you.

Chairman KLINE. The gentlelady's time has expired. We are shrinking the available time even more. I am telling my colleagues as we are moving towards the hard stop. Mr. Allen, you are recognized for three minutes.

Mr. ALLEN. Thank you, Mr. Chairman, and thank you, Madam Secretary, and thanks for your call, by the way. I am sorry I did not get back to you.

I wanted to just comment on a couple of things. One is you mentioned you have lowered the taxpayer growth in Medicare. I need some background on that, because I am not seeing that, so if you could get that to me.

The other number that I am seeing is "totally insured." I am not seeing that in my district. In fact, a very small percentage of my district is insured. In fact, doctors tell me at the emergency room that nothing has changed, many people are showing up without insurance as before.

Also, on your comment about you do not pay more for preexisting conditions, I met a lady yesterday that told me about her son and his condition, and she wanted to know why his premiums had got-

ten so high and his deductible was like $10,000. I said well, I will get an answer for you. I need you to get that to me.

Last but not least, the President signed into law, and I voted for, the Hyde Amendment, which was an attachment to the appropriations bill. How are you monitoring your funding of these various claims that no taxpayer funds are being used for abortions? How do you monitor that, and what are you doing to oversee that?

Secretary BURWELL. With regard to where that would occur, it would occur in HRSA, the Health Resources Services Administration, which are the clinics that we fund directly, and there are stringent guidelines with regard to that, that the clinics both know and are educated on, so it is not just a matter of telling the clinics, it is a matter of HRSA making sure they know and understand what those guidelines are so we can follow them.

Mr. ALLEN. You are auditing these clinics?

Secretary BURWELL. With regard to the specifics of how that goes, I will come back to you.

Mr. ALLEN. Okay. Alright. The other thing, we have some States that are opting out of the Exchanges. I think Oregon and Kentucky is talking about getting out of the State Exchanges and going back to the Federal Exchange.

Do you want to explain why that is going on? I mean our governor was criticized because he did not opt to go into the State Exchange, because he knew eventually the Federal Government was not going to fund it any more. Of course, in Georgia, we are required to balance our budget. He did not think the funds would be there.

What is your take on this?

Secretary BURWELL. With regard to either approach, I think it is about a State's choice and a decision in terms of whether or not they want to do the setup of the piece that will attach their consumer to their ability to access it.

In Kentucky, it is a system that is a well-integrated system that helps with and creates efficiencies for both their CHIP and Medicaid. I think they decided to do it because it creates that. Other States choose not to and use the Federal marketplace.

Either way can work as a system. We just want to work with States to do what is their preference as a State.

Mr. ALLEN. I yield back.

Chairman KLINE. The gentleman yields back. Ms. Wilson?

Ms. WILSON. Thank you, Mr. Chair. Welcome, Madam Secretary.

Secretary BURWELL. Thank you.

Ms. WILSON. Unfortunately, Florida, my State, is one of 19 States that has failed to expand Medicaid under the ACA. Can you speak to why Medicaid expansion is so important for communities of color, especially in my home State, and across the country?

Secretary BURWELL. So, while we have made great progress in terms of communities of color, 3 million uninsured reduction in the African American community, 4 million in the Latino community, we know that the uninsured rates are still disproportionately high. We know that if Medicaid expansion occurs, that a disproportionate number of folks that are minorities will be covered.

So, we are excited to continue pushing and pushing hard because we think it will have a disproportionate benefit to communities of color.

Ms. WILSON. Our governor has repeatedly rejected expansion, citing budget restraints. Can you speak to how Florida and other States may actually see budgetary relief under Medicaid expansion?

Secretary BURWELL. So, what we know, and the University of Louisville together with Deloitte has done a piece of work and a piece of research on their work and their expansion, and it led to the creation—it would lead to the creation by 2021 of 40,000 jobs, as well as $30 billion flowing into the State.

We know we see reductions in uncompensated care for hospitals and communities across the State when expansion occurs. It is about the individual, but it is also about the economic impact.

Ms. WILSON. How are we assured that our communities of color are getting the information they need to successfully enroll?

Secretary BURWELL. One of the things we do during open enrollment, and I had the opportunity to spend a lot of time in your State, have gone to every place from beauty salons to barber shops, because we need to meet people where there are trusted voices.

In Texas, actually in all States, we do second Sunday, where on Sundays, we work with the faith communities across the States to help people get information that is important information from trusted voices.

Ms. WILSON. Just keep up the good work. I yield back.

Chairman KLINE. The gentlelady yields back. Mr. Carter?

Mr. CARTER. Thank you, Mr. Chairman. Thank you, Madam Secretary, for being here. Madam Secretary, as you know, I am a pharmacist, so I am very concerned about issues, obviously, dealing with patients and dealing with them getting their medications.

Specifically, I wanted to ask you about compounding, compounding for office use only. I am very concerned about the FDA interpreting legislative intent, and certainly this is something that comes into play when we are talking about for office use only.

I know the FDA continues to prevent medications to be compounded for office use only, and what this causes is for the patients to have to go back to the pharmacy, get a specific prescription, compound it for them, then go back to the doctor to have it applied.

I am wondering where you are at in that process? Many States have already allowed for this to take place. Many States have already had regulations and laws in place that allow for office use only, for compounds to be made, and for the physician to have them there in the office where the physician has the ability to apply and use that medication instead of the patient having to go get a specific prescription filled for them as opposed to having it for office use only.

I just want to know where we are at in that process.

Secretary BURWELL. So, we do not have any guidance out preventing that, so maybe I can follow up with your staff to understand, that our team can follow up to understand. We welcome the input on the guidance on the issue.

It does not exist, so right now, compounding should be occurring.

Mr. CARTER. Compounding is occurring—

Secretary BURWELL. There is not a problem in terms of any guidance or any rules about it right now.

Mr. CARTER. I beg to differ. The problem is you are requiring each specific patient to have a specific prescription for medication, for a compounded medication. What in the past we have been able to do is just to supply—

Secretary BURWELL. In the doctor's office?

Mr. CARTER. Exactly, with a compound that is for office use only, in which they can apply that medication.

Secretary BURWELL. It is my understanding that is able to be done—if there is something that is happening that is not, that is why I would like to follow up because what you are articulating is not my understanding. Let's understand.

Mr. CARTER. Absolutely.

Secretary BURWELL. Is it a State issue or something else or maybe we are not communicating.

Mr. CARTER. We are looking for guidance from the FDA on this, and this is an issue that we are very concerned with because again it has to do with patient care. We want to make sure that patients are getting the care they need.

Secretary BURWELL. And we would like your input on any guidance that we would do in this space.

Mr. CARTER. Okay, thank you. Mr. Chairman, I yield back.

Chairman KLINE. I thank the gentleman. Ms. Adams?

Ms. ADAMS. Thank you, Mr. Chair, and thank you, Madam Secretary, for being here. I am going to move along quickly. I just want to give a shout out to my police department in High Point for the work they are doing in opioid abuse, and I thank you for your work.

Let me ask you about the health of our Nation's most marginalized young people as it relates to sexual health services. A lot of data and research performed by CDC, American Academy of Pediatrics, and even your Office of Adolescent Health show that far too many young people in the U.S. face barriers accessing and receiving adequate health care services regarding sexual health education.

So, can you please speak to existing efforts that HHS is leading to ensure that our Nation's youth, especially those most vulnerable, have the education, skills, and access to sexual education services?

Secretary BURWELL. So, across the board in terms of our tools, it is our community clinics that we have talked about. It is the CDC, as you mentioned. It is also our funding in terms of access through Title X. Those are three different ways we do that.

Also, some of the most vulnerable that you are talking about are through our minority health issues as well, so that is the other place I would mention that we work on these issues.

Ms. ADAMS. One follow up. So, what is the administration doing to address not only the Southern States that are disproportionately affected by HIV disease, but also the rural communities that are seeing the majority of the diagnoses?

Secretary BURWELL. There is $54 million in minority health for HIV specifically proposed in our budget that we will hope will continue these efforts and work with those Southern States that have a disproportionate number, like North Carolina.

Ms. ADAMS. Okay. Thank you very much. Mr. Chairman, I am yielding back.

Chairman KLINE. I thank the gentlelady. Mr. Thompson?

Mr. THOMPSON. Thank you, Mr. Chairman. Secretary Burwell, thank you so much for the phone call, very much appreciate you reaching out.

I just want to note the current crisis with the opioids, there is obviously some impact from infants to the elderly. We need to approach this from a broader perspective, this is symptomatic. I view it as a broader epidemic of substance abuse. It does not matter how large or how small the community is, it is present.

This is kind of an all hands on deck for the Executive Branch, Legislative Branch, and all of the partners, we need to be working together.

My question though is regarding access to health care. In your testimony, you state that through targeted investments, the administration's budget expands access to health care, particularly for rural and underserved areas. I represent Pennsylvania's Fifth Congressional District. It is the State's most rural, largest congressional district, about 24 percent of the land mass. I know rural. I know it well.

As a former health care provider for almost 30 years, access requires the presence of providers in our communities, first. I do not care how you pay for it or all the other moving parts of it. You have to have that access. There has to be a presence.

Really, a tremendous concern considering the fact that more than 45 rural hospitals have closed since 2010, and approximately 300 others are in danger of closing. I struggle to understand how these facts support your conclusion that the *Affordable Care Act* is having a positive effect on the well-being of employers, employees, providers, health care professionals, and most importantly, patients in rural areas.

Can you expand on your statement in regard to those facts? That is a trend line that is not good and it scares me.

Secretary BURWELL. It is a trend line that started before the passage of the *Affordable Care Act*, and it is a trend line that has a number of different elements that contributed to it, and I think as you articulated, as you described your district, the issues of population density, the issue of providers being willing to go to places where there is not a lot of population density in terms of their choices they make, as well as one of the contributors I think we do see is uncompensated care in the form of Medicaid expansion.

So, we do see a difference in the places where it has expanded, and the number of hospitals that are closing. We see a reduction in that because of the reduction in uncompensated care.

Mr. THOMPSON. Obviously, I keep my finger on the pulse of this because that was my life, working to provide access to cost effective care. I see rapid expansion monopolies, that compounds it by raising costs, monopolies tend to do that, it takes the pressure off for increased quality. I think there are a lot of issues going on, and I would say they have been compounded since that time.

Thank you so much. I look forward to continuing the discussion offline.

Chairman KLINE. The gentleman yields back. We have rapidly run out of time. Let me yield to Mr. Scott for any closing remarks he might have.

Mr. SCOTT. Thank you, Mr. Chairman. Madam Secretary, I thank you particularly for your comments on the *Affordable Care Act*, where we have changed the situation from thousands of people every day losing their insurance to millions more being covered, and the cost savings, rather than often double digit increases to the lowest increases in modern history, showing a significant savings over what the costs would have been had it not for the *Affordable Care Act*. And people with preexisting conditions with no insurance to being able to get insurance at standard rates, and more progress could be made if Medicaid were expanded in those States, and those with insurance are actually picking up a lot of that cost, because of uncompensated care is cost shifted to those with insurance.

I appreciate your response to the opioid situation. Finally, I think we are getting a consensus that early intervention and prevention is better than hospitalization and jails.

We put all the money in the criminal justice system, and when have you ever heard a dealer tell a customer I could not get any heroin today because the police have cracked down, and a customer say, oh, my God, my dealer got busted, I cannot get any heroin.

All that money spent on the criminal justice system could have been spent on research-based and evidence-based approaches that would actually reduce the amount of opioids being consumed.

Appreciate your work with Head Start, homeless youth. We did not get into foster care. I do appreciate your request for additional resources in foster care to achieve permanent placements, to the extent that we can get young people on the right track and keep them on the right track, we will have fewer problems in the future.

And finally, I express appreciation for your effective response to Zika, and the request you have made, I hope we can fund that, and to Flint, Michigan.

So, thank you for your testimony, and look forward to continuing to work with you.

Chairman KLINE. Madam Secretary, I want to thank you also. I want to thank you for your testimony, for your service, for your engagement with the members here, and for allowing us to go three minutes over the closing time.

There being no further business, the Committee stands adjourned.

[Additional submission by Mr. Carter follows:]

EARL L. "BUDDY" CARTER
1st District, Georgia

EDUCATION AND THE WORKFORCE COMMITTEE

COMMITTEE ON HOMELAND SECURITY

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March 22, 2016

The Honorable Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell:

Thank you for your testimony to the House Education and the Workforce Committee on Tuesday, March 15, 2016.

During the hearing, I questioned you about "office-use" compounding and the guidance, or lack thereof, by Food and Drug Administration (FDA) concerning the use of "office-use" compounding related to physician offices. I specifically asked whether the FDA was going to issue guidance on the current confusion with its interpretation and implementation of the Drug Quality and Security Act (DQSA) in regards to both compounded and repackaged medications for "office-use."

Over the last 18-months, the FDA has stated several times that a compounding pharmacist or physician may not dispense compounded medications for "office-use" without first obtaining or issuing a prescription for an individually identified patient. This move has caused many States to take action limiting "office-use" compounding. Your response to my questioning indicating that there is nothing preventing a 503A pharmacy from compounding for "office-use" purposes failed to address FDA guidance that has yet to clarify that 503A pharmacies will be exempt from individual prescription requirements. In addition, you omitted the fact that 503A pharmacies are currently being regulated under Good Manufacturing Practices (cGMPs) standards rather than U.S. Pharmacopeia (USP) Convention standards, which have been the standards for 503A pharmacies for years. As such, FDA has ignored that its actions have, in some cases, denied access to life-saving medications in a timely manner when manufactured products are unavailable or do not fit a patient's needs.

In addition, I am concerned the FDA's application of DQSA section 503A requirements to 503A pharmacies in the same manner as large outsourcing facilities is placing undue burden on 503A pharmacies and the patients they serve. Pharmacies that produce small amounts of compounded products in advance of receiving a patient-specific prescription and practice within States where "office-use" is authorized and regulated by State Boards of Pharmacy should not be the focus of FDA oversight. Oversight by FDA of 503A pharmacies is unreasonable and was not Congress' intent during passage of DQSA.

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To address these concerns, please respond to the following questions:

1. It is my understanding that FDA is currently working on guidance to clarify that 503A pharmacies, who are regulated by State Boards of Pharmacy, will be exempt from DQSA requirements when participating in "office-use" compounding. When can we expect FDA to release this guidance?

2. For years, 503A pharmacies have operated under the standards contained in the U.S. Pharmacopeia (USP) Convention for sterile and non-sterile compounding. What prompted FDA to begin inspecting these 503A pharmacies under current Good Manufacturing Practices (cGMPs) as opposed to USP standards?

3. The FDA has begun inspecting state licensed 503A pharmacies using cGMP standards rather than USP standards or other applicable pharmacy inspection standards adopted by state law or regulation in the state where the pharmacy is licensed. Section 105 of DQSA states that any finding by the FDA must be turned over to the appropriate State Board of Pharmacy for review and consideration of corrective actions to bring the pharmacy back into compliance with state law. What authority, with clear congressional intent to state otherwise, does FDA have to inspect 503A pharmacies with cGMPs when federal oversight of 503A pharmacies was never the intent of Congress?

Thank you for your attention to this important matter. Please address the questions and topics set forth within 10 business days.

Sincerely,

Earl L. 'Buddy' Carter

Earl L. 'Buddy' Carter
Member of Congress

[Additional submission by Chairman Kline follows:]

Statement
of the
U.S. Chamber
of Commerce

ON: ***"Innovations in Health Care: Exploring Free-Market Solutions for a Healthy Workforce"***

TO: ***THE HOUSE EDUCATION AND THE WORKFORCE COMMITTEE'S SUBCOMMITTEE ON HEALTH, EMPLOYMENT, LABOR, AND PENSIONS***

DATE: ***April 28, 2016***

The Chamber's mission is to advance human progress through an economic, political and social system based on individual freedom, incentive, initiative, opportunity and responsibility.

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system.

More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented. The Chamber has membership in all 50 states.

The Chamber's international reach is substantial as well. We believe that global interdependence provides opportunities, not threats. In addition to the American Chambers of Commerce abroad, an increasing number of our members engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

Statement on
"Innovations in Health Care:
Exploring Free-Market Solutions for a Healthy Workforce"
Submitted to
THE HOUSE EDUCATION AND THE WORKFORCE COMMITTEE'S
SUBCOMMITTEE ON
HEALTH, EMPLOYMENT, LABOR, AND PENSIONS
on behalf of the
U.S. CHAMBER OF COMMERCE
April 14, 2016

The U.S. Chamber of Commerce, the world's largest business federation representing the interests of more than three million businesses and organizations of every size, sector, and region, appreciates this opportunity to provide a statement for the record as part of the House Education and the Workforce Committee's Subcommittee on Health, Employment, Labor, and Pensions April 14, 2016, hearing titled "Innovations in Health Care: Exploring Free-Market Solutions for a Healthy Workforce." The Chamber and its members continue to strongly support employer-sponsored health care coverage and the innovations it produces throughout the health care system. We have summarized our views, and the views of the employer community, below for the record.

The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system. More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large. Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented.

The Chamber and its members have long championed the invaluable benefits that the employer-sponsored health care system provides to both employees and employers alike. As Subcommittee Chairman Roe and Subcommittee Ranking Member Polis noted in their opening statements, more than 175 million Americans currently rely on health insurance through employer-sponsored plans, making it the most popular form of insurance today. Most importantly, the employer-sponsored system allows employers to customize the benefits offered to best serve the needs of their workforce and manage cost growth in health care.

Employer-sponsored health coverage has always been an important component of employee compensation and is also critical for businesses to attract and retain employees. The private sector has played an essential role in benefit developments that are improving health, reducing unnecessary costs and rewarding high value care throughout the health care system. Employers have crafted workplace wellness programs, disease management and care coordination initiatives, value-based insurance incentives, and health information technology resources to improve the health of their employees.

As the witnesses demonstrated, employers have driven recent advancements in health care coverage through the adoption of workplace wellness programs, the implementation of private exchanges, use of the Accountable Care Organization (ACO) model, and the integration of telemedicine into plans. However, providing affordable health insurance coverage is becoming progressively more challenging with new restrictions on plan design and new requirements governing employer-sponsored coverage.

For example, despite being incentivized under the Affordable Care Act (ACA), employer wellness programs are currently in a state of limbo. Employers whose programs are compliant with the Health Insurance Portability and Accountability Act (HIPAA) and the ACA cannot be sure that they will not be sued by the Equal Employment Opportunity Commission (EEOC). In 2014, EEOC filed several high profile cases against employers that alleged that the employers' wellness programs were not voluntary under the Americans with Disabilities Act (ADA). Since then, the EEOC has released proposed rules seeking to incorporate a variety of new restrictions on workplace wellness programs. Onerous regulations like these will deter employers from being able to innovate and offer workplace wellness programs best suited to their employees' needs.

Any forthcoming health care reforms must take into consideration the vital role of the employer-sponsored system in facilitating the innovation and creativity that is happening in the private sector offering of health care coverage. As the foundation of our health care system, we support flexibility for our nation's employers as they continue their commitment to providing innovative, sustainable and high-value care for all Americans.

The Chamber thanks you for taking the time to hold this important hearing on the importance of encouraging innovations in health care and how employers continue to support a healthy workforce. We look forward to working with you as you continue to examine this important issue. Please do not hesitate to contact us if we may be of assistance in this matter.

[Additional submission by Mr. Pocan follows:]

http://letterstopresidentobama.tumblr.com/post/140398509929/meet-brent-brown-from-mosinee-wisconsin-he-never.

To My President,

I sincerely hope that this reaches you, as far too often praise is hard to come by. Apologies to people who deserve it perhaps even less so.

I did not vote for you. Either time. I have voted Republican for the entirety of my life.

I proudly wore pins and planted banners displaying my Republican loyalty. I was very vocal in my opposition to you–particularly the ACA.

Before I briefly explain my story allow me to first say this: I am so very sorry. I understand written content cannot convey emotions very well–but my level of conviction has me in tears as I write this. I was so very wrong. So very very wrong.

You saved my life. I want that to sink into your ears and mind. My President, you saved my life, and I am eternally grateful.

I have a 'pre-existing condition' and so could never purchase health insurance. Only after the ACA came into being could I be covered. Put simply to not take up too much of your time if you are in fact taking the time to read this: I would not be alive without access to care I received due to your law.

So thank you from a dumb young man who thought he knew it all and who said things about you that he now regrets. Thank you for serving me even when I didn't vote for you.

Thank you for being my President.

Honored to have lived under your leadership and guidance,

Brent Nathan Brown

[Questions for the record and their responses follow:]

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September 9, 2016

The Honorable Sylvia Mathews Burwell
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell:

Please find enclosed additional questions submitted by Committee members following the hearing on "Examining the Policies and Priorities of the U.S. Department of Health and Human Services." Please provide written responses no later than September 23, 2016, for inclusion in the official hearing record. Responses should be sent to Callie Harman of the Committee staff. She can be contacted at (202) 225-7101.

Thank you again for your contribution to the work of the Committee.

Sincerely,

John Kline

JOHN KLINE
Chairman
Committee on Education and the Workforce

Enclosure

cc: The Honorable Robert C. "Bobby" Scott, Ranking Member, Education and the Workforce Committee

Chairman Kline (MN)

1. The open enrollment period for the federal exchange on Healthcare.gov was November 1, 2015, through January 31, 2016. However, in 2015 there were 34 special enrollment periods available to individuals who had certain "life events." Reports suggest that individuals are abusing the system and enrolling during a special enrollment period without being properly verified. This calls into question the administration's overall verification process for those receiving subsidies and the viability of the exchanges themselves.

    - Are you concerned with how special enrollment periods are destabilizing the exchange by unnecessarily increasing costs for individuals and insurers? What changes have you made to improve verification to ensure that only eligible individuals are able to purchase during these special enrollment periods?

2. The Center for Program Integrity of the Centers for Medicare and Medicaid (CMS) is planning to conduct an assessment of enrollment that occurred during the most frequent special enrollment periods to consider what additional actions may be necessary to ensure only eligible individuals are appropriately enrolled into coverage.

    - What is the status of this assessment? Will you share preliminary findings with the Committee? What changes, if any, are planned for the special enrollment periods as a result of those findings?

3. The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a report in December 2015 entitled "CMS Could Not Effectively Ensure that Advance Premium Tax Credit Payments Made Under the Affordable Care Act Were Only for Enrollees Who Paid their Premiums." The OIG made two recommendations. First, HHS should develop an automated process to verify subsidy payments outside of insurer attestations. Second, HHS should consult with the Internal Revenue Service (IRS) to explore sharing subsidy payment data continuously throughout the year, which would allow the IRS to reconcile the information and accurately administer the subsidies during the appropriate tax filing season. CMS agreed with and took action on the first recommendation; however, CMS rejected the second recommendation to work with the IRS.

    - Should HHS share subsidy payment data with the IRS throughout the year? Would sharing such data with the IRS not be beneficial to HHS' verification process and the accuracy of the distribution of premium tax credits to individuals? Are there any barriers that would prohibit HHS from sharing such data with the IRS throughout the year, and what would it take for those barriers be removed?

4. The employer notice and appeals process under Section 1411 of the health care law is of great interest to this Committee because of its effect on employees, employers, and verification of advanced premium tax credits. This process was intended to provide HHS and the exchanges with real-time information to verify employees' claims that they were not offered employer coverage. Under the law, if employees are not offered affordable, minimum value coverage, they may be eligible for premium tax credits. The notice and appeals process

is intended to protect employees from any unanticipated tax liabilities that could occur once the IRS reconciles all of this information.

However, these processes have not been fully implemented. In fact, this notice and appeals process is only now being phased in for states using Heathcare.gov. This delay is extremely troubling, especially since the process is helpful for verifying eligibility for advanced premium tax credits before they are distributed to individuals. Two years after the first premium tax credits were first distributed to individuals, the Department should have a process in place to verify an offer of employer coverage *before* hard-earned taxpayer dollars are allowed to go out the door.

- Individuals have been receiving premium tax credits since 2014. Why has the Department not fully implemented the notice and appeals process to date? When will the Department complete full implementation of the notice and appeals process?

- For tax years 2014 and 2015, how many individuals paid back some or all of their advanced premium tax credit funds because they had an offer of employer coverage? How many individuals do you expect will face the same circumstances this year (2016)?

Rep. Foxx (NC)

1. We have heard a lot of concern from self-insured employers about the Transitional Reinsurance Fee Program. They are required to make contributions under this program, which was designed to support the exchanges established by the health care law. But these self-insured employers – and their employees – do not see any benefit from their contributions because they do not purchase coverage on the exchanges. Unionized employees that receive health coverage through a multiemployer health plan are also subject to the fee and likewise see no benefit.

   Chairman Kline, myself, and several other members on this Committee, as well as members of the Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee, wrote to Acting CMS Administrator Andy Slavitt back in October 2015 about this program. In that letter we urged Mr. Slavitt to end the regulatory requirements that self-insured companies and multiemployer health plans contribute to the Transitional Reinsurance Fee Program.

   - Does the Department intend to exclude self-insured and multiemployer health plans from the Transitional Reinsurance Fee Program contributions for the 2016 plan year? Why or why not?

2. Under the statute, the Transitional Reinsurance Fee Program will expire after this year. However, I worry that this administration will find a way to extend the program and not follow the law as written, as it has done with so many other ObamaCare provisions.

- Does the Department intend to extend the transitional reinsurance fee program beyond 2016, either in collection of contributions or distribution of funds? If so, pursuant to what legal authority?

3. In response to our letter, Acting Administrator Slavitt responded that it is CMS' interpretation that "contribution amounts remaining unexpended as of December 2016, may be used to make payments under any reinsurance program of a state in the individual market in effect in the 2-year period beginning on January 1, 2017."

    - If the Department believes, as Acting Administrator Slavitt stated in his response, that it has the ability to continue to distribute funds past 2016 (for a 2-year period beginning on January 1, 2017), how much of the funds does the Department anticipate distributing each year during this two-year period? Also, under what reinsurance program would these funds be distributed – the Risk Corridor Program?

Rep. Roe (TN)

1. According to the Kaiser Family Foundation's most recent study on employer-provided health benefits, 83 percent of covered workers at large firms were enrolled in plans that were either partially or completely self-funded. As you know, stop-loss insurance is a financial risk management tool used by self-funded employers to protect against unusually high health care claims. Stop-loss insurance is not health insurance and clearly beyond federal regulation because it is not subject to the *Employee Retirement Income Security Act* (ERISA), yet administration officials have expressed interest in regulating this important tool.

    - Will you commit to the Committee that the Department will not regulate stop-loss insurance as health insurance in the future?

    - In your view, how would federal regulation of stop-loss insurance affect self-insured employers, especially small employers?

Rep. Walberg (MI)

1. Employers sponsor wellness programs to improve the well-being of their workforce by incentivizing employees and their families to adopt healthy lifestyles. This reduces health care costs and increases productivity. One of the few bipartisan provisions in the *Patient Protection and Affordable Care Act* (PPACA) encouraged and expanded these wellness programs. However, the Equal Employment Opportunity Commission (EEOC) continues to wage an aggressive attack on employer wellness programs. The EEOC recently finalized rules to amend regulations under the *Americans with Disabilities Act* and the *Genetic Information Nondiscrimination Act,* which will inhibit the ability of employers to offer these programs. That's why I cosponsored H.R. 1189, the *Preserving Employee Wellness Programs Act*. That bill protects wellness programs from EEOC's counterproductive and burdensome requirements.

- Do you share our concerns that EEOC's rules are counterproductive? Was the Department in contact with EEOC as they finalized the rules? If so, what was communicated to the EEOC regarding its proposals?

2. Private sector wellness programs benefit employees, their families, and employers. But, employers need flexibility in developing and administering these programs. The *Preserving Employee Wellness Programs Act* (H.R. 1189) improves current law to provide employers with certainty and flexibility in structuring their wellness programs.

    - How is the Department ensuring that wellness programs flourish, so that health care costs are minimized for employer sponsored coverage and employees alike?

Rep. Heck (NV)

1. This past January the U.S. Preventive Services Task Force (USPSTF) finalized its recommendations for breast cancer screenings for women between age 40 and 49. USPSTF assigned this age group a "C" grade, which will effectively limit insurance coverage of mammograms and other screenings. This recommendation is markedly in contrast to the recommendations made by nationally-recognized medical organizations, like the American College of Radiology, which has expressed its serious concerns with the life-threatening barriers this recommendation will create for women in this age group.

    In 2012, with respect to prostate cancer screening for men, the USPSTF recommended against the use of prostate-specific antigen (PSA) based screenings in the general population of men. This proposal is also opposed by nationally-recognized medical societies, like the American Cancer Society and American Urological Association, among others.

    - These recommendations confuse Americans and interfere with the doctor-patient relationship. Understanding that these recommendations are contradictory to those by nationally-recognized medical societies and opposed by Congress, why does CMS still intend to adopt and enforce these limitations on cancer screening for millions of Americans?

2. In the President's FY 2017 Budget, the Area Health Education Centers (AHEC) Program was again eliminated. The mission of AHEC Program is to reach out to rural and urban areas with shortages of health care professionals. For example, the AHEC centers serve as the bridge between academic health programs and the community in every single county in Nevada. AHEC offers continuing education programs for physicians, nurses, social workers, emergency medical personnel, and other health professionals in rural areas.

    - Since this program's funding has been proposed to be eliminated in FY 2017, what plan is in place to support the continuation of the AHEC Program and the offices and centers that serve over 85 percent of counties across the country?

3. Congress passed legislation extending the HRSA Teaching Health Center Graduate Medical Education (THCGME) Program through FY 2017. The THCGME Program provides funding

to support primary care medical and dental residents training in community-based settings; a majority of the currently-funded medical residency programs are osteopathic or dually-accredited (DO/MD).

According to HRSA, physicians who train in Teaching Health Centers (THCs) are three times more likely to work in such centers and more than twice as likely to work in underserved areas as physicians who train in other settings. In FY2014, approximately 64 percent of residents who completed the THCGME Program reported their intent to practice in a primary care setting.

Since its inception in 2011, this innovative program has substantially grown out of necessity. In FY 2011, the THCGME Program commenced with little more than 10 residency programs to train just over 60 residents in the nation's underserved rural and urban communities. In FY 2014, the number of THCs grew to nearly 60, training more than 550 residents, providing more than 700,000 primary care visits across the nation. As the program has continued to grow, THCs are currently funded to train 690 residents.

- How is HHS prioritizing this program and working to ensure its sustainability long-term, so that the program can continue to address primary care physician workforce shortages, while delivering health care services to underserved communities most in need?

4. I hear from many of my physician colleagues in my district about the significant burdens imposed on doctors by a seemingly endless stream of new federal rules and regulations. I know you are familiar with these concerns and how they affect the practice of medicine – whether frustration with the check-the-box mentality of Meaningful Use and other programs, "measurement fatigue," or just spending more time looking at a computer screen instead of interacting with our patients. However, I'd also like to examine another angle of this problem, which is how these burdens affect physicians as small business owners.

   The Agency for Healthcare Research and Quality (AHRQ) indicates that the cost of implementing an electronic health record system can cost a small practice $162,000 – with an additional $85,500 in maintenance expenses in the first year alone. These are huge financial costs, but beyond the dollar amounts, there are costs of training and hiring staff to maintain and operate these systems.

   You know, as I do, that many physicians are solo practitioners or part of small practices. These doctors are the backbone of many communities, especially in rural and underserved areas where they may be the only provider for miles. Many of these practices are overwhelmed by a constant addition of new requirements, new measures to report, new boxes to check, and hiring more staff just to maintain a system when the real need is improving access and increasing the quality of care.

   - Congress has stepped in to relieve some of these burdens, but what is HHS doing or is intending to do to relieve burdens on physicians as small businesses?

5. We all recognize the problem of physician shortages and how that is projected to increase due to the limited number of publicly-funded residency slots. While medical school enrollments are increasing, the numbers of residency slots are not. This problem is particularly acute throughout my home state and in my district, in specialties from family practice, to obstetrics and gynecology, to orthopedic surgery.

   I have introduced bipartisan legislation called the *Creating Access to Residency Education* (CARE) Act to help address this problem, and I have cosponsored bipartisan legislation to increase the number of residency slots in Medicare. Through the Veterans Choice Act that we passed in 2014, Congress provided 1,500 new GME residency slots in the Department of Veterans Affairs. But this isn't enough.

   - What does HHS intend to do to help reduce the growing physician shortage, and how you see the future of the graduate medical education system? What can we do to ensure that medical residents have the opportunity to train in the 3rd District of Nevada, and to ensure that my constituents have access to the physicians they need?

Rep. Messer (IN)

1. The Department recently released guidance that would ultimately prohibit major universities from providing graduate students with PPACA compliant student health insurance coverage at little or no cost. I understand that many schools provide such insurance coverage to help lower the overall cost of graduate education and to ensure their students have access to affordable, high quality health insurance coverage. However, it appears that HHS deems such access as a violation of the employer mandate, which means that schools could face significant fines of $36,500 a year per impacted student ($100 per day) if they continue providing this subsidized coverage to their graduate students. At some of the major research universities, this would affect thousands of graduate students and cost schools millions of dollars.

   - Was this the intention of ObamaCare? Why are we penalizing universities for offering students access to lower cost, high quality PPACA compliant health insurance? Do you not think loss of this health care assistance will disincentivize individuals from seeking graduate education opportunities?

   - Will you commit to us that you will find a way to permit schools to continue to help these graduate students with a practice that works for them, instead of costing them valuable resources?

Rep. Byrne (AL)

1. The non-partisan Congressional Research Service (CRS) determined that the CMS is violating the law in its distribution of certain funds to the ACA Transitional Reinsurance Program and that CMS's interpretation of the statute governing the Transitional Reinsurance Program would not be entitled to *Chevron* deference. At the hearing, you refused to respond to CRS's analysis, stating that the agencies' reading of the law was "accurate."

- What is your response to CRS's analysis?

- Additionally, you stated that CMS was justified in its actions because its interpretation was put out for "notice and comment." How does soliciting public comment justify CMS in violating the plain text of the statute?

Rep. Carter (GA)

1. It is my understanding that the Food and Drug Administration (FDA) is currently working on guidance related to "office-use" compounding. In this guidance, will you still clarify that 503A pharmacies, who are regulated by State Boards of Pharmacy, be exempt from the *Drug Quality and Security Act* (DQSA) requirements when participating in "office-use" compounding?

2. For years, 503A pharmacies have operated under the standards contained in the U.S. Pharmacopeia (USP) Convention for sterile and non-sterile compounding.

    - Other than the limited northeast outbreak, what prompted FDA to begin inspecting these 503A pharmacies under current Good Manufacturing Practices (cGMPs) as opposed to USP standards?

3. The FDA has begun inspecting state licensed 503A pharmacies using cGMP standards rather than USP standards or other applicable pharmacy inspection standards adopted by state law or regulation in the state where the pharmacy is licensed. Section 105 of DQSA states that any finding by the FDA must be turned over to the appropriate State Board of Pharmacy for review and consideration of corrective actions to bring the pharmacy back into compliance with state law.

    - What authority, with clear congressional intent to state otherwise, does FDA have to inspect 503A pharmacies with cGMPs when federal oversight of 503A pharmacies was never the intent of Congress?

Rep. Bishop (MI)

1. Medicare Advantage (MA) Employer Group Waiver Plans (EGWPs) are fundamentally different than Medicare Part D EGWPs. MA EGWPs are designed to meet the needs of employers providing medical benefits to retirees who live all across the country.

    As addressed in the Advance Notice of Methodological Changes for Calendar Year 2017[1] and your comments during the Education and the Workforce hearing, CMS states their goal is to put forth a policy that aligns the bidding structure in Part D EGWPs with MA EGWPs. However, CMS is overlooking fundamental differences between these two programs. For example, providing a national pharmacy benefit is very different than providing a national

[1] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf

provider network. MA EGWPs offer employer products that are designed to ensure beneficiaries have meaningful access to primary care physicians as well as specialists in urban and rural areas.

Additionally, CMS did not consider the differences between the individual MA and EGWP markets in the development of the proposed MA EGWP bid-to-benchmark ratio. CMS's proposal is based off the MA individual market, which is predominately HMO compared to EGWPs, which are predominately PPOs. Notably, 74 percent of MA individual enrollment is in HMOs and 15 percent is in Local PPOs, whereas in MA retiree coverage, 34 percent of enrollment is in HMOs and 65 percent is in Local PPOs.

- Did CMS consider these differences when developing the proposed policy to EGWPs?

- Additionally, CMS published its analysis that the proposal would cut the program by 2.5 percent for 3.3 million seniors nearly 3 weeks after the release of the 2017 Advance Notice. Was this impact analysis part of CMS's policy development?

Rep. Allen (GA)

1. Self-funded plans are required to contribute to the Transitional Reinsurance Fee Program, which redistributes the funds to insurers who experienced higher than anticipated claims in the exchanges. However, while they make significant contributions, self-funded plans receive absolutely no benefit or payments from this program. And, they make these contributions at the same time they are covering the cost of their own high risk medical claims. It seems unfair that self-funded plans be required to shoulder some of the burden for insurers' gamble in the individual market, in addition to covering their own high risk costs.

    - Can you tell the Committee how much in fees have been collected from self-funded plans (for 2014 and 2015) – or are estimated to be collected from self-funded plans (for 2016) – for each year of the Transitional Reinsurance Fee Program?

2. The Department's 2014 Notice of Benefit and Payment Parameters Final Rule established a co-insurance rate and level at which reimbursement of claims would begin for the Transitional Reinsurance Fee Program payments to incentivize insurers to control cost. CMS has since redesigned the rule, using all available funds in the year for which they are contributed and then additional funds rolled over from previous years, instead of lowering the required contribution amount for subsequent years.

    - What is the justification for eliminating the incentive to control costs at the expense of contributing entities?

Rep. Scott (VA)

1. In 2007, the Office of Legal Counsel published a memorandum in response to a request from a Department of Justice grantee, World Vision. This memorandum had the effect of granting

an exemption to a federal grantee to allow discrimination in employment, while still receiving federal funds. Over the past nine years, the Department of Justice has not only allowed this exemption to stay in place, but this taxpayer funded discrimination has been extended to other programs in other agencies, such as those administered by the Department of Health and Human Services. What steps can the Department take to end this federally sanctioned discrimination and to ensure that organizations operating programs on behalf of the federal government comply with their civil rights obligations?

2. In December 2014, CMS changed the "free care policy," announcing that Medicaid reimbursement would be available for covered services provided to Medicaid beneficiaries, even if the services are made available to the community at large for free. I thank you for taking this important step to provide school officials, parents, advocates and providers with an opportunity to increase and improve services available in schools. Could you provide an update on the implementation of the new policy?

Rep. Fudge (OH)

1. Last year's Notice of Proposed Rulemaking for Head Start Program Performance Standards was a long-overdue overhaul to align the Standards with the 2007 Head Start Act. While there are some positives such as improving Head Start's focus on using evidence, data, and continuous quality improvement systems, I am interested to know how these new standards – namely the full day, full year components – will be implemented without reductions in slots. What steps is HHS taking to ensure this Final Rule does not have a negative impact on increasing overall access to Head Start?

2. CDC estimates our economy loses $50 billion a year to due to lead exposure. Children and adults exposed to lead struggle to finish school, find work, and contribute to our economy. The social and economic implications of lead exposure are life-long. I am pleased that your department has provided much needed support to Flint, MI. However, many children in schools across the country face health threats caused by environmental trauma, including those in Cleveland, OH. What is HHS's long-term plan to address the needs of children of all ages?

   We were making progress in lead abatement programs. Can you expand on how cutting corners in the federal budget will actually lead to higher costs and increased burden for agencies such as HHS in the future?

3. Drug overdose is now the leading cause of injury-related deaths in the United States, surpassing suicide, homicide, and now even motor vehicle accidents. In their December report, the CDC named Ohio one of five states with the highest rates of drug overdose deaths in the nation. Ohio alone experienced an 18.3 percent increase in the rate of drug overdose deaths from 2013 to 2014. The outdated Institutions for Mental Diseases (IMD) exclusion keeps millions of Americans from accessing lifesaving treatment because of prohibitions on Medicaid reimbursement. Given the public health crisis that is the opioid and heroin epidemic, what steps is HHS taking to end the outdated IMD exclusion and open up access to treatment?

4. In Cleveland, approximately 13 out of every 1,000 babies born passes away before their first birthday. This number is even higher within the African-American community. All too often, our healthcare system for under resourced families has been reactive. What proactive steps is HHS taking to address the systemic causes of infant mortality, specifically in African-American communities?

Rep. Polis (CO)

Cancer Moonshot

1. ORIEN, the Oncology Research Information Exchange Network, is a unique research partnership that involves 11 hospitals, including the University of Colorado Cancer Center. Through this alliance, researchers are integrating big data by sharing electronic medical records as supported by the ACA to identify patients from a broad pool that share specific genetic mutations, in the hopes that a larger sample size will ultimately further cancer research and care. How does the President's budget request further the opportunity for this type of collaboration, and how do you see it fitting with the Vice President's recent "Cancer Moonshot" initiative?

Telemedicine

2. Telemedicine is an exciting frontier. It can facilitate a real-time interaction between a physician on Colorado's Front Range and a patient at a health clinic in a more remote part of my district. For an adolescent with Type 1 diabetes, for example, telemedicine means his or her doctor can check in remotely, without the hassle of parent and child taking off from work and school to make the lengthy trip to a specialist, helping to lower the risk of an emergency room visit. I am encouraged by the ways that technology is facilitating high-quality care in places where geography might otherwise be a barrier to efficient delivery. What is the Department doing to support the growth of these programs in terms of reimbursements and ease of adoption, and what can Congress do to help boost the use of telemedicine nationwide?

Exchange Eligibility Determination

3. It is my understanding that HHS's rule for the 2017 open enrollment period would require web brokers to direct consumers to complete their applications on exchange websites. I am aware, however, that there are many web brokers who have been performing this role for the past several years. Can you provide information as to why this change was included in the 2017 rule? Furthermore, is the Department willing to consider allowing web brokers to offer enhanced direct enrollment?

Rep. Wilson (FL)

1. On February 19, as a part of the FY 2017 Medicare Advantage Rate Notice, CMS proposed a cut to Medicare Advantage EGWPs, otherwise known as Medicare Advantage Retiree

Coverage. About 3.3 million seniors receive their Medicare Advantage coverage through these plans.

- When developing the Advance Notice, did CMS consider the impact the cuts to MA Retiree Coverage would have on the 3.3 million seniors who depend on this form of coverage?

2. This proposed cut faces strong opposition from labor unions, state/local government organizations, and private corporations whose retirees depend upon MA Retirement Coverage for health insurance coverage, including the Service Employees International Union, the UAW Retiree Medical Benefits Trust, the Carpenters' Health & Welfare Trust Fund of St. Louis, the State Teachers Retirement System of Ohio, and the Chicago Transit Authority Retirement Plan. In my home state of Florida, these cuts will impact several thousands of 1199 SEIU retirees as well as seniors who have retired in Florida from public service careers in Ohio, West Virginia, Kentucky, North Carolina, and Texas.

   - Did CMS take into account product mix or geographical distribution of members when conducting its bid-to-benchmark analysis? If not, why?

3. As you know, under the current structure, MA plans know their bids in April, allowing EGWPs time to solicit bids and make coverage determinations in the early summer. If this proposal moves forward, the date plans know their bids will be sustainably delayed, pushing back the entire timeline, leaving EGWP plans with less time to make decisions, and potentially leaving seniors with less time to make decisions regarding their own coverage prior to the January 1 effective date. Additionally, most EGWPs have several regulatory and/or governing bodies that must sign off on coverage determinations.

   - Is CMS concerned with the proposed cut's potential impact on this timeline?
   - Is CMS prepared to address disrupted timelines across several states with already differing timelines?
   - CMS's own analysis showed a 2.5 percent cut. Can you address what steps CMS will take to ensure beneficiaries do not face disruptions if employer organizations are forced to reduce the benefit package available to retirees or raise premiums or co-payments?
   - Has CMS done any additional modeling to estimate the impact on beneficiaries?
   - Is CMS going to move forward with the proposal as is currently written?

I urge you to carefully weigh this proposed cut's potential harm on the seniors who depend on MA Retiree Coverage for stability and security.

Rep. Clark (MA)

1. We all know that Head Start has improved the lives of disadvantaged families and children for more than 50 years. Congress is committed to continuous quality improvement of the Head Start program.

    - As a Head Start alumna, would you share with the Committee how Head Start has positively impacted your life, and can you speak to the latest advancements in continuous quality improvement within the Head Start program?

United States House Committee on Education and Workforce
Public Hearing
"Examining the Policies and Priorities of the Department of Health and Human Services"
March 15, 2016

Questions Submitted for the Record
For HHS Secretary Sylvia Mathews Burwell

All responses are accurate of March 15, 2016.

Chairman Kline (MN)

1. **The open enrollment period for the federal exchange on Healthcare.gov was November 1, 2015, through January 31, 2016. However, in 2015 there were 34 special enrollment periods available to individuals who had certain "life events." Reports suggest that individuals are abusing the system and enrolling during a special enrollment period without being properly verified. This calls into question the administration's overall verification process for those receiving subsidies and the viability of the exchanges themselves.**

    - **Are you concerned with how special enrollment periods are destabilizing the exchange by unnecessarily increasing costs for individuals and insurers? What changes have you made to improve verification to ensure that only eligible individuals are able to purchase during these special enrollment periods?**

2. **The Center for Program Integrity of the Centers for Medicare and Medicaid (CMS) is planning to conduct an assessment of enrollment that occurred during the most frequent special enrollment periods to consider what additional actions may be necessary to ensure only eligible individuals are appropriately enrolled into coverage.**

    - **What is the status of this assessment? Will you share preliminary findings with the Committee? What changes, if any, are planned for the special enrollment periods as a result of those findings?**

Answer 1&2: Special enrollment periods (SEPs) are one way to make sure that people who lose health insurance during the year or who experience major life changes like getting married have the opportunity to enroll in coverage outside of the annual Open Enrollment period. SEPs are a longstanding feature of employer insurance. We are committed to making sure that SEPs are available to those who qualify for them, while also putting in place measures to protect SEP program integrity. CMS has announced that the Tax Season special enrollment period will no longer be offered.

We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.[1]

[1] All responses are accurate as of March 15, 2016.

3. **The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a report in December 2015 entitled "CMS Could Not Effectively Ensure that Advance Premium Tax Credit Payments Made Under the Affordable Care Act Were Only for Enrollees Who Paid their Premiums." The OIG made two recommendations. First, HHS should develop an automated process to verify subsidy payments outside of insurer attestations. Second, HHS should consult with the Internal Revenue Service (IRS) to explore sharing subsidy payment data continuously throughout the year, which would allow the IRS to reconcile the information and accurately administer the subsidies during the appropriate tax filing season. CMS agreed with and took action on the first recommendation; however, CMS rejected the second recommendation to work with the IRS.**

    - **Should HHS share subsidy payment data with the IRS throughout the year? Would sharing such data with the IRS not be beneficial to HHS' verification process and the accuracy of the distribution of premium tax credits to individuals? Are there any barriers that would prohibit HHS from sharing such data with the IRS throughout the year, and what would it take for those barriers be removed?**

Answer: I appreciate the work of the OIG, and both my team and I take every recommendation seriously. CMS and IRS share responsibility for program operations supporting the payment of and accounting for Advance Premium Tax Credit (APTC) payments as required under section 1412 of the Affordable Care Act (ACA) and as outlined in the inter-agency Memorandum of Understanding (MOU). Under the MOU, CMS is responsible for making sure that APTC payments are made only for confirmed enrollees. The IRS is responsible for reconciling CMS-authorized APTC payments made to QHP issuers to enrollees' tax returns. CMS conducts its verification of APTC payments in accordance with the MOU. CMS works collaboratively with IRS to make sure that APTC payments are reconciled through the tax filing process.

IRS has various methods in place to ensure coordination with CMS for sharing of data related to processing of PTC amounts. Specifically, CMS sends monthly and annual reports to IRS which include the consumer's start and end dates of coverage, and the amount of APTC sent to the issuer on behalf of the consumer. If a consumer was effectuated and then later terminated, IRS will be notified through those reports. Additionally, consumers who receive APTC must file and reconcile with IRS at tax season to continue receiving APTC the following coverage year. IRS uses the monthly reports sent by CMS to compare and verify APTC information on the consumers' forms during tax filing.

4. **The employer notice and appeals process under Section 1411 of the health care law is of great interest to this Committee because of its effect on employees, employers, and verification of advanced premium tax credits. This process was intended to provide HHS and the exchanges with real-time information to verify employees' claims that they were not offered employer coverage. Under the law, if employees are not offered affordable, minimum value coverage, they may be eligible for premium tax credits. The notice and appeals process is intended to protect employees from any unanticipated tax liabilities that could occur once the IRS reconciles all of this information.**

However, these processes have not been fully implemented. In fact, this notice and appeals process is only now being phased in for states using Heathcare.gov. This delay is extremely troubling, especially since the process is helpful for verifying eligibility for advanced premium tax credits before they are distributed to individuals. Two years after the first premium tax credits were first distributed to individuals, the Department should have a process in place to verify an offer of employer coverage *before* hard-earned taxpayer dollars are allowed to go out the door.

- **Individuals have been receiving premium tax credits since 2014. Why has the Department not fully implemented the notice and appeals process to date? When will the Department complete full implementation of the notice and appeals process?**

Answer: CMS continues to work to improve its verification process in order to strengthen program integrity, minimize tax filer liability, and protect taxpayer dollars. The Federally-facilitated Marketplace (FFM) is phasing-in the employer notice program to improve operational efficiency and minimize confusion for employers and employees. In 2015, the FFM focused on educating the public about the employer notice and appeals requirements, and conducted outreach to stakeholders to ensure effective implementation of the program. CMS met with various employer groups and large and small business stakeholders to discuss their concerns related to the employer notice and appeals process. The meetings helped shape the program CMS is implementing in 2016. This year, the FFM is notifying certain employers whose employees enrolled in Marketplace coverage with Advance Payments of the Premium Tax Credit (APTC). The FFM is sending notices to employers if the employee received APTC for at least one month in 2016 and if the FFM has an address for that employer. The FFM will continue to send employer notices on a regular basis going forward and will expand to more employers in later years. The FFM has also provided extensive policy and technical guidance to state-based Marketplaces on fulfilling these requirements.

The employer notice and appeals process was not intended to provide real-time verification of an employee's offer of employer-sponsored health coverage or to verify eligibility for APTC before it is paid on a tax filer's behalf.

- **For tax years 2014 and 2015, how many individuals paid back some or all of their advanced premium tax credit funds because they had an offer of employer coverage? How many individuals do you expect will face the same circumstances this year (2016)?**

Answer: With respect to the 2016 coverage year, as was the case for the 2014 and 2015 coverage years, consumers must attest during the application process that they were neither enrolled in employer sponsored coverage nor eligible for employer sponsored coverage that is affordable and meets the minimum value standard. To help consumers determine whether their employer-sponsored coverage is affordable and meets the minimum value standard, employees can fill out the "Employer Coverage Tool" worksheet, a tool that has been available since the first open enrollment period in 2013.

The Department of Health and Human Services does not have access to the individual tax return information implicated by this question. I would refer you to my colleagues at the Internal Revenue Service for any statistics or information on the tax filings.

Rep. Foxx (NC)

1. **We have heard a lot of concern from self-insured employers about the Transitional Reinsurance Fee Program. They are required to make contributions under this program, which was designed to support the exchanges established by the health care law. But these self-insured employers – and their employees – do not see any benefit from their contributions because they do not purchase coverage on the exchanges. Unionized employees that receive health coverage through a multiemployer health plan are also subject to the fee and likewise see no benefit.**

   Chairman Kline, myself, and several other members on this Committee, as well as members of the Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee, wrote to Acting CMS Administrator Andy Slavitt back in October 2015 about this program. In that letter we urged Mr. Slavitt to end the regulatory requirements that self-insured companies and multiemployer health plans contribute to the Transitional Reinsurance Fee Program.

   - **Does the Department intend to exclude self-insured and multiemployer health plans from the Transitional Reinsurance Fee Program contributions for the 2016 plan year? Why or why not?**

Answer: CMS interprets section 1341 of the Affordable Care Act (ACA) to provide for reinsurance contributions from both health insurance companies and self-insured group health plans. The regulation on this issue defines a contributing entity as a health insurance issuer; or for the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third party administrator; and for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of the Public Health Service Act.

We do not believe we can exempt covered self-insured group health plans and multi-employer plans from the requirement to make reinsurance contributions. Further, we note that Congress directed in the statute that the reinsurance payments be made to health insurance issuers that cover high-risk individuals in the individual market and did not provide the flexibility for the benefits of the program to also extend to plans in the group market, whether self-funded or insured by health insurance issuers.

2. **Under the statute, the Transitional Reinsurance Fee Program will expire after this year. However, I worry that this administration will find a way to extend the program and not follow the law as written, as it has done with so many other ObamaCare provisions.**

    - **Does the Department intend to extend the transitional reinsurance fee program beyond 2016, either in collection of contributions or distribution of funds? If so, pursuant to what legal authority?**

3. **In response to our letter, Acting Administrator Slavitt responded that it is CMS' interpretation that "contribution amounts remaining unexpended as of December 2016, may be used to make payments under any reinsurance program of a state in the individual market in effect in the 2-year period beginning on January 1, 2017."**

    - **If the Department believes, as Acting Administrator Slavitt stated in his response, that it has the ability to continue to distribute funds past 2016 (for a 2-year period beginning on January 1, 2017), how much of the funds does the Department anticipate distributing each year during this two-year period? Also, under what reinsurance program would these funds be distributed – the Risk Corridor Program?**

Answer 2&3: The Affordable Care Act includes programs based on similar, successful programs in the Medicare Part D prescription drug benefit – reinsurance, risk adjustment, and risk corridors – to stabilize premiums and the health insurance market. These programs mitigate the impact of potential adverse selection inside and outside the Marketplaces, while stabilizing premiums and encouraging plan participation in the individual and group markets, including in the Marketplaces. The programs help ensure that the Affordable Care Act works as intended, with insurance plans competing on the basis of quality and service.

The statute provides that contributions for the reinsurance program are to be collected for 2014 through 2016. We note that section 1341(b)(4)(B) of the ACA provides that contribution amounts remaining unexpended as of December 2016 may be used to make payments under any reinsurance program of a state in the individual market in effect in the 2-year period beginning on January 1, 2017. However, consistent with the policy finalized through notice and comment rulemaking, if any contribution amounts remain after calculating reinsurance payments for the 2016 benefit year (and after HHS increases the coinsurance rate to 100 percent for the 2016 benefit year), the 2016 benefit year attachment point of $90,000 will be decreased to make payments to issuers of reinsurance-eligible plans in an equitable manner for the 2016 benefit year.

<u>Rep. Roe (TN)</u>

1. **According to the Kaiser Family Foundation's most recent study on employer-provided health benefits, 83 percent of covered workers at large firms were enrolled in plans that were either partially or completely self-funded. As you know, stop-loss insurance is a**

financial risk management tool used by self-funded employers to protect against unusually high health care claims. Stop-loss insurance is not health insurance and clearly beyond federal regulation because it is not subject to the *Employee Retirement Income Security Act* (ERISA), yet administration officials have expressed interest in regulating this important tool.

- **Will you commit to the Committee that the Department will not regulate stop-loss insurance as health insurance in the future?**

- **In your view, how would federal regulation of stop-loss insurance affect self-insured employers, especially small employers?**

Answer: As you may know, the Department of Labor, which has jurisdiction over the Employee Retirement Income Security Act (ERISA), released guidance in the fall of 2014 about state regulation of stop-loss insurance. According to that guidance, in general, private sector employment-based group health plans that self-insure are not subject to State health insurance laws, including coverage laws, rating policies, and certain other State consumer protections applicable to health insurance. Such plans are also not subject to some requirements under the Affordable Care Act that are applicable only to health insurance issuers, but they are subject to consumer protections in the group market reform provisions, such as the prohibition on lifetime and annual limits, prohibition on pre-existing condition exclusions, and coverage of dependents to age 26. If you have additional questions about ERISA, I would refer you to the Department of Labor.

Rep. Walberg (MI)

1. **Employers sponsor wellness programs to improve the well-being of their workforce by incentivizing employees and their families to adopt healthy lifestyles. This reduces health care costs and increases productivity. One of the few bipartisan provisions in the *Patient Protection and Affordable Care Act* (PPACA) encouraged and expanded these wellness programs. However, the Equal Employment Opportunity Commission (EEOC) continues to wage an aggressive attack on employer wellness programs. The EEOC recently finalized rules to amend regulations under the *Americans with Disabilities Act* and the *Genetic Information Nondiscrimination Act,* which will inhibit the ability of employers to offer these programs. That's why I cosponsored H.R. 1189, the *Preserving Employee Wellness Programs Act.* That bill protects wellness programs from EEOC's counterproductive and burdensome requirements.**

   - **Do you share our concerns that EEOC's rules are counterproductive? Was the Department in contact with EEOC as they finalized the rules? If so, what was communicated to the EEOC regarding its proposals?**

2. **Private sector wellness programs benefit employees, their families, and employers. But, employers need flexibility in developing and administering these programs. The *Preserving Employee Wellness Programs Act* (H.R. 1189) improves current law to provide employers with certainty and flexibility in structuring their wellness programs.**

- **How is the Department ensuring that wellness programs flourish, so that health care costs are minimized for employer sponsored coverage and employees alike?**

Answer 1&2: The Administration supports workplace health promotion and prevention as a means to reduce chronic illness, improve health, and limit health care cost growth, while ensuring that individuals are protected from discriminatory underwriting practices. Treatment for individuals with chronic conditions accounts for over 75 percent of our annual medical care costs, and the indirect costs associated with poor health – such as worker absenteeism, reduced productivity, and disability – may be significantly higher. Wellness programs generally are good policy –for employers and employees alike –but we must protect privacy and prevent discrimination in the process. As with most Administration regulations, HHS participated in the interagency clearance process for these rules.

Rep. Heck (NV)

1. **This past January the U.S. Preventive Services Task Force (USPSTF) finalized its recommendations for breast cancer screenings for women between age 40 and 49. USPSTF assigned this age group a "C" grade, which will effectively limit insurance coverage of mammograms and other screenings. This recommendation is markedly in contrast to the recommendations made by nationally-recognized medical organizations, like the American College of Radiology, which has expressed its serious concerns with the life-threatening barriers this recommendation will create for women in this age group.**

   In 2012, with respect to prostate cancer screening for men, the USPSTF recommended against the use of prostate-specific antigen (PSA) based screenings in the general population of men. This proposal is also opposed by nationally-recognized medical societies, like the American Cancer Society and American Urological Association, among others.

   - **These recommendations confuse Americans and interfere with the doctor-patient relationship. Understanding that these recommendations are contradictory to those by nationally-recognized medical societies and opposed by Congress, why does CMS still intend to adopt and enforce these limitations on cancer screening for millions of Americans?**

Answer: HHS understands the confusion that may be caused when recommendations of the USPSTF differ from the recommendations of other professional medical associations or groups. However, the law places certain requirements on non-grandfathered group health plans and health insurance issuers based on the USPSTF recommended A or B services.

In December the President signed the *Consolidated Appropriations Act 2016,* which ensures that women's coverage for mammography will remain the same through 2017. Women 40 years and older enrolled in most health insurance plans will continue to be covered for screening mammography every 1-2 years without copays, coinsurance, or deductibles if the woman and her

doctor decide a mammogram is appropriate for her – just as they are today. The USPSTF encourages women ages 40-49 to discuss with their doctors the risks and benefits of mammography screening and then make informed decisions that take into account their own values and situations.

In Medicare, mammography is a statutorily-covered benefit. Under the Affordable Care Act, cost-sharing is waived for Medicare-covered preventive services that have an "A" or "B" rating by the USPSTF *"for any indication or population"* and *"are appropriate for the individual."* We have interpreted this to mean that, because the USPSTF has assigned a letter grade of "B" for breast cancer screening for women age 50-74, screening mammography is covered annually, without cost-sharing, for all women with Medicare age 40 and older (and one baseline mammogram is covered for women age 35-39).

As you note, the USPSTF has issued a final recommendation against the use of prostate-specific antigen (PSA) based screening for prostate cancer for men, regardless of age. The recommendation does not require a change in coverage of prostate cancer screenings or treatment for individuals in non-grandfathered group health plans or health insurance coverage. PSA tests are also covered by statute under Medicare. While prostate cancer screening never met the criteria for a waiver of cost-sharing under the Affordable Care Act, Medicare pays 100% of its approved charge for all clinical laboratory tests, including PSA tests.

2. **In the President's FY 2017 Budget, the Area Health Education Centers (AHEC) Program was again eliminated. The mission of AHEC Program is to reach out to rural and urban areas with shortages of health care professionals. For example, the AHEC centers serve as the bridge between academic health programs and the community in every single county in Nevada. AHEC offers continuing education programs for physicians, nurses, social workers, emergency medical personnel, and other health professionals in rural areas.**

    - **Since this program's funding has been proposed to be eliminated in FY 2017, what plan is in place to support the continuation of the AHEC Program and the offices and centers that serve over 85 percent of counties across the country?**

Answer: While the Area Health Education Centers (AHEC) Program exposes medical students and health professions students to primary care and practice in rural and underserved communities, the FY 2017 President's Budget reflects the prioritization of funding to programs that directly increase the number of primary care providers (e.g., through the National Health Service Corps).

In its current management of the AHEC Program, the Health Resources and Services Administration (HRSA) is in the process of refining the program to enhance aspects related to practice transformation and the distribution and diversity of the health workforce, as well as improve documentation of program outcomes.

If FY 2017 funds are not appropriated by Congress, HRSA believes that the AHEC grantees will be well-positioned to sustain program efforts in the absence of federal funding. Applicants are

asked to provide plans for the sustainability of their programs following the funding period, and are scored on their plans to create sustainable programs. It is also anticipated that the AHEC Program grantees may be able to support on-going activities through other funding sources.[2]

3. **Congress passed legislation extending the HRSA Teaching Health Center Graduate Medical Education (THCGME) Program through FY 2017. The THCGME Program provides funding to support primary care medical and dental residents training in community-based settings; a majority of the currently-funded medical residency programs are osteopathic or dually-accredited (DO/MD).**

   According to HRSA, physicians who train in Teaching Health Centers (THCs) are three times more likely to work in such centers and more than twice as likely to work in underserved areas as physicians who train in other settings. In FY2014, approximately 64 percent of residents who completed the THCGME Program reported their intent to practice in a primary care setting.

   Since its inception in 2011, this innovative program has substantially grown out of necessity. In FY 2011, the THCGME Program commenced with little more than 10 residency programs to train just over 60 residents in the nation's underserved rural and urban communities. In FY 2014, the number of THCs grew to nearly 60, training more than 550 residents, providing more than 700,000 primary care visits across the nation. As the program has continued to grow, THCs are currently funded to train 690 residents.

   - **How is HHS prioritizing this program and working to ensure its sustainability long-term, so that the program can continue to address primary care physician workforce shortages, while delivering health care services to underserved communities most in need?**

Answer: HHS is committed to addressing primary care physician workforce shortages, and continuing to deliver health care services to underserved communities, through this program and others. As you know, the Teaching Health Center Graduate Medical Education (THCGME) Program provides funding for residency training in primary care medicine and dentistry in community-based, ambulatory settings. In addition to the $60 million in funding appropriated in the Medicare Access and CHIP Reauthorization Act (MACRA), the President's FY 2017 Budget includes $527 million over FYs 2018-2020 to sustain the current number of FTE slots at the previous $150,000 per resident level.

4. **I hear from many of my physician colleagues in my district about the significant burdens imposed on doctors by a seemingly endless stream of new federal rules and regulations. I know you are familiar with these concerns and how they affect the practice of medicine – whether frustration with the check-the-box mentality of Meaningful Use and other programs, "measurement fatigue," or just spending more time looking at a computer screen instead of interacting with our patients. However, I'd**

[2] All responses are accurate as of March 15, 2016.

also like to examine another angle of this problem, which is how these burdens affect physicians as small business owners.

The Agency for Healthcare Research and Quality (AHRQ) indicates that the cost of implementing an electronic health record system can cost a small practice $162,000 – with an additional $85,500 in maintenance expenses in the first year alone. These are huge financial costs, but beyond the dollar amounts, there are costs of training and hiring staff to maintain and operate these systems.

You know, as I do, that many physicians are solo practitioners or part of small practices. These doctors are the backbone of many communities, especially in rural and underserved areas where they may be the only provider for miles. Many of these practices are overwhelmed by a constant addition of new requirements, new measures to report, new boxes to check, and hiring more staff just to maintain a system when the real need is improving access and increasing the quality of care.

- **Congress has stepped in to relieve some of these burdens, but what is HHS doing or is intending to do to relieve burdens on physicians as small businesses?**

Answer: CMS has been working side by side with physician and consumer communities and has listened to their needs and concerns about the Medicare Electronic Health Record Incentive Program as we transition to the Merit-based Incentive Payment System (MIPS).

Our work moving forward will be guided by several critical principles that promote better care for Medicare beneficiaries:

1. Rewarding clinicians for the outcomes technology helps them achieve with their patients.
2. Allowing clinicians the flexibility to customize health IT to their individual practice needs. Technology must be user-centered and support clinicians.
3. Leveling the technology playing field to promote innovation, including for start-ups and new entrants, by unlocking electronic health information through open application programming interfaces (APIs) – technology tools that underpin many consumer applications. This way, new apps, analytic tools and plug-ins can be easily connected so that data can be securely accessed and directed where and when it is needed in order to support patient care.
4. Prioritizing interoperability by implementing federally recognized, national interoperability standards and focusing on real-world uses of technology, like ensuring continuity of care during referrals or finding ways for patients to engage in their own care. We will not tolerate business models that prevent or inhibit the flow of data necessary to meet the needs of the patient.

Further, in December 2015, CMS, in conjunction with the Office of the National Coordinator for Health Information Technology, issued an RFI to assess policy options that could improve the effectiveness of the certification of health information technology and specifically the certification and testing of EHR products used for the reporting of quality measures. We know physicians and other clinicians have a lot of demands on their time, and we are grateful for the robust response from the stakeholder community to these requests for feedback. We are currently

in the process of reviewing and incorporating the feedback we received, and we anticipate publishing a proposed rule for MIPS, including a 60-day comment period, this Spring.

We look forward to continued engagement from Congress and the health care community on this important issue.

5. **We all recognize the problem of physician shortages and how that is projected to increase due to the limited number of publicly-funded residency slots. While medical school enrollments are increasing, the numbers of residency slots are not. This problem is particularly acute throughout my home state and in my district, in specialties from family practice, to obstetrics and gynecology, to orthopedic surgery.**

   I have introduced bipartisan legislation called the *Creating Access to Residency Education* (CARE) Act to help address this problem, and I have cosponsored bipartisan legislation to increase the number of residency slots in Medicare. Through the Veterans Choice Act that we passed in 2014, Congress provided 1,500 new GME residency slots in the Department of Veterans Affairs. But this isn't enough.

   - **What does HHS intend to do to help reduce the growing physician shortage, and how you see the future of the graduate medical education system? What can we do to ensure that medical residents have the opportunity to train in the 3rd District of Nevada, and to ensure that my constituents have access to the physicians they need?**

Answer: HHS recognizes the importance of graduate medical education (GME), and we are committed to doing all that we can to addressing physician shortages and strengthening services. The President's FY 2017 Budget will help graduate medical education programs promote high quality primary care services that address relevant public health needs by allowing the Secretary to target funding to activities that will help reduce the physician shortage.

For example, HRSA's Children's Hospitals Graduate Medical Education (CHGME) Payment Program supports GME in freestanding children's teaching hospitals. CHGME helps eligible hospitals maintain GME programs to provide graduate training for physicians to provide quality care to children and enhance their ability to care for low-income patients. Adequate residency training in pediatric care is important for residents who pursue a variety of specialties. Compared with other teaching hospitals, freestanding children's hospitals receive little to no GME funding from Medicare because children's hospitals have such a low Medicare caseload.

In FY 2014, 54 children's hospitals received CHGME funding. Based on the most recent year for which performance information was reported, CHGME grantees reported being responsible for the training of 6,698 full-time equivalent (FTE) residents on and off site. Approximately 43 percent of the FTEs were pediatric residents, 32 percent were pediatric subspecialty residents, and 25 percent were non-pediatric residents such as family practice residents or cardiology residents rotating in children's hospitals to learn about care of children in their respective areas of expertise. The FY 2017 Budget Request is $295 million to continue to ensure a health care workforce prepared to provide quality care to children.

Additionally, Medicare provides several opportunities for an increase in the nation's number of residents. Hospitals that have never been teaching hospitals can become new teaching hospitals at any time and receive Medicare GME payments to train residents. Rural teaching hospitals can establish new residency programs at any time and receive an increase in their residency caps. Urban teaching hospitals that establish separately accredited, approved rural training tracks in a rural area can receive an increase in their caps based on the amount of time residents in the track train at the urban hospital.

Rep. Messer (IN)

1. **The Department recently released guidance that would ultimately prohibit major universities from providing graduate students with PPACA compliant student health insurance coverage at little or no cost. I understand that many schools provide such insurance coverage to help lower the overall cost of graduate education and to ensure their students have access to affordable, high quality health insurance coverage. However, it appears that HHS deems such access as a violation of the employer mandate, which means that schools could face significant fines of $36,500 a year per impacted student ($100 per day) if they continue providing this subsidized coverage to their graduate students. At some of the major research universities, this would affect thousands of graduate students and cost schools millions of dollars.**

    - **Was this the intention of ObamaCare? Why are we penalizing universities for offering students access to lower cost, high quality PPACA compliant health insurance? Do you not think loss of this health care assistance will disincentivize individuals from seeking graduate education opportunities?**

    - **Will you commit to us that you will find a way to permit schools to continue to help these graduate students with a practice that works for them, instead of costing them valuable resources?**

Answer: We share your commitment to ensuring that all Americans, including young adults, have access to quality health care. One of the key advances of the ACA was to ensure that young adults up to 26 could stay on their parents' health insurance plans.

I believe that you are referring to recent guidance that the Department of Health and Human Services issued together with the Departments of Labor and the Treasury. The guidance issued in February 2016 discussed the application of certain health insurance market reform provisions of the Affordable Care Act to premium reduction arrangements, which might constitute a group health plan, offered in connection with student health plans, and provided temporary transition relief from enforcement in certain circumstances.

Many colleges and universities provide students (typically graduate students) with student health coverage at greatly reduced or no cost as part of their student aid package. Because some of these students also perform services for the school, such as teaching or research, the question has been raised whether such premium reduction arrangements might be employer-sponsored group health plans, and, as a result, violate market reform provisions of the Affordable Care Act.

As noted in the guidance, we understand that some schools that have been offering such premium reduction arrangements might not have recognized that these arrangements could violate the PHS Act because they are not integrated with group health plan coverage. As a result, the Departments recognized that schools may need additional time to adopt a suitable alternative or make other arrangements to come into compliance. Accordingly, the Departments agreed not to take enforcement action against a university premium reduction arrangement if the arrangement is offered in connection with other student health coverage (insured or self-insured) for a plan year or policy year beginning before January 1, 2017—therefore including, for example, plan years or policy years that roughly align with academic years beginning in the summer or fall of 2016 and ending in 2017.

The Departments have been engaging in productive conversations with representatives of colleges and universities and other stakeholders about these arrangements, and are considering whether further guidance may be appropriate.

Rep. Byrne (AL)

1. **The non-partisan Congressional Research Service (CRS) determined that the CMS is violating the law in its distribution of certain funds to the ACA Transitional Reinsurance Program and that CMS's interpretation of the statute governing the Transitional Reinsurance Program would not be entitled to *Chevron* deference. At the hearing, you refused to respond to CRS's analysis, stating that the agencies' reading of the law was "accurate."**

    - **What is your response to CRS's analysis?**

    - **Additionally, you stated that CMS was justified in its actions because its interpretation was put out for "notice and comment." How does soliciting public comment justify CMS in violating the plain text of the statute?**

Answer: Section 1341 of the Affordable Care Act directs that a transitional reinsurance program be in effect in each state from 2014 through 2016. The reinsurance program is designed to partially reimburse insurers for the costs of high-cost enrollees in the individual market, helping to smooth risk as the 2014 market reforms are implemented and the Marketplaces facilitate increased enrollment. In accordance with section 1341, health insurance issuers and certain group health plans make contributions. From these contributions, reinsurance payments are made to issuers for enrollees in certain individual market plans with claims costs within a pre-determined level as described below.

To implement the transitional reinsurance program, CMS followed the standard public rulemaking process, seeking public comment on all reinsurance policy proposals. Less than six months after enactment of the Affordable Care Act, CMS published a Request for Comment, inviting the public to provide input regarding the rules that would govern the Marketplace and related functions such as reinsurance and risk adjustment. In July 2011, CMS published the first proposed rule related to reinsurance, risk adjustment, and risk corridors, in anticipation of these provisions taking effect in 2014 and to provide issuers and other stakeholders with adequate

notice of our intended policies.[3] Since that time, each rule implementing various aspects of the reinsurance program has been proposed and finalized according to our established rulemaking process. Annual per capita contribution rates and payment parameters for the reinsurance program were proposed and finalized in our Payment Notices for 2014, 2015, and 2016 benefit years. Consistent with Section 1341(b)(4)(A),[4] CMS adopted a regulation to use remaining funds collected for reinsurance payments (if any) from one year to make payment in the subsequent years of the program.

CMS sought public comment on all aspects of its proposal to implement a prioritization of reinsurance contributions to reinsurance payments over payments to the U.S. Treasury. CMS also invited comments on alternative allocation approaches to maximize the premium stabilization benefits of the reinsurance program. All public comments CMS received were supportive of the proposed policy. These comments included support for CMS' legal authority regarding prioritization of reinsurance contributions. In the 2015 Exchange and Insurance Market Standards Final Rule, published in2014, CMS finalized its proposed reallocation approach with minor modifications.[5] As we explained in the final rule,

> Section 1341 of the Affordable Care Act directs that a transitional reinsurance program be established in each State for a three-year period to reduce premiums and to ensure market stability for enrollees in the individual market as the new consumer protections and market reforms are implemented in 2014. The statute does not, however, prescribe how HHS should approach the distribution of reinsurance contributions if insufficient amounts are collected to fully fund all three components of the program (that is, reinsurance payments, administrative expenses, and payments to the U.S. Treasury). We agree that HHS has discretion to implement the program to determine the priority, method, and timing for the allocation of reinsurance contributions collected. Section 1341(b)(3)(B)(iii) uses mandatory language with respect to the collection of amounts for the reinsurance payment pool and states that the total contribution amounts "shall . . . equal $10,000,000,000" for 2014 and specific, lesser amounts for 2015 and 2016. Thus, the statute explicitly directs the Secretary to collect these amounts for the reinsurance payment pool (based on the best estimates of the NAIC). On the other hand, the statute uses more permissive language in sections 1341(b)(3)(B)(ii) and (iv) with respect to the collection of amounts for administrative expenses and payments for the U.S. Treasury (that is, "can" and "reflects", respectively). We believe that this language, as well as language directing that amounts collected pursuant to section 1341(b)(3)(B)(iv) be collected "in addition to the aggregate contribution amounts under clause (iii)," as well as the general authority granted to the Secretary under section 1341(b)(3)(A) to design the method for determining the contribution amount toward reinsurance payments, gives the Secretary

[3] Standards Related to Reinsurance, Risk Corridors and Risk Adjustment proposed rule (https://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf)

[4] Section 1341 (b)(4)(A) of the Affordable Care Act provides that "the contribution amounts collected for any calendar year may be allocated and used in any of the three calendar years for which amounts are collected based on the reinsurance needs of a particular period or to reflect experience in a prior period."

[5] CMS-9949-F: Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond (http://www.gpo.gov/fdsys/pkg/FR-2014-05-27/pdf/2014-11657.pdf)

discretion to prioritize the collections for the reinsurance program. We also believe that it is significant that prioritizing the allocation of reinsurance contributions to the reinsurance payment pool furthers the statutory goals for this program by bringing more certainty to the individual market and helping moderate future premium increases.

Rep. Carter (GA)

1. **It is my understanding that the Food and Drug Administration (FDA) is currently working on guidance related to "office-use" compounding. In this guidance, will you still clarify that 503A pharmacies, who are regulated by State Boards of Pharmacy, be exempt from the *Drug Quality and Security Act* (DQSA) requirements when participating in "office-use" compounding?**

Answer: Any pharmaceutical compounding conducted under Section 503A, added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Food and Drug Administration Modernization Act in 1997, requires a valid prescription for a specific individual patient. Compounding can occur either after the compounder receives the prescription, or in limited quantities before the compounder receives the prescription under certain conditions. The Drug Quality and Security Act of 2013 did not change the prescription requirement in section 503A of the FD&C Act. I cannot comment more specifically on forthcoming guidance, which is under review at this time.[6]

2. **For years, 503A pharmacies have operated under the standards contained in the U.S. Pharmacopeia (USP) Convention for sterile and non-sterile compounding.**

    - **Other than the limited northeast outbreak, what prompted FDA to begin inspecting these 503A pharmacies under current Good Manufacturing Practices (cGMPs) as opposed to USP standards?**

Answer: The 2012 fungal meningitis outbreak was not limited to the northeast; rather, over 750 patients in 20 states (including Georgia) experienced infections who received the contaminated compounded drugs. More than 60 of these patients died, most of whom lived outside the northeast. Many other outbreaks associated with contaminated compounded drugs, some resulting in deaths, have occurred both before and since the 2012 fungal meningitis outbreak. In addition, FDA has received reports of serious adverse events associated with sterile and non-sterile compounded drugs that were sub- or super-potent.

After the 2012 fungal meningitis outbreak, FDA began to focus its inspections of compounding facilities on conditions and practices that are critical to maintaining drug product sterility. During inspections, FDA investigators identify deviations from appropriate sterile practices that could lead to contamination of drugs, potentially putting patients at risk. Although to date, FDA has focused its inspections on sterile compounding, investigators may also identify deviations that could affect the quality of non-sterile compounded drugs. During many of these inspections, FDA has identified insanitary conditions, which create a lack of sterility assurance of purportedly

[6] All responses are accurate of March 15, 2016.

sterile drugs at the facility, prompting numerous pharmacies to recall purportedly sterile drug products and cease sterile drug production.

After the inspection, when determining whether to pursue further action, FDA considers a number of factors, including evidence concerning compliance with the conditions of section 503A of the FD&C Act. When FDA finds that a pharmacy compounds drugs in accordance with section 503A and does not violate other applicable Federal laws, FDA generally defers regulatory oversight of the pharmacy to the state. But when a pharmacy fails to produce drugs in accordance with section 503A or violates Federal laws, such as by preparing, packing, or holding drugs under insanitary conditions, FDA may pursue regulatory action. After inspecting a compounding facility purportedly operating under section 503A, FDA does not cite current good manufacturing practice (CGMP) violations in a regulatory action unless FDA determines, based on evidence collected during the inspection, that the compounding facility is not meeting the conditions of section 503A and does not, therefore, qualify for an exemption from CGMP requirements. In the majority of our inspections, we have found that firms are not compliant with section 503A and that they therefore produce drug products that are subject to CGMP requirements.

FDA does not know until it reviews all of the evidence collected during an inspection whether the compounding facility's drugs qualify for the exemption under section 503A from CGMP requirements. However, going forward, FDA is considering whether it would be possible to determine if the facility is meeting the conditions of section 503A before the close of an inspection, so that the investigator will only include observations related to CGMP violations in the list of inspectional observations issued to the compounder if the firm is not meeting the conditions of section 503A.[7]

3. **The FDA has begun inspecting state licensed 503A pharmacies using cGMP standards rather than USP standards or other applicable pharmacy inspection standards adopted by state law or regulation in the state where the pharmacy is licensed. Section 105 of DQSA states that any finding by the FDA must be turned over to the appropriate State Board of Pharmacy for review and consideration of corrective actions to bring the pharmacy back into compliance with state law.**

    - **What authority, with clear congressional intent to state otherwise, does FDA have to inspect 503A pharmacies with cGMPs when federal oversight of 503A pharmacies was never the intent of Congress?**

Answer: As explained above, FDA does not cite pharmacies that compound all of their drugs in accordance with the conditions of section 503A for violations of CGMP requirements. It is important to note, however, that although drugs compounded by pharmacies that meet the conditions of section 503A qualify for exemptions from three provisions of the FD&C Act, including CGMP requirements, they remain subject to all other applicable provisions of the FD&C Act related to the production of drugs, including the prohibition on producing drugs under insanitary conditions. FDA inspects compounding facilities for compliance with these Federal requirements, not inspection standards adopted by state law or regulation. FDA cannot

[7] All responses are accurate of March 15, 2016.

tailor each inspection to the unique standards of 50 different states, and a pharmacy may be licensed in many states, each with different requirements. For example, some states require compliance with USP chapters on compounding, but many do not[8]. FDA must determine, during inspections, whether the compounding facility has violations of applicable Federal laws, such as the law pertaining to insanitary conditions. In addition, if the facility is not meeting the conditions of section 503A, FDA must determine whether it is in compliance with CGMP requirements.

In accordance with section 105 of the DQSA, FDA notifies state boards of pharmacy when it determines that a pharmacy is "acting contrary to section 503A." Section 105 does not direct FDA to "turn over" to the states the information on which FDA based its determination.

Although FDA works closely with its state regulatory partners on compounding, including inviting the state to accompany FDA on every inspection of a compounding pharmacy and sharing certain findings from inspections where deviations are observed, FDA has an obligation to take its own action to protect the American public from adulterated, misbranded, and/or unapproved new drugs produced by compounding facilities in violation of Federal law. If it does not, it may become more likely that another outbreak like the 2012 fungal meningitis outbreak could occur, which resulted in over 60 deaths and over 750 cases of infection.

Rep. Bishop (MI)

1. **Medicare Advantage (MA) Employer Group Waiver Plans (EGWPs) are fundamentally different than Medicare Part D EGWPs. MA EGWPs are designed to meet the needs of employers providing medical benefits to retirees who live all across the country.**

   As addressed in the Advance Notice of Methodological Changes for Calendar Year 2017[9] and your comments during the Education and the Workforce hearing, CMS states their goal is to put forth a policy that aligns the bidding structure in Part D EGWPs with MA EGWPs. However, CMS is overlooking fundamental differences between these two programs. For example, providing a national pharmacy benefit is very different than providing a national provider network. MA EGWPs offer employer products that are designed to ensure beneficiaries have meaningful access to primary care physicians as well as specialists in urban and rural areas.

   Additionally, CMS did not consider the differences between the individual MA and EGWP markets in the development of the proposed MA EGWP bid-to-benchmark ratio. CMS's proposal is based off the MA individual market, which is predominately HMO compared to EGWPs, which are predominately PPOs. Notably, 74 percent of MA individual enrollment is in HMOs and 15 percent is in Local PPOs, whereas in MA retiree coverage, 34 percent of enrollment is in HMOs and 65 percent is in Local PPOs.

[8] USP Chapters <795> and <797>
[9] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf

- **Did CMS consider these differences when developing the proposed policy to EGWPs?**

- **Additionally, CMS published its analysis that the proposal would cut the program by 2.5 percent for 3.3 million seniors nearly 3 weeks after the release of the 2017 Advance Notice. Was this impact analysis part of CMS's policy development?**

Answer: We have the shared goal of ensuring America's seniors have access to quality care through both Original Medicare and Medicare Advantage. Employer Group Waiver Plans (EGWPs) – which are also referred to as Medicare Employer Retiree Plans - serve specific employer groups, and are either offered through negotiated arrangements between Medicare Advantage plans and employer groups or by the employer directly. Because of the nature of these unique agreements, EGWPs do not compete against other plans through the bidding process, and therefore have little incentive to submit lower bids. CMS has previously waived bidding requirements for Part D for EGWPs and set payment amounts for Part D plans based on the competitive bids submitted for non-EGWP Part D plans. CMS is adopting a similar waiver and payment policy for EGWP Part C plans for 2017.

Under this approach, payments to EGWPs will more closely align with payments made to MAOs under a competitive MA bidding structure.

As you note, CMS was asked to provide an estimate of the expected impact of the proposed change for Part C payments to EGWPs. CMS estimated that the average 2017 impact for EGWPs of the proposed Part C EGWP payment change is -2.5%. CMS estimated that average 2017 program-wide impact of the proposed Part C EGWP payment change is -0.4%. When evaluating the proposed policy change, the financial impact was a part of a broader assessment CMS performed. [10]

<u>Rep. Allen (GA)</u>

1. **Self-funded plans are required to contribute to the Transitional Reinsurance Fee Program, which redistributes the funds to insurers who experienced higher than anticipated claims in the exchanges. However, while they make significant contributions, self-funded plans receive absolutely no benefit or payments from this program. And, they make these contributions at the same time they are covering the cost of their own high risk medical claims. It seems unfair that self-funded plans be required to shoulder some of the burden for insurers' gamble in the individual market, in addition to covering their own high risk costs.**

    - **Can you tell the Committee how much in fees have been collected from self-funded plans (for 2014 and 2015) – or are estimated to be collected from self-**

[10] All responses are accurate of March 15, 2016.

funded plans (for 2016) – for each year of the Transitional Reinsurance Fee Program?

Answer: CMS interprets section 1341 of the Affordable Care Act to provide for reinsurance contributions from both health insurance companies and self-insured group health plans. The regulation defines a contributing entity as a health insurance issuer; or, for the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third-party administrator; and, for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third-party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the Public Health Service Act.

We do not believe we can exempt covered self-insured group health plans and multi-employer plans from the requirement to make reinsurance contributions. Further, we note that Congress directed in the statute that the reinsurance payments be made to health insurance issuers that cover high-risk individuals in the individual market and did not provide the flexibility for the benefits of the program to also extend to plans in the group market, whether self-funded or insured by health insurance issuers.

On June 30, 2015, CMS issued the Summary Report on Transitional Reinsurance Payments and Permanent Risk Adjustment Transfers for the 2014 Benefit Year. For the 2014 benefit year, over $7.9 billion in reinsurance payments were made to 437 issuers nationwide. The June 30 report includes issuer-specific reinsurance contribution and payment amounts. CMS expects to issue a report on the 2015 benefit year on June 30, 2016.

2. **The Department's 2014 Notice of Benefit and Payment Parameters Final Rule established a co-insurance rate and level at which reimbursement of claims would begin for the Transitional Reinsurance Fee Program payments to incentivize insurers to control cost. CMS has since redesigned the rule, using all available funds in the year for which they are contributed and then additional funds rolled over from previous years, instead of lowering the required contribution amount for subsequent years.**

    - **What is the justification for eliminating the incentive to control costs at the expense of contributing entities?**

Answer: Through notice and comment rulemaking, we have outlined how reinsurance contributions will be allocated when requests for payments are less than the amount of collections, as well as situations when the collections fall short of the target amounts, in a given benefit year. As stated in the HHS Notice of Benefit and Payment Parameters for 2015 Final Rule, consistent with 45 CFR 153.230(d), since reinsurance contributions exceeded the total requests for reinsurance payments for the 2014 benefit year, the coinsurance rate was increased to 100 percent for non-grandfathered reinsurance-eligible individual market plans'

covered claims costs between the attachment point of $45,000 and the reinsurance cap of $250,000. Issuers remained responsible for all amounts incurred before the attachment point and after the reinsurance cap. Further, since collections fell short of the estimates for the 2014 benefit year, the first $10 billion in contributions collected will be allocated wholly for reinsurance payments and any amounts remaining will be rolled over for use in future benefit years.

The statute provides that contributions for the reinsurance program are to be collected for 2014 through 2016. We note that section 1341(b)(4)(B) of the Affordable Care Act provides that contribution amounts remaining unexpended as of December, 2016, may be used to make payments under any reinsurance program of a state in the individual market in effect in the 2-year period beginning on January 1, 2017.

Rep. Scott (VA)

1. **In 2007, the Office of Legal Counsel published a memorandum in response to a request from a Department of Justice grantee, World Vision. This memorandum had the effect of granting an exemption to a federal grantee to allow discrimination in employment, while still receiving federal funds. Over the past nine years, the Department of Justice has not only allowed this exemption to stay in place, but this taxpayer funded discrimination has been extended to other programs in other agencies, such as those administered by the Department of Health and Human Services. What steps can the Department take to end this federally sanctioned discrimination and to ensure that organizations operating programs on behalf of the federal government comply with their civil rights obligations?**

Answer: HHS takes very seriously its obligations under federal civil rights laws and legal protections for religious liberty and conscience. The Department plays an important role not only in complying with federal civil rights laws, but also in enforcing them—including title VI of the Civil Rights Act, the Rehabilitation Act of 1983, the Americans with Disabilities Act, provisions of the Public Health Service Act, title IX of the Education Amendments of 1972, and section 1557 of the Affordable Care Act. Indeed, in September 2015 the Department issued a proposed rule implementing section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities that receive federal financial assistance. We anticipate issuing a final rule later in the spring. Consistent with federal law, in considering a request for an exemption from application of a federal civil rights law pursuant to federal legal protections for religious freedom or conscience, we would evaluate all relevant facts and circumstances.

2. **In December 2014, CMS changed the "free care policy," announcing that Medicaid reimbursement would be available for covered services provided to Medicaid beneficiaries, even if the services are made available to the community at large for free. I thank you for taking this important step to provide school officials, parents, advocates and providers with an opportunity to increase and improve services available in schools. Could you provide an update on the implementation of the new policy?**

Answer: CMS is working with states that are interested in broadening covered services as a result of the change in the free care policy. The free care policy can help better support services provided in schools. In late 2015, CMS approved a state plan amendment (SPA) in Louisiana that expanded school nursing services to all Medicaid eligible children under age 21 in schools. In addition, CMS is working with at least one other state that is exploring broadening school services to all Medicaid eligible children.

Concurrently, CMS is working actively with federal partners, state and local school personnel, and external organizations on the change in the free care policy. CMS has participated in various meetings and continues to collaborate with federal partners, states, and non-profit organizations on the Free Care guidance. In early 2016, CMS released joint policy guidance with the Department of Education regarding health and education services that included a reference to the CMS Free Care guidance.

Rep. Fudge (OH)

1. **Last year's Notice of Proposed Rulemaking for Head Start Program Performance Standards was a long-overdue overhaul to align the Standards with the 2007 Head Start Act. While there are some positives such as improving Head Start's focus on using evidence, data, and continuous quality improvement systems, I am interested to know how these new standards –namely the full day, full year components – will be implemented without reductions in slots. What steps is HHS taking to ensure this Final Rule does not have a negative impact on increasing overall access to Head Start?**

Answer: A broad set of research – including research on full-day state-supported preschool programs, full-day kindergarten, instructional time, summer learning loss, and attendance -- indicates the amount of time spent in high-quality programs is central to improving child outcomes. Combined with the other improvements to the performance standards, providing a full school day and full school year program to preschoolers is essential to ensuring Head Start has strong, positive and lasting effects on children's learning.

In the public comment process we heard from many individuals and groups that strongly supported increasing the learning time for Head Start children, and we also heard from many with concerns that without resources to support this change, fewer children could be served in the future. We are carefully considering these comments and working through these issues as we are developing the final rule.

We also note that in FY 2016, Congress appropriated $294 million to support serving Head Start children for a longer amount of time, and in FY 2017 the President has requested and additional $292 million to continue making progress on this important quality improvement. [11]

2. **CDC estimates our economy loses $50 billion a year to due to lead exposure. Children and adults exposed to lead struggle to finish school, find work, and contribute to our economy. The social and economic implications of lead exposure are life-long. I am pleased that your department has provided much needed support to Flint, MI.**

[11] All responses are accurate of March 15, 2016.

However, many children in schools across the country face health threats caused by environmental trauma, including those in Cleveland, OH. What is HHS's long-term plan to address the needs of children of all ages?

We were making progress in lead abatement programs. Can you expand on how cutting corners in the federal budget will actually lead to higher costs and increased burden for agencies such as HHS in the future?

Answer: The childhood lead poisoning problem in the U.S. today is multifaceted, with exposure risk coming from lead paint in the more than 24 million at-risk houses, from the millions of miles of lead drinking-water pipes, from the many industrial sites where lead is mined or used, and from other more minor uses such as pottery. The Centers for Disease Control (CDC) and its state and local public health partners have historically played a key role in identifying and mitigating children's exposure to lead from all of these sources by collecting and analyzing blood samples, conducting environmental assessments and investigations, and referring affected children for clinical and educational interventions.

It is estimated that at least 4 million households have children living in them that are being exposed to high levels of lead. There are approximately half a million U.S. children ages 1-5 with blood lead levels above 5 micrograms per deciliter, the reference level at which CDC recommends public health actions be initiated. No safe blood lead level in children has been identified, and millions of children are still being exposed to lead in their homes. The Childhood Lead Poisoning Prevention program is helping reduce the number of children exposed to lead, which will help reduce healthcare costs and improve academic achievement and later life success for at-risk children.

The CDC's Childhood Lead Poisoning and Prevention Program provides an active surveillance system for twenty-nine states, the District of Columbia, and five cites to collect data on individual children so appropriate public health services can be provided. The lead program data are used by state and local lead programs to track children with elevated blood lead levels and focus on areas of high need. The lead program surveillance data is also used by state decision makers to target resources for intervention.

State and local agencies rely on federal grants to fund community-based programs and associated jobs. Budget cuts greatly impact the programs and staffing available across the board to address crises, such as the Flint water crisis, and future public health emergencies. The federal government is currently providing a whole-of-government response in Flint. Early in the Flint response, there were over 100 federal staff on the ground in Flint working with residents, community leaders, and officials from state and county agencies to support the community. Federal agencies have provided more than $13 million in grant funding to state and local agencies and organizations. This comes in addition to in-kind services, commodities, and technical assistance—including early education, nutrition, and health care. Federal and state support has played a critical role in moving the community toward long-term system recovery.

3. **Drug overdose is now the leading cause of injury-related deaths in the United States, surpassing suicide, homicide, and now even motor vehicle accidents. In their December**

report, the CDC named Ohio one of five states with the highest rates of drug overdose deaths in the nation. Ohio alone experienced an 18.3 percent increase in the rate of drug overdose deaths from 2013 to 2014. The outdated Institutions for Mental Diseases (IMD) exclusion keeps millions of Americans from accessing lifesaving treatment because of prohibitions on Medicaid reimbursement. Given the public health crisis that is the opioid and heroin epidemic, what steps is HHS taking to end the outdated IMD exclusion and open up access to treatment?

Answer: CMS has taken several significant steps to provide flexibility in the application of the Medicaid payment exclusion for Institutions for Mental Disease (IMD), in order to improve patient access to short-term residential treatment for substance use disorder (SUD). In July 2015, CMS issued a State Medicaid Director letter that provides states with the opportunity to request a Section 1115 demonstration waiver, as part of a comprehensive substance use disorder strategy,to receive federal matching funding for expenditures for individuals residing in IMDs to treat SUD as long as they meet certain requirements. CMS is also providing technical assistance to states as part of the Innovation Accelerator Program (IAP) to states that are developing stronger care delivery approaches to SUD. Some of these IAP states may seek 1115 IMD waivers.[12] Also, in recent regulations governing Medicaid managed care, CMS has provided flexibility for states to make capitation payments when managed care entities provide enrollees access to otherwise covered services furnished during short-term treatment in sub-acute IMDs in lieu of receiving such treatment in other covered settings, provided certain conditions are met. [13]

4. **In Cleveland, approximately 13 out of every 1,000 babies born passes away before their first birthday. This number is even higher within the African-American community. All too often, our healthcare system for under resourced families has been reactive. What proactive steps is HHS taking to address the systemic causes of infant mortality, specifically in African-American communities?**

Answer: Later this year, I will visit Ohio to learn firsthand about the work communities across the state are undertaking to improve the infant mortality rate. After years of reduction in the infant mortality rate, unfortunately those rates have plateaued. Black infant mortality rates continue to be twice that of whites. Five leading causes account for more than half of all infant deaths: birth defects, short gestation and low birthweight, Sudden Infant Death Syndrome (SIDS), maternal complications, and unintentional injuries (accidental deaths). There is a potential for reducing each of these causes of death, particularly among low-income families and communities. HHS is taking a number of critical steps on this issue.

The Federal Home Visiting Program supports voluntary, evidence-based home visiting services for at-risk pregnant women and parents with young children up to kindergarten entry in all 50 states, the District of Columbia, and five territories. Home visitors provide information or referrals to address preterm birth (prenatal care), postpartum care, screening for maternal depression and referral for services, breastfeeding, well-child visits, tobacco use in the home, safe sleep, prevention of child injury and maltreatment, improved parent-child interaction, child

[12] All responses are accurate of March 15, 2016.
[13] See 42 C.F.R. 438.6(e)

development (screening for developmental delays), and continuity of health care insurance, which help prevent the five leading causes of infant deaths. The Ohio Department of Health, a grant recipient of the Federal Home Visiting Program since 2010, has implemented Healthy Families of America, an evidence-based model that aims to: reduce child maltreatment, improve parent-child interactions and children's social-emotional well-being, increase school readiness, promote child physical health and development, promote positive parenting, promote family self-sufficiency, increase access to primary care medical services and community services, and decrease child injuries and emergency department use. The model requires home visitors (family support staff) to have a minimum of a high school diploma, experience working with culturally diverse communities and providing services to children and families, and the ability to establish trusting relationships. These staff requirements and qualifications are consistent with the requirements for community health workers (CHWs). Ohio is also implementing the Nurse-Family Partnership (NFP) model, which is designed for first-time, low-income mothers and their children. It includes one-on-one home visits by a trained public health registered nurse to participating clients. The visits begin early in the woman's pregnancy (with program enrollment no later than the 28th week of gestation) and conclude when the woman's child turns 2 years old. NFP is designed to improve prenatal health and outcomes, child health and development, and families' economic self-sufficiency and/or maternal life course development.

The Healthy Start (HS) program, which targets the needs of vulnerable mothers and infants in areas of the country with disproportionally high rates of infant mortality, further aims to reduce disparities in infant mortality and adverse perinatal outcomes by: 1) improving women's health; 2) promoting quality services; 3) strengthening family resilience; 4) achieving collective impact; and 5) increasing accountability through quality improvement, performance monitoring, and evaluation. HRSA funds five HS communities in Ohio (Cincinnati, Cleveland, Columbus, Dayton, and Toledo).

Rep. Polis (CO)

Cancer Moonshot

1. **ORIEN, the Oncology Research Information Exchange Network, is a unique research partnership that involves 11 hospitals, including the University of Colorado Cancer Center. Through this alliance, researchers are integrating big data by sharing electronic medical records as supported by the ACA to identify patients from a broad pool that share specific genetic mutations, in the hopes that a larger sample size will ultimately further cancer research and care. How does the President's budget request further the opportunity for this type of collaboration, and how do you see it fitting with the Vice President's recent "Cancer Moonshot" initiative?**

Answer: Advances in biomedical research that inform our understanding of cancer and influence decisions on how to treat or prevent it are increasingly reliant on large, diverse data sets and complex analyses by research teams, aided by emerging computational and other technologies. Many powerful sources of data are being rapidly generated in the research and clinical communities. However, these are currently not being fully leveraged, due to the pace at which data are accruing, lack of a coordinated effort to assemble the data in readily accessible fashion, and inability to effectively process the data in an inter-operative fashion. It is now well

recognized that these data are critical for identifying and utilizing associations between molecular information (e.g., genomic data from patient samples or model systems) and clinical outcomes in patients (e.g., progression or response or resistance to therapy), but the ability to take full advantage of this opportunity is hindered by the current challenges in the storage, accessibility, and processing of these data.

The President's budget request for FY2017 included new funding for the Cancer Moonshot, an initiative intended to accelerate cancer research and to make more therapies available to more patients, while also improving our ability to prevent cancer and treat it at an early stage. To ensure that the Cancer Moonshot's goals and approaches are grounded in the best science, a Blue Ribbon Panel (BRP) of experts was established as a working group of NCI's National Cancer Advisory Board (NCAB) to assist the NCAB in providing this advice. The BRP will be issuing a set of recommendations to NCAB in September.

The President also established a White House Cancer Moonshot Task Force to focus on making the most of federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care. The Task Force report, including recommendations on broad data sharing, is expected to be completed and submitted to the President by the end of the year.

NCI currently supports a number of data sharing efforts, a key example being NCI's Genomic Data Commons. The GDC is a data sharing platform that promotes precision medicine in oncology. It is not just a database or a tool; it is an expandable knowledge network supporting the import and standardization of genomic and clinical data from cancer research programs. The GDC contains NCI-generated data from some of the largest and most comprehensive cancer genomic datasets, including The Cancer Genome Atlas and Therapeutically Applicable Research to Generate Effective Therapies. For the first time, these datasets have been harmonized using a common set of bioinformatics pipelines, so that the data can be directly compared.

The GDC is providing publicly accessible, robust, scalable infrastructure for the secure sharing of patient-level genomic data along with associated patient outcomes, diagnostic information, and therapeutic course. The GDC will enable researchers and cancer health care providers to leverage information from tens of thousands of cancer cases with carefully annotated genomic abnormalities. [14]

Telemedicine

2. **Telemedicine is an exciting frontier. It can facilitate a real-time interaction between a physician on Colorado's Front Range and a patient at a health clinic in a more remote part of my district. For an adolescent with Type 1 diabetes, for example, telemedicine means his or her doctor can check in remotely, without the hassle of parent and child taking off from work and school to make the lengthy trip to a specialist, helping to lower the risk of an emergency room visit. I am encouraged by the ways that technology is facilitating high-quality care in places where geography might otherwise be a barrier**

[14] All responses are accurate of March 15, 2016.

to efficient delivery. What is the Department doing to support the growth of these programs in terms of reimbursements and ease of adoption, and what can Congress do to help boost the use of telemedicine nationwide?

Answer: Telemedicine is an important tool for improving access and enhancing health care outcomes. CMS is supporting innovative new models of reimbursement and care delivery reforms that include a rural focus through the work of the CMS Innovation Center. Maryland, Oregon, Minnesota, Idaho, Washington, and Vermont all have used their State Innovation Model grants to develop creative ways to address rural health challenges. Our hope is that by helping rural communities take advantage of the broad range of programs and resources across HHS, we can assist these communities in addressing some of the key challenges faced by rural hospitals. Every year, CMS seeks input on which telehealth services Medicare should cover in its annual payment rules and we would welcome your thoughts on this issue. In the past two years, CMS has added:

- Psychoanalysis and family psychotherapy,
- annual wellness visits,
- prolonged evaluation and management services.
- additional inpatient prolonged service, and
- certain end-stage renal disease (ESRD) related services
- inclusion of Certified Registered Nurse Anesthetists as practitioners for telehealth services.

Through HHS' Federal Office of Rural Health Policy, we're working with Critical Access Hospitals (CAHs) to shore up their financial operations and focus on quality through the Medicare Rural Hospital Flexibility Grant (Flex) program, which provides $25 million in grants for these activities. Every CAH gets a customized financial and quality report it can use to identify areas of improvement and to engage in benchmarking activities with other CAHs and small rural hospitals. The Flex funds provide support for hospital-specific interventions. We are also planning to award 24 Network Planning grants totaling $2.4 million in FY 2016. We put a particular emphasis in the grant guidance on communities that were either at risk of or have seen a hospital closure. FORHP will also award approximately 21 Small Health Care Provider Quality Improvement grants totaling $4.2 million in FY 2016, providing additional resources for small rural hospitals and clinics to focus on quality. Our goal is that by emphasizing value and improved quality, rural hospitals can reduce the rate of patients leaving their community for care and retain those health care dollars, thereby strengthening the local health care system. Telehealth can play a role in this strategy, and we have a national network of telehealth resource centers to help rural communities best leverage available technology. We've also expanded eligibility for the National Health Service Corps to CAHs to help these hospitals address the ongoing need for doctors, nurse practitioners, and mental health providers.

Exchange Eligibility Determination

3. **It is my understanding that HHS's rule for the 2017 open enrollment period would require web brokers to direct consumers to complete their applications on exchange websites. I am aware, however, that there are many web brokers who have been performing this role for the past several years. Can you provide information as to why**

this change was included in the 2017 rule? Furthermore, is the Department willing to consider allowing web brokers to offer enhanced direct enrollment?

Answer: In the HHS Notice of Benefit and Payment Parameters for 2017 Final Rule, we discussed our intent to develop an expanded direct enrollment pathway option for web-brokers and QHP issuers in future coverage years, under which an applicant who initiates enrollment directly with the QHP issuer or web-broker for enrollment through the Marketplace can receive an eligibility determination on the issuer's website without being redirected to the Marketplace. Our amendments provide a framework for the QHP issuer or web-broker to use an FFM application to obtain this determination, and they provide for protections to ensure that these determinations are accurate and that consumers are aware of their Marketplace options. We intend to supplement the framework with more specific requirements in future rulemaking. Until then, entities must continue to comply with rules governing the current direct enrollment process.

Rep. Wilson (FL)

1. **On February 19, as a part of the FY 2017 Medicare Advantage Rate Notice, CMS proposed a cut to Medicare Advantage EGWPs, otherwise known as Medicare Advantage Retiree Coverage. About 3.3 million seniors receive their Medicare Advantage coverage through these plans.**

    - **When developing the Advance Notice, did CMS consider the impact the cuts to MA Retiree Coverage would have on the 3.3 million seniors who depend on this form of coverage?**

2. **This proposed cut faces strong opposition from labor unions, state/local government organizations, and private corporations whose retirees depend upon MA Retirement Coverage for health insurance coverage, including the Service Employees International Union, the UAW Retiree Medical Benefits Trust, the Carpenters' Health & Welfare Trust Fund of St. Louis, the State Teachers Retirement System of Ohio, and the Chicago Transit Authority Retirement Plan. In my home state of Florida, these cuts will impact several thousands of 1199 SEIU retirees as well as seniors who have retired in Florida from public service careers in Ohio, West Virginia, Kentucky, North Carolina, and Texas.**

    - **Did CMS take into account product mix or geographical distribution of members when conducting its bid-to-benchmark analysis? If not, why?**

Answer 1&2: We share the goal of ensuring America's seniors have access to quality care through both Original Medicare and Medicare Advantage. Employer Group Waiver Plans (EGWPs) – which are also referred to as Medicare Employer Retiree Plans - serve specific employer groups, and are either offered through negotiated arrangements between Medicare Advantage plans and employer groups or by the employer directly. Because of the nature of these unique agreements, EGWPs do not compete against other plans through the bidding

process and therefore have little incentive to submit lower bids. CMS has previously waived bidding requirements for Part D for EGWPs and set payment amounts for Part D plans based on the competitive bids submitted for non-EGWP Part D plans. CMS is adopting a similar waiver and payment policy for EGWP Part C plans for 2017.

Under this approach, payments to EGWPs will more closely align with payments made to MAOs under a competitive MA bidding structure.

CMS was asked to provide an estimate of the expected impact of the proposed change for Part C payments to EGWPs. CMS estimated that the average 2017 impact for EGWPs of the proposed Part C EGWP payment change is -2.5%. CMS estimated that average 2017 program-wide impact of the proposed Part C EGWP payment change is -0.4%. When evaluating the proposed policy change, the financial impact was a part of a broader assessment CMS performed.[15]

3. **As you know, under the current structure, MA plans know their bids in April, allowing EGWPs time to solicit bids and make coverage determinations in the early summer. If this proposal moves forward, the date plans know their bids will be sustainably delayed, pushing back the entire timeline, leaving EGWP plans with less time to make decisions, and potentially leaving seniors with less time to make decisions regarding their own coverage prior to the January 1 effective date. Additionally, most EGWPs have several regulatory and/or governing bodies that must sign off on coverage determinations.**

    - **Is CMS concerned with the proposed cut's potential impact on this timeline?**
    - **Is CMS prepared to address disrupted timelines across several states with already differing timelines?**
    - **CMS's own analysis showed a 2.5 percent cut. Can you address what steps CMS will take to ensure beneficiaries do not face disruptions if employer organizations are forced to reduce the benefit package available to retirees or raise premiums or co-payments?**
    - **Has CMS done any additional modeling to estimate the impact on beneficiaries?**
    - **Is CMS going to move forward with the proposal as is currently written?**

    I urge you to carefully weigh this proposed cut's potential harm on the seniors who depend on MA Retiree Coverage for stability and security.

Answer: We have the shared goal of ensuring America's senior have access to quality care through both Medicare and Medicare Advantage. With respect to Employer Group Waiver Plans specifically, CMS proposed to modify the bidding process to provide these plans with a fair benchmark, reflective of local Medicare Advantage prices. This proposal addresses the fact that EGWP plans do not compete against other Medicare Advantage plans for enrollees and therefore

[15] All responses are accurate as of March 15, 2016.

tend to bid higher. CMS has already implemented this policy for EGWP plans in Part D without any disruption for retirees.[16]

Rep. Clark (MA)

1. **We all know that Head Start has improved the lives of disadvantaged families and children for more than 50 years. Congress is committed to continuous quality improvement of the Head Start program.**

    - **As a Head Start alumna, would you share with the Committee how Head Start has positively impacted your life, and can you speak to the latest advancements in continuous quality improvement within the Head Start program?**

Answer: In a rural town like Hinton, West Virginia, Head Start was one of the only early educational opportunities around. It meant a lot to the families in my town, and still does. It was a summer program at the time—probably just before they switched to the school year—and we met in what would eventually be my 5th grade classroom at Central Elementary School. We hatched chickens in an incubator—starting my lifelong love of science—and I would play with Kristie, who is still my best friend and was in my wedding.

Thanks to an excellent teacher, Mrs. Pack, I did get a head start. I learned to love learning, and that love has stayed with me my whole life. In fact, when my mom called my Head Start teacher, she said every day I came bounding in the door with the same question: "What are we going to learn today?"

Since the program's inception in 1965, Head Start has served over 33 million children across the nation. I was one of those 33 million children that had the opportunity to experience firsthand a Head Start program. The program reminded me every single day how much fun learning can be. Every day, in Hinton and around the country, Head Start programs deliver comprehensive, high-quality individualized services for children and families that support school readiness and the healthy development of children from low-income families. This Administration has been committed to further strengthening Head Start and has done so by expanding the program to serve more children and to use regulatory changes, oversight, and training and technical assistance to bring the latest advancement in quality improvements to further strengthen the program.

We have issued three regulations stemming from the Improving Head Start for School Readiness Act of 2007. The first required programs that fail to meet a new set of rigorous quality benchmarks to re-compete for continued federal funding. That regulation, released in 2011, represented the most significant change in Head Start operations in the program's history and laid out a specific timeline for its implementation. The second, released in 2015, established new eligibility requirements to ensure that the neediest children and families benefit from Head Start services first. The third, a Notice of Proposed Rulemaking issued in June 2015, is a comprehensive update of the full set of Head Start Program performance standards, which are the foundation on which programs design and deliver comprehensive, high-quality

[16] All responses are accurate as of March 15, 2016.

individualized services to children. The scale of this revision is the first of its nature since the standards were first established in 1975.[17]

[17] All responses are accurate of March 15, 2016.

[Whereupon, at 12:03 p.m., the Committee was adjourned.]

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