

THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES (HHS)
FISCAL YEAR 2017 BUDGET REQUEST

HEARING
BEFORE THE
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTEENTH CONGRESS
SECOND SESSION

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**THE DEPARTMENT OF
HEALTH AND HUMAN SERVICES (HHS)
FISCAL YEAR 2017 BUDGET REQUEST**

WEDNESDAY, FEBRUARY 16, 2016

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
Washington, DC.

The committee met, pursuant to notice, at 2:00 p.m., in Room 1100, Longworth House Office Building, the Honorable Kevin Brady, [chairman of the committee] presiding.

[The advisory announcing the hearing follows:]



Chairman Brady Announces Hearing on the Department of Health and Human Services' Fiscal Year 2017 Budget Request

The Chairman of the House Committee on Ways and Means, Kevin Brady (R-TX), today announced that the Committee will hold a hearing on the Department of Health and Human Services' (HHS) Fiscal Year 2017 Budget Request. Testifying at the hearing will be HHS Secretary Sylvia Mathews Burwell. **The hearing will take place Wednesday, February 10, 2016, in Room 1100 of the Longworth House Office Building, beginning at 2:00 P.M.**

Oral testimony at this hearing will be from HHS Secretary Burwell only. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

Details for Submission of Written Comments:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, <http://waysandmeans.house.gov>, select "Hearings." Select the hearing for which you would like to make a submission, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Wednesday, February 24, 2016**. For questions, or if you encounter technical problems, please call (202) 225-3625 or (202) 225-2610.

Formatting Requirements:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for

printing the official hearing record.

2. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

3. Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at <http://www.waysandmeans.house.gov/>.

Chairman BRADY. Thank you for joining us today, Secretary Burwell. We appreciate your time and welcome to the Ways and Means Committee to speak about the President's fiscal year 2017 budget request for the Department of Health and Human Services.

I would like to begin the day by speaking generally about this year's budget. Even though the President knows that he does not have much time left in office to solve real problems, he has decided to put forward in my view a budget that really is not rooted in reality for yet another year's budget proposed trillions of dollars of new tax increases and more wasteful Washington spending.

The President's efforts to secure his liberal legacy does not come cheap. While the United States likes to break records, the American people are not cheering for the most expensive budget in our Nation's history.

The President has chosen to completely ignore the very real fiscal challenges our country faces in the immediate future. This budget is a missed opportunity, especially for the programs at your department that impact the lives of millions of Americans.

For example, last year when you testified at the Energy and Commerce Committee you said the Affordable Care Act was leading to substantial savings for households, businesses, and the Federal Government, but we know that is not the case today.

In fact, the nonpartisan Congressional Budget Office recently found the government spending on health care programs would grow from \$1.1 trillion this year to \$2 trillion in 2026.

We also know that many Affordable Care Act recipients are watching their premiums increase by double digits every year. And the Medicare Hospital Insurance Trust Fund that our seniors rely on will be exhausted in 2026, four years earlier than projected.

These are serious problems that need real solutions, but these solutions are nowhere to be found in this irresponsible and very expensive budget.

To add insult to injury, the budget also duplicates programs that already exist at your own agency. One proposal calls for a new program to provide short-term financial help to those in need, even though that is already the central purpose of the Temporary Assistance for Needy Families Program.

Another calls for a new Home Visiting Program run by the Ag. Department, despite the current Home Visiting Program run by HHS.

Instead of duplicating programs we already have, Washington needs to effectively reform our welfare program and finally help more Americans climb the economic ladder through work, and while we will disagree more than we agree today, I do believe there are some important areas of cooperation.

I am glad the White House has finally faced reality in one area and agreed that the so-called Cadillac tax simply is not workable.

We must also work to put Medicare on a sustainable path, and while we do not agree with the specifics in the proposal presented today, we do agree we need to address spending on post-acute care and medical education.

I believe we can also find some common ground in the TANF reauthorization proposal that includes many of the items that were released by this Committee last July in its TANF discussion draft.

And when it comes to child welfare, there is broad agreement about the need to keep kids from entering foster care in the first place. We share the belief that all programs should be evaluated and held accountable for making a positive difference in the lives of children across our country.

So, Secretary, thank you again for joining us today. I now yield to the distinguished ranking member from Michigan, Mr. Levin, for the purposes of an opening statement.

Mr. LEVIN. Thank you, Mr. Chairman.

And, Madam Secretary, a warm welcome.

I think this will be your last appearance at least as you plan before us unless there is a special call, and I hope you will not brag about it, but you come with a sense of accomplishment and pride in those accomplishments.

If you just look back a few years, there has been so much positive change. Eighteen million previously uninsured Americans now have health insurance, 18 million. The growth of health care cost has been substantially reduced. One hundred and twenty-nine million Americans now do not have to worry about having their health care coverage denied or their premiums increased because of pre-existing conditions.

The tens of millions who now have free preventive care and we do not see the consequences perhaps in this Committee, but they are real.

The re-admissions have gone down also because of ACA, and the last enrollment period, and we hope you will cover on this, 13 million, 13 million signed up.

About ten days ago I met a woman who told us this story. She had breast cancer. She lost her job. She lost her health insurance. Because of ACA, she was able now to be covered, and then her breast cancer reoccurred, and she looked at all of us and essentially said, "I would not be here today if it were not for health care reform and ACA."

There are millions of people like this, some with breast cancer, some with diabetes, some with other chronic ailments who have coverage, and without that coverage would be sicker, without that coverage they may not have survived.

So you will hear a lot of ideology today. We have been through that so many times on the floor of the House, efforts to repeal, but I think the realities are so different than that ideology.

The President's budget also proposes important reforms to Medicare. I hope you will cover on those.

And for Mr. Blumenauer and myself and others, there has been finalized advanced care planning codes, which is important. The Administration is also suggesting that we head on tackle the opioid abuse epidemic, as well as providing some additional money for mental health.

I want to close by touching on a real health crisis. I was in Flint two days this weekend. What has happened there is not only intolerable, inexcusable, but with consequences that we cannot foretell. Dan Kildee has proposed a bill with the support of a lot of us to address the needs there.

This is a national crisis. The Senate is now debating a bill, and there is an effort by two Senators from Michigan to add some funds

to help address this crisis, this human crisis, in Flint for families and especially for children.

And so I will be asking you questions about the possible role of HHS. I think you have already begun.

I think it highlights what is really in the end the test for all of us. Behind these statistics, behind all of the data are the lives of individuals in this country, and all of us who supported ACA are proud to have done that, and as we go forth in our district and beyond, we see what it has meant in the lives of the people in our district and this country.

I yield back.

Chairman BRADY. Without objection, all the members' opening statements will be made part of the record.

Our sole witness today is the Honorable Sylvia Matthew Burwell, Secretary of the U.S. Department of Health and Human Services. Sworn in on June 9th, 2014, Secretary Burwell is the 22nd Secretary of Health and Human Services.

Prior to serving at HHS, Secretary Burwell was the Director of the Office of Management and Budget.

Welcome, Secretary Burwell. The committee has received your written statement. It will be made part of the formal hearing record, and you have five minutes to deliver your remarks, and you may begin when you are ready.

Welcome.

STATEMENT OF THE HONORABLE SYLVIA BURWELL, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary BURWELL. Thank you, Mr. Chairman and Ranking Member Levin, as well as Members of the Committee. I want to thank you for the opportunity to discuss the President's budget for the Department of Health and Human Services.

As many of you know, I believe that all of us share common interests and that we can find common ground. The last legislative session, this Committee embraced the spirit of bipartisan leadership when it took historic steps to pass the Medicare Access and CHIP Reauthorization Act of 2015, and I want to thank you for your leadership on that issue.

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

For HHS, the budget proposes \$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 ten years, these reforms to Medicare would result in net savings of \$419 billion.

This budget invests in the safety and health of all Americans. An issue that we have been working on at home and abroad I want to start with and that is as we work to stop the spread of the Zika

virus, the Administration is also requesting more than \$1.8 billion in emergency funding, with \$1.48 billion for HHS.

We appreciate the Congress' consideration of this important and timely request so that we can implement the essential strategies to combat this virus.

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

Today too many of our Nation's adults and children with diagnosable mental health disorders do not receive the treatment that they need. So this budget proposes \$780 million to close that gap.

Research shows that early interventions can set the course of a child's success, and that is why we propose extending and expanding the Home Visiting Program to help even more families in need support their children's growth.

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. This is a vital investment for our future. Each one percent drop in cancer death rates saves our economy approximately \$500 billion, not to mention the comfort and security that it brings families across the country.

Today we are entering a new era in medical science. With a proposed increase of \$107 million for the Precision Medicine Initiative and \$45 million for the Administration's Brain Initiative, we can continue that progress.

But for Americans to benefit from these breakthroughs in medical science, we need to ensure that all Americans have quality, affordable and accessible health care. The Affordable Care Act has helped make historic progress. Today more than 90 percent of Americans have health coverage. This is the first time in our Nation's history that this has been true.

This budget seeks to build on that progress by improving the quality of care that patients receive, spending our health dollars more wisely and putting an engaged, empowered, and educated consumer at the center of their care. By advancing and improving the way we pay doctors, coordinate care, and use health data and information, we are building a better, smarter, healthier system.

Finally, I want to thank the employees of HHS. In the past year they have helped to end the Ebola outbreak in West Africa. They have advanced the frontiers of medical science. They have helped millions of Americans enroll in health coverage, and they have done the quiet day-to-day work that makes our Nation healthier and stronger, and I am honored to be a part of this team.

As members of this Committee, I think, know, I am personally committed to working closely with you and your staff to find common ground and deliver impact for the American people.

With that, thank you and I am happy to take your questions.

[The prepared statement of Ms. 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 Ways and Means

U.S. House of Representatives
February 10, 2016

Chairman Brady, Ranking Member Levin, 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). Last legislative session, this Committee took historic steps to pass the bipartisan Medicare Access and CHIP Reauthorization Act of 2015. We thank you for your leadership on that important issue 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 convened

state leaders in our fight against prescription drug abuse 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 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 1.2 million patients at 447 centers in Texas and 600,000 patients at 247 centers in Michigan. 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, mental 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 mental and behavioral health services. We know this is a priority for many of you on this Committee.

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.

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. The Department has already committed to moving Medicare fee-for-service payments to 30% in alternative payment models by the end of 2016, and 50% by 2018. We believe that we are on track to meet our goal, and 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 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 drug abuse, invests in crucial behavioral health services, and strengthens our nation's public health infrastructure.

Preventing Prescription Drug Abuse. Prescription drug abuse impacts the lives of millions of people across the country—with 78 Americans dying in opioid-related deaths 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 addiction 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 Mental and Other 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 mental health care, to help engage individuals with serious mental illness in care, improve access to care by increasing service capacity through certified community behavioral health clinics, boost the behavioral health workforce, and ensure that behavioral health care systems work 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—established by section 223 of the Protecting Access to Medicare Act of 2014 under this Committee’s leadership.

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 more than \$1.8 billion in emergency funding, including \$1.48 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 epidemiology and expanding laboratory and diagnostic testing capacity; improving health services and supports for low-income pregnant women, and enhancing the ability of Zika-affected countries 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 recent increase in unaccompanied children apprehended at the Southwest border, ACF is taking prudent steps to add temporary capacity so that we are adequately prepared. To ensure that HHS can provide care for all 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.

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 in rural areas and families working non-traditional hours.

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.

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 14 alone the HCFAC program returned over \$3.3 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 BRADY. Thank you for your testimony.

We will now proceed to the question and answer session.

Secretary, exchange enrollment for 2016 will be significantly lower than the nonpartisan Congressional Budget Office projected when the law passed, in fact, about half that level, and it has been lower for every year since the law passed, and despite spending over \$1.7 trillion on coverage, poor enrollment results show Americans just are not buying what the President is selling on this law. In fact, millions would rather pay the punitive individual mandate tax penalty than buy Washington designed insurance they do not want and often cannot see their preferred doctors or hospitals.

So it is not surprise the law is not working as advertised, and that is because the theories behind this, the Washington designed products, punitive mandates are just fundamentally flawed.

So do you believe the exchange enrollment projections—I am not talking Medicaid—exchange enrollment projections made by CBO at the time of the law's passage and not met each year since are fundamentally flawed?

Secretary BURWELL. So with the——

Chairman BRADY. Is the CBO wrong or is it the enrollment just continues to fail to even come close?

Secretary BURWELL. I think with regard to the most recent CBO numbers, as we look at those numbers, the most important thing to focus on is the number of uninsured, and when we look at CBO's original projection there, in terms of that drop, and what we have achieved as a Nation, we are actually slightly higher in terms of the number of reduction of uninsured.

And I think we all would accept that in terms of how we get to that reduction, it is good when we have a lower unemployment rate, and that often leads to fewer people being uninsured. It is good when it comes through the marketplace, and it also happens through Medicaid.

With regard to the comparison of the numbers, I think you know that at the end of this open enrollment, CBO's adjusted number is around 13 million. Our number is about 12.7 in terms of the enrollment in the marketplace, and one of the big changes from CBO's original estimates, CBO estimated a couple of things.

One is that there would be great movement from the employer-based market to the marketplace, and that we have not seen, and as part of CBO's changes, I think that is an important part of what they are considering.

We now have the numbers before us, and one of the numbers that CBO expressed, whether it is a concern or not, is that people would move from their employer-based care to the marketplace care, and when we have not seen that, but you see an uninsured number going down, but you do not see as many people in the marketplace as they originally projected.

Chairman BRADY. Two thoughts. One, you focused on what happens in the insured, including Medicaid, when the question is really related to the exchange enrollment area, and the numbers you cite are enrolled, not paying customers within that, which we know it will lower again taking us below the projections.

We just see structural problems, disagree with the approach of this law. This Congress, this Committee will continue to work toward repealing it and replacing it with more patient-centered care.

Final question while you are here. I want to talk to you about my requests for information regarding the Obamacare Cost Sharing Reduction Program. For more than a year, both Energy and Commerce and this Committee have been asking HHS for documents and interviews about how the Administration decided to funds cost sharing reduction payments from an account dedicated to something else, premium tax credits.

The law is very clear. It states payments from the premium tax credit account only may be made for tax refunds and refundable tax credits. Cost sharing reduction payments are neither of these. They are payments made to insurers to reimburse for additional benefits provided to eligible beneficiaries.

Nevertheless, this Administration has paid out more than \$5 billion in these payments in clear disregard of the law. This Committee has the constitutional obligation to oversee how the Administration implements the programs paid for by American taxpayers and has waited patiently for the necessary information.

In response to our inquiry on January 19th of this year your assistant secretary wrote that Congress did not have a legitimate oversight need for the information requested. This does not represent a good faith attempt to respond to congressional oversight. This Committee determines what constitutes legitimate oversight, not a HHS assistant secretary.

So let me be clear. It should not be necessary to subpoena the information this Committee needs to conduct oversight, but if HHS does not respond to this Committee's information request, I will not hesitate to issue subpoenas for these documents.

So my question to you, and you can resolve this today: will you provide this Committee the documents requested and allow requested employees to speak with staff, or will I have to compel your cooperation?

Secretary BURWELL. Mr. Chairman, my understanding of where we are, and we have had letters back and forth, I have had an opportunity to speak with Chairman Upton where this is also in terms of your committee and Chairman Upton's committee that we are having both of these conversations; have spoken directly with him, and my understanding is with regard to that issue that we are at a place in terms of an agreement of what our next steps forward are in that space.

I think with regard to the substance of the issue at hand, which was the question of the authorities, that we believe and have cited we believe that the authority exists in U.S. Code 13-3124, which I think is the exact provision. We have filed our brief as recently as last week.

I think you know this is a matter where the House of Representatives is suing the department and myself with regard to this issue, and so we have filed that brief. I think we are in conversations with your staff to provide in terms of the issues in the conversation that you have asked for.

And so I think that we are taking that next step right now, is my understanding of where we are.

Chairman BRADY. I do not think that is the case, but here is my point. This Committee has oversight interests separate from the House's litigation. We have responsibilities and oversight that extend well beyond this particular program that the Administration's actions have affected.

The law is clear. The dollars will be spent. The Administration spent it in complete disregard to that law. That is why we are investigating this action, and so we are going to continue to seek those documents, and I am hopeful that the agency will be forthcoming both on the documents and making those staff available for interviews because we will not give up in this regard.

So with that I would like to recognize the distinguished Ranking Member from Michigan, but I have been instructed that the House will adhere to the 15 minute rule very tightly. So we are going to recess until after these three votes, Madam Secretary, and then we will be back at that point.

The committee is recessed.

[Recess.]

Chairman BRADY. Secretary, thank you for being patient. We just took a short hearing and made it shorter. So after Mr. Levin questions, we will be going to three-minute questioning, and it will be strictly enforced. We want as many members to be able to visit with you today as possible.

I will now recognize the distinguished ranking member, Mr. Levin.

Mr. LEVIN. Thank you.

In order to expedite, Mr. Chairman, everybody's opportunity, I will limit myself to three minutes.

Thank you.

There was discussion here about the cost sharing issue. I just want to mention, Mr. Chairman, the Republicans decided to file a lawsuit, and now they want to take depositions outside of that lawsuit. I am not sure what the motivation might be.

You mentioned in your opening statement about TANF. I think you and I agreed that we would have an effort on a bipartisan basis with the subcommittee leadership on both sides to work out possible changes, and I hope we will proceed on that basis.

Let me just ask you about Flint. There is a panel discussion going on now. The person who first came across, I think, the deep problems there is testifying. I think also the Mayor of Flint is there.

So if you would discuss the HHS role because there are so many health aspects to this in terms of the CDC role, in terms of health care for these kids in their schools, et cetera.

So could you briefly describe what you are undertaking? The State failed in its responsibility. The Federal Government is stepping up to the plate here. Tell us what you contemplate.

Secretary BURWELL. So the President asked HHS to take the lead in terms of the interagency effort, working with EPA, HUD, USDA and FEMA, and we have done that. The Assistant Secretary for Preparedness and Response, Dr. Nicki Lurie, is leading that effort from an HHS perspective with Dr. Karen DeSalvo, the nominee for the office of the Assistant Secretary for Health. So that is our lead team.

Our efforts are focused on two fundamental things in terms of where we are and the go forward, supporting the State, the county and the community in two fundamental things.

The first is clean water and water that is potable, drinkable, and usable for the community. That has some short-term issues, and that has to do with things like FEMA helping get bottled water out, the installation of filters, which HUD is helping with, in terms of making sure people are putting in those filters right.

So there is the short-term solution, and then there is the longer term solution in terms of piped water being clean and usable. Focusing on that part, EPA obviously is leading much of the Federal Government's work in that space.

The second part of our effort in terms of what we are focused on in our plan is to support the local community as well as the State in determining the extent of the problem cost. In other words, how many children are suffering from elevated levels of lead, and then the attendant circumstances from a public health's perspective that come with that?

As we determine that, then determine how we go forward and assist in mitigating those circumstances.

Mr. LEVIN. And in terms of health services, in particular, if you would just describe that because in mental health I was deeply troubled to learn there is one social worker, I think, for the entire elementary school system, and you have here a major health crisis for thousands of children who are now threatened through no fault of their families at all. Tell us a bit about that.

Secretary BURWELL. So the mental health and the behavioral health we think is an extremely important thing, and when we activated our efforts and the President asked us to go in, we activated SAMHSA, the Substance Abuse and Mental Health part of HHS so that they are supporting and providing behavioral health for the children, for the parents, for everyone.

We do that in crisis whether that is where other kind of crises occur, natural disasters, shootings or other things. And so SAMHSA is also a part of our extended effort on behavioral health.

With regard to other parts of the health issue, we have worked with USDA, and USDA is making sure that WIC will pay for a formula that does not need to be water mixed.

Mr. LEVIN. If it is mixed with water, it makes it worse.

Secretary BURWELL. Right. So USDA is taking those steps. So we are working on the health issues both in a preventative form, in terms of pregnant mothers, as well as making sure that these children are getting tested.

And we are using our HHS facilities and sites to help with that, and whether that is using our health centers that are funded through HHS or using our Head Start facilities to get the information correctly to parents so they know that they need to get tested, and so we are supporting the State and the local community in that effort to get the children tested and then to do the follow-up services needed.

Testing is also something paid for in Medicaid.

Mr. LEVIN. Thank you very much.

Thank you, Mr. Chairman.

Chairman BRADY. Thank you.

Mr. Johnson, you are recognized for three minutes.

Mr. JOHNSON. Thank you, sir.

Madam Secretary, I would like to start by asking you about the President's budget for refugee resettlement. Is it not correct that he proposes increasing the number of refugees to at least 100,000?

Secretary BURWELL. That is correct, by 2017. By 2016, 85.

Mr. JOHNSON. Now, that is an increase of over 30,000 from 2015, with many of those refugees coming from Syria. It is no secret I oppose the President's plan. We just cannot take the chance of a terrorist slipping through because we cannot vet these folks.

Since Texas receives about ten percent of all refugees, my constituents are very troubled, but you know what else is troubling? These refugees end up on social welfare programs like food stamps and Medicaid, and for more than just a few of them. In fact, in 2013, over 91 percent of Middle East refugees received food stamps while fewer than half worked any point in the last five years.

Madam Secretary, with all of these Syrian refugees coming in, how much is this going to cost the American taxpayer, given their long-term use of social welfare programs?

And what are we looking at? After all, we are over \$19 trillion in debt right now.

Secretary BURWELL. So with regard to the issue and our role in the refugees, I think you know our role is at the point at which the refugees have been placed that we do limited support to the local communities and to the refugees for a limited space of time.

I would be interested in making sure we get the numbers that you have with regard to the work numbers because the numbers that I have seen are generally higher than that in terms of the percentage of people that actually through our refugee programs that end up working. So I would love to make sure we can follow up with your staff to understand if there is a difference in the numbers that we are seeing because that is related to this issue of the estimates of the total cost to communities and other services.

Mr. JOHNSON. Yes, we would be glad to get those to you.

Where are you on issuing new Medicare cards without Social Security numbers? Are you still on track to reissue all Medicare cards by 2019?

Secretary BURWELL. Congressman, this is one that you and I had both similar interests and similar questions, and in terms of 2019 and that time frame, yes, we are very much on track to meet those deadlines that have been legislated. I have actually pushed the team to see if there is any way that we can beat those deadlines, but we are certainly on track at this point.

Mr. JOHNSON. Thank you, ma'am.

Mr. Rangel, you are recognized.

Mr. RANGEL. Thank you, Mr. Chairman.

Welcome. Puerto Rico, I understand that you have had some changes with the DSH formula as well as removing the cap from Medicaid, but since I have been in the Congress, Puerto Rico's health care system has been far below the national in terms of the access to quality health care, and as a result of the recent fiscal crisis, it is my understanding a lot of doctors and health providers have left the island.

This changing in the formula, what does this mean in dollars and cents as relates to \$82 billion discretionary funds that you have?

Secretary BURWELL. So with regard to the proposal that we currently have, I think as you said, what we want to do is try and get the Medicaid efforts to a place where they are more similar to those for the rest of Americans in the country.

Mr. RANGEL. They are crippled now, and all I want to know is in terms of fiscal relief, I mean, what you talk about is equity and fairness that we should have had. Now they are crippled for a variety of reasons, and health care is a major reason.

In the three minutes I have, could you tell me out of your budget how much is set aside to try to give assistance to our citizens, most of whom are not Muslim, but to make it easier; how much money is set aside to help them in this fiscal crisis?

Secretary BURWELL. So there are a number of places in the President's budget that—

Mr. RANGEL. Total, if you brought them all together, what would it amount to?

Secretary BURWELL. That I will have to go because I need to work with my colleagues at Treasury and we will get back to you.

Mr. RANGEL. Why do you not give an estimate so I will have some idea of the degree of urgency that HHS has placed on this?

Because a large part of their problem is within the power of HHS.

Secretary BURWELL. I think at this point I will have to get back in terms of the number. The number is a large one.

Mr. RANGEL. Well, whatever formulas you have changed, when we do anything on the committee, we have to put a dollar estimate on what is it going to cost.

Secretary BURWELL. And we do have a dollar estimate in the budget, and I will get back on the number. I am—

Mr. RANGEL. You could not even guess how much of the 82 billion we are changing the formula, bringing equity and fairness, bringing it up to Stateside, providing more money for a disproportionate share, Medicaid caps removed.

Secretary BURWELL. With regard, there are a series of proposals throughout the budget—

Mr. RANGEL. How soon can I brag about how your office has comes to the assistance of our citizens in Puerto Rico?

Secretary BURWELL. You will be able to do it by the end of the day.

Mr. RANGEL. That is fair enough. I pass.

Chairman BRADY. Thank you.

Mr. Tiberi, you are recognized.

Mr. TIBERI. Thank you, Mr. Chairman.

Secretary Burwell, thank you for being here.

As you know, I think you would agree—maybe not—Obamacare's co-ops have been a disaster, and after using American taxpayers' piggybank, more than half have failed. This morning, the Columbus Dispatch, my hometown newspaper, I was greeted with this headline: "Customers mad about late notice. Ohio Health dropped."

So Ohio Health is the largest hospital system in central Ohio, the largest, and these articles, and there is a second one that I am

going to submit for the record, Mr. Chairman, both of them, and we will get you a copy of both of these articles.

They indicate that a company called InHealth, which is a co-op, headquartered in Westerville, Ohio, is under enhanced oversight, which means CMS is concerned about its financial stability and it is closely monitoring its operations.

The article that I read this morning says about 9,000 Ohioans are enrolled in InHealth, and they recently got some bad and surprising news. At the last minute, InHealth decided to drop most Ohio Health hospitals and doctors from their network, leaving them with few options now that the enrollment period has passed.

So this article from this morning's paper talks about a couple in Marion, Ohio. Marion County has one hospital. It is an Ohio Health hospital. So this couple now has to drive over 20 miles to go to a hospital outside of the county to get an in-network hospital rather than go to the one just down the road that they have been using for years.

Another article from last week quotes a man from Westerville where InHealth is headquartered in my district, also had a preferred hospital, Ohio Health, that he went to that is now out of network for him.

So these folks in this article have been going to doctors and hospitals that they wanted to until they got onto this co-op that was created under Obamacare. So the article goes on to talk about how this co-op is struggling, and the article now also says that these folks are now going to have a narrower provider network because of the mandates and regulations under Obamacare.

So what I do not understand is how the Administration that has been crowing about consumer and patient protections in the President's health care law allow a co-op that was created under the health care law, can allow this co-op that is supposed to be closely monitored, pull the wool out.

And you will see the article here. Some of these people are just devastated from losing their doctors and hospitals, to allow a provider to pull out of a provider network, provide a major announcement, major changes, after the enrollment period has passed.

[The information follows:]

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OHIOHEALTH DROPPED

Customers mad about late notice

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By Ben Sutherly The Columbus Dispatch

Some central Ohio consumers say a Westervillebased health insurer intended to keep quiet about its plan to drop OhioHealth hospitals and doctors from its provider network until it was too late for many of its enrollees to change their health plan.

As of
Tuesday, 45
people had
filed
complaints
with the Ohio
Department
of Insurance,
and The
Dispatch
obtained

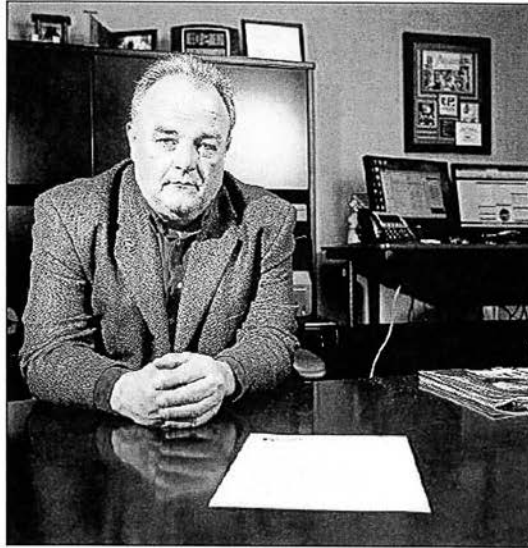
about half of the complaints through a public-records request.

In those complaints, the consumers, who mostly live in Franklin or Delaware counties,

expressed frustration over InHealth Mutual's last-minute notice to consumers about its plan to drop most OhioHealth providers as of March 1. As many as 9,000 people could be affected statewide.

Many consumers said they were not notified of InHealth's plan to narrow its provider network until last week, though some received robocalls on Jan. 30, the day before the deadline to sign up for health insurance through the federally run health-insurance marketplace.

Richard "Rich" Schooley, himself an insurance agent, said he carefully vetted InHealth's coverage before he purchased coverage through the marketplace, only to receive a letter last Wednesday telling him that OhioHealth would be dropped from the network on March 1.



“It’s terribly wrong, and it really screwed the consumer,” said Schooley, 53, of Canal Winchester. “We’re stuck; they can do anything they want to do. That’s not fair; that’s not right.”

InHealth officials declined to be interviewed for this article, but in a statement, the company reiterated that it is a nonprofit mutual insurance company that is “doing all we can to work in the best interests of our members.”

In an interview last week, an InHealth official acknowledged that efforts to get OhioHealth to agree to lower reimbursement rates had broken down by late December.

During the first half of January, InHealth’s leaders decided to drop OhioHealth from the provider network. An official with the Ohio Department of Insurance said that InHealth contacted the department late on Jan. 15, triggering a required 15-day review period during which department officials review documents to ensure that insurance companies clearly explain provider-network changes to consumers.

However, an official with the Ohio Department of Insurance said nothing stops insurers from starting the notification process during the 15-day review period. The Department of Insurance did not encourage InHealth to begin the notification process earlier.

“We consider this decision to be a business decision of the company,” the official said.

The official said the department sometimes gets notices from insurance companies about their plans for a “market

disruption” that ultimately doesn’t happen. “This is, from our perspective, not a done deal until it’s a done deal.”

But some Ohioans said they are furious that InHealth is putting coverage with Ohio-Health on the line.

“I feel cheated,” said Victoria Lawson of Franklin County’s Pleasant Township. She and her husband, both in their 60s, have an InHealth policy. “InHealth needs to pony up and come to an agreement with OhioHealth.”

InHealth has said that OhioHealth is an “outlier” in how much it charges for care. OhioHealth has said what it charges is competitive.

Ohioans who buy coverage through healthcare.gov typically cannot sign up for a different plan after the open-enrollment period ends. There are some exceptions that allow for a special enrollment period; among them, the loss of a job, a move or the birth of a child.

But an eleventh-hour change in an insurance company’s provider network isn’t one of them.

The federal government will not create a special enrollment period for people affected by InHealth’s decision, said Andy Slavitt, acting administrator for the Centers for Medicare & Medicaid Services, in a conference call last week.

But Aaron Albright, a CMS spokesman, said the federal government will review InHealth’s provider network to make sure it is adequate.

Sonya Peria and her husband, Chris, live in Marion and said they will not have an in-network hospital close by as a result of the change.

“It does put us in a very difficult situation,” Mrs. Peria said. “It’s not my fault that this happened.”
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HEALTH COVERAGE

Insurer, OhioHealth split could hurt 9,000

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By Ben Sutherly The Columbus Dispatch

true

While wintering in Florida this past weekend, Rick and Linda Vierow received a troubling voicemail from their health insurer, In Health Mutual.

In Health was cutting a major central Ohio hospital system, Ohio Health, from its provider network on March 1. For the Vierows, who are early retirees in their 50s, that meant their physicians and some of their preferred hospitals would no longer be part of their health plan's provider network.

The Vierows had just purchased their health policy through Ohio's federally run health-insurance marketplace. So they scrambled to find another plan whose network included their doctors before Sunday, the last day to sign up for marketplace coverage for 2016.

They enrolled in an Anthem Blue Cross and Blue Shield policy whose network included their doctors but not their preferred hospital, OhioHealth Riverside Methodist Hospital. And the new policy is not compatible with a health-savings account.

The Vierows, who live in Westerville, were not happy with the last-minute notice that they received from InHealth. They are among more than 9,000 Ohioans enrolled in InHealth coverage through the marketplace who could be affected by the split.

“We find it very difficult to believe that providers and insurers can change the product that radically midstream,” Mr. Vierow said.

People who buy coverage through Ohio’s health-insurance marketplace typically cannot sign up after the open-enrollment period ends. There are some circumstances that can trigger a special enrollment period — the loss of a job, a move, the birth of a child— but an eleventh-hour change in a plan’s provider network isn’t one of them.

The last-minute notice “is a significant concern to this organization,” said Dr. Bobbie Freeman, chairwoman of InHealth’s operating board, as well as its chief administrative officer and chief medical officer. “We did everything we could to get the decision made and notification given in a timely fashion.”

She said the Ohio Department of Insurance completed a mandated review of InHealth’s plan to drop OhioHealth from its network on Friday, after which InHealth immediately began to notify its members of the change.

InHealth had 2,646 members with marketplace and non-marketplace coverage that accessed care through OhioHealth last year. Hundreds of members who are pregnant, already undergoing a course of treatment or possessing a current authorization for health-care services with an affected facility or provider can receive that care at in-network rates, InHealth said.

Freeman called Ohio-Health “an outlier” in how much it charges for care, noting hospitals associated with Mount Carmel Health System and Ohio State University offered lower rates. InHealth doesn’t negotiate directly with OhioHealth, instead accessing its services through a third-party agreement with a company called Ohio Health Choice.

In an emailed statement, OhioHealth said: “We do not disclose our negotiations publicly. What we can say is that our contract reflects what we believe to be a competitive, commercial market rate.”

About 15 percent of OhioHealth providers will remain part of InHealth’s network through other contracts, Freeman said.

Last fall, the federal government placed InHealth under “enhanced oversight.” It is one of about two dozen “consumer operated and oriented plans,” many of which have shut down in the past year.

InHealth remains financially sound, Freeman said, though it might not turn a profit until 2018.

InHealth said this past fall that it was trying to slow the rate at which it’s burning through its cash reserves, in part by working to get hospitals, doctors and other providers in its

health network to agree to lower reimbursement rates.
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Secretary BURWELL. With regard——

Chairman BRADY. Madam Secretary, I apologize. Time has expired in the three minutes, and hopefully you will get a chance to respond to that a little later.

Dr. McDermott, you are recognized.

Mr. MCDERMOTT. Thank you, Mr. Chairman.

I will respond. The Republicans gutted the risk corridor money, and so these co-ops are going down. That is what happened in Ohio. So there is no mystery to what happened.

The newspaper just did not go to the fact that the Republicans in the Congress had taken away the risk corridor money.

Mr. TIBERI. Will the gentleman yield?

Mr. MCDERMOTT. No. I have got only three minutes.

I want to ask you a question about drug costs because drug costs are scaring the living daylights out of people, and when we put Part D in the law, the Republicans put it in by caving to the pharmaceutical industry and tied the hands of the Secretary and taped his or her mouth shut so you cannot negotiate any kind of reductions in drug prices; is that correct?

Secretary BURWELL. At this point I do not have negotiating authority. That is one of the things we had asked for in our budget, for specialty and high cost drugs. That is one of the proposals that is in the President's budget right now.

Mr. MCDERMOTT. Does the Veterans Administration have the ability to negotiate reductions?

Secretary BURWELL. Yes, they do.

Mr. MCDERMOTT. Do you know the percentage reductions that they have negotiated there?

Secretary BURWELL. We know that they have been able to achieve cost savings.

Mr. MCDERMOTT. Twenty percent, 30 percent?

Secretary BURWELL. I would have to ask the Secretary of the VA.

Mr. MCDERMOTT. You do not know them?

Secretary BURWELL. Yes.

Mr. MCDERMOTT. How much money do you spend in Medicare on pharmaceuticals?

Secretary BURWELL. The number, the percentage continues to risk, and that is why this is one of the areas of focus for us in terms of we know that in the most recent year for statistics, 2014, we saw a 12 percent increase in just the pharmaceutical costs.

Mr. MCDERMOTT. What is the dollar amount that you spend?

Secretary BURWELL. We can get back on the dollar amount. In percentage terms it is a growing percentage of the overall Medicare budget, which is 52 percent of all of the entitlements at HHS.

Mr. MCDERMOTT. Let's say you spent \$100 billion on pharmaceuticals, right? Just for a hypothetical.

Secretary BURWELL. Yes.

Mr. MCDERMOTT. If you reduced that, if you could negotiate a 20 percent reduction, that would be \$20 billion saved; is that correct?

Secretary BURWELL. Yes, it is.

Mr. MCDERMOTT. If you could negotiate a 40 percent reduction, it would be 40 billion, right?

That is what the Veterans Administration says, somewhere between 40 and 60 percent reduction, and it seems to me that you have asked for that in this budget. Tell us about what is in the budget as far as negotiating ability.

Secretary BURWELL. So there are number of things that are in the budget with regard to the high cost drug issue. This is one of them in terms of negotiating authority. We have also asked for the authority for us to pool with States and Medicaid to create Medicaid pools so that the States can negotiate in a more effective way in terms of drug costs for the States.

The third thing that I would mention in the area of high cost drugs that is in this budget that I think is important is speeding up the closure of the doughnut hole for our seniors. Right now through the ACA, the closure that originally occurred has saved \$20 billion for ten million seniors in the country, and so working through our ability to do that are three of the priorities we have.

Chairman BRADY. Thank you. All time has expired.

Mr. Reichert.

Mr. REICHERT. Thank you, Mr. Chairman.

Thank you, Madam Secretary.

I just want to cover quickly some of my major concerns with the President's budget. Reduces biologics market exclusivity from 12 to seven years, a serious impact on TPP and the biologics industry.

It cuts medical education payments to hospital by ten percent; cuts reimbursement to critical access hospitals, which are the small rural hospitals like Sequim Valley Hospital that you are familiar with coming from Washington State for those many years; cuts payments to long-term care hospitals, skilled nursing facilities, home health agencies; cuts Medicare Hospice payments. Those are some of my major concerns.

But I want to also in my short time thank you for your work with the Bill and Melinda Gates Foundation, for promoting women's health, children's health, and fighting global poverty, and all those things that you have done. You know, I know your heart. It is a caring heart, and so I am going to move away from partisanship messages for a moment and ask for your help, and I'm going to ask for the President's help and the Vice President's help, the Administration's help on this.

I am on a mission, and I want you to be a part of the mission, and the mission is this. The President has said we are taking a moon shot on cancer, \$755 million in this effort. But here is a group of people I am going to share with you who are left out.

One of the most common side effects from cancer treatments is lymphedema. It afflicts an estimated 15 percent of all survivors and 40 percent of all breast cancer patients. As beneficiaries live longer, an even greater emphasis must be placed on self-care. These lymphedema patients need these compression garments. I am asking today, Madam Secretary, for your help, the Administration's help in providing the care for 40 percent of breast cancer survivors who need these garments.

The money we save, the health issues that we can avoid, providing these garments, well, they are not measurable. Can you help us with that?

Secretary BURWELL. Congressman, I will look at it and follow up and follow up directly with you.

Mr. REICHERT. Can you help us with that?

Secretary BURWELL. I assume it is a payment issue in terms of what we do and do not pay for? Is that what it is?

Mr. REICHERT. We just need your help. Yes. Would you help us with that?

Secretary BURWELL. I will look into it and work to see what we can do within our authorities. You know, when it is a payment issue—

Mr. REICHERT. It has been years, and the \$755 million we are asking for, the President asked for, at least some consideration for the help of these people suffering from this disease should be considered.

I yield back.

Chairman BRADY. Thank you.

Mr. Lewis, you are recognized.

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

Madam Secretary, welcome.

Secretary BURWELL. Thank you.

Mr. LEWIS. Thank you for your service and for all your great and good work.

Madam Secretary, as you well know, the CDC is headquartered in my congressional district. Can you talk about public health preparedness generally? Are we ready? Are we prepared?

My understanding is that the Zika cases have already been reported in the United States. Do we have an estimate or the potential cost of this virus?

Secretary BURWELL. So the Zika virus, I think, is part of the broader preparedness, and fortunately, the work that we did in Ebola has put us in a place where there are a number of things that help us.

But with regard to the Zika virus specifically, I think it is important to note a number of things that are very important. First of all, the most important concern we have right now is pregnant women, and I think you know we have put out the guidance that indicates that any woman that is pregnant, the CDC recommends you do not travel to any of the regions because microcephaly, the birth defect, that while we have not been able to scientifically put the causal link, we have enough concern that we have made that recommendation.

So focus on pregnant women. Next is we need to make sure that we are focusing on controlling the mosquitos that cause it. This is different, and I think many people will harken back to Ebola, but this is fundamentally different because it is passed by a mosquito biting someone who has the disease and then biting another person.

Eighty percent of the people that have it do not know, and so this is a part of what is a very large problem, and for those that do have it, it is about a week's worth of fever, and sometimes they think that it is the flu or something else.

With regard to our domestic preparedness, we have a plan together with the CDC, the NIH, the Assistant Secretary for Preparedness Response in terms of our homeland preparedness.

What we need to do though, and we have the supplemental that we have proposed, is make sure that we are able as Nation to be prepared as we go into the summer months, especially in the South.

So there are two mosquitos that transmit this. One is a very efficient transmitter, meaning it will bite four individuals in a meal, and so you can imagine how that gets passed. The other mosquito, that mosquito is limited into the Deep South in our country. The other mosquito can cover almost up to 20 or so States. That one bites other things, but I still may be a transmitter.

So we need to get in place the right communications, the right public health, and the right mosquito control before we hit the South.

Right now in the United States no continental cases have been passed by a mosquito to a person. It is travelers coming back, and one sexual transmission in Dallas. In Puerto Rico, we have a situation where already we are seeing mosquito pest cases.

And so those are the elements we need to do. We have a plan. That is why we have asked for the funding.

Mr. LEWIS. Thank you, Madam Secretary.

Chairman BRADY. Thank you.

Dr. Boustany, you are recognized.

Mr. BOUSTANY. Thank you, Mr. Chairman.

Secretary Burwell, I want to get the Administration's clarification on health reimbursement arrangement or health reimbursement accounts. In 2013, harsh penalties were applied to small business owners who use these health reimbursement accounts for their employees to the tune of \$100 per day per employee.

I questioned Secretary Lew about this last year during the budget talks, and subsequently the Administration put this on hold for less than a year.

I heard from Randy Noel in Louisiana, who is a small business owner, he has been advised to pay these penalties because the time in which this was put on hold was less than a year.

There has been so much uncertainty, but this is a very draconian penalty. Is the Administration going to eliminate this penalty or would you work with us? Because Mike Thompson and I have bipartisan legislation; it is bicameral and it is also bipartisan in the Senate, to eliminate these harsh penalties.

Secretary BURWELL. Is this the rulemaking that you spoke with Marilyn Tavenner about? Is it that particular rulemaking?

Mr. BOUSTANY. I actually had a conversation with Secretary Lew about this. I think I did raise this with Marilyn Tavenner as well.

Secretary BURWELL. I want to follow up because there are two different provision, and I am not sure which one we are talking about here.

Mr. BOUSTANY. Well, this is specifically about the health reimbursement arrangements which allow for employers to provide dollars' assistance to their employees. It is fine under ACA, but for some reason the Administration going back to 2013 imposed a \$100 per day per employee penalty.

It is very draconian on these small businesses, and Secretary Lew admitted it was a problem last year. It was put on hold, but

for really less than a year. I think it was like six or seven months, and now we have this penalty re-imposed.

These small business owners do not know what to do. We think it ought to be eliminated. These employers are trying to help their employees and provide for insurance.

Secretary BURWELL. Let me check and follow up. It is on the tax side though. Is that why you went to Secretary Lew?

Mr. BOUSTANY. Well, I did raise it because it is a tax issue, but it also is a health issue.

Secretary BURWELL. Okay. I will follow up on our end.

Mr. BOUSTANY. I intend to ask Secretary Lew about it when we have him in front of the committee as well.

Secretary BURWELL. Okay. I will follow up with the Secretary. This one probably sits with them, but as you reflect, it is an important part of the—

Mr. BOUSTANY. It is a health issue.

Secretary BURWELL. Yes. So I will follow up.

Mr. BOUSTANY. Thank you.

I yield back.

Chairman BRADY. Thank you.

Mr. Neal, you are recognized.

Mr. NEAL. Thank you, Mr. Chairman.

Thank you, Madam Secretary.

Madam Secretary, the Massachusetts delegation lunched today with Michael Botticelli and the Sheriffs' Association of Massachusetts to talk about the opiate crisis. Governor Baker, to his credit, has suggested that more than 1,200 to 1,300 people died last year in Massachusetts of opiate addiction.

Heroin is being sold on the streets of Springfield and Hartford for \$2.50 a bag, and clearly the movie HBO presented called "Heroin on Cape Cod" is riveting. I would recommend it to anybody who might be interested in what has happened.

The President's Drug Czar today, Mr. Michael Botticelli, said that part of the problem clearly is the overuse of prescription drugs, and that it has heralded a new era in how to treat addiction.

Seventy-eight people as you noted lose their lives every day as a result of these drugs, and you have offered several proposals in your budget to deal with this alarming epidemic.

Could you give us greater detail as to how you suggest that we might proceed?

And applause to the President for suggesting \$1 billion in new expenditure to address this issue.

Secretary BURWELL. So an issue that is deeply important to me. As many of you know, I am from the State of West Virginia where the problem has been acute for many, many years. So a priority since I came.

When I came to HHS, we put together a three-part strategy in order to make progress on it. The first has to do with prescribing. We know in 2012 there were 250 million prescriptions of opioids. I think you all know how many adults there are in our country, and the idea that in 2012 there were 250 million prescriptions, the overprescribing is a problem. We need to take that on.

As part of that, the CDC will be issuing new regulations. We know pain is important. It is important to be treated, but the over-

prescribing that has occurred, we need better direction. So that's part one.

Part two is medication assisted treatment, and right now as you reflect in terms of the numbers that are in your State and in many of the States represented here, we need these people to be in medication assisted treatment. There is not access to the treatment, and that is one of the major parts of the funding that you mentioned. It is to create an ability for States and communities.

So the money would go to SAMHSA and a little bit to HRSA, and that money would then go on to States and communities because we need to build the capacity for the medication assisted treatment for these people because right now they come into law enforcement.

You were just meeting with the sheriffs. I have met with the sheriffs. I met with them in Massachusetts with Governor Baker. What they will tell you is we are not social workers, but we see these people time and time again and have nowhere to send them.

The third element of the strategy, and sadly we have to have this element, is naloxone or some people call it Narcan, which is the drug when people have overdosed because sadly we have so many people that are in a state from either heroin or prescription drugs and they have overdosed, and at that point we are just trying to save lives.

And so some of the money will go to move and fund naloxone at the community level.

Much of the money we are asking for is about moving it to the States and communities that are in need so that they can build their capacity to work against these three strategies.

Chairman BRADY. Thank you.

Mr. Roskam, you are recognized.

Mr. ROSKAM. Thank you.

Madam Secretary, two quick issues. I think they are pretty straightforward and pretty simple. The House has inquired about the basic health program, and I was able to receive a briefing from your Assistant Secretary for Financial Management, Elaine Murray, who is here today and came and gave me some good insight into the process.

Out of that discussion, we put forward a request for documents on something that we learned about, and that was a document called "the big ugly table" that she said was critical in putting together the basic health plan.

Now, recognizing that we are not in litigation so that there is no concern there, we have requested this document and other documents, including the memorandum of understanding between CMS and the IRS.

The results have not been forthcoming. We have gotten, you know, redacted information followed up, back-forth, back-forth. The latest was literally a 234-page printout of public information from the CMS Web site that is submitted to Congress.

In the spirit of Congressman Rangel and the dispatch with which you were able to easily answer his inquiry, can you get us this "big ugly table" by the end of the day along with the CMS-IRS memorandum of understanding?

Secretary BURWELL. So, Congressman, my understanding is that we have turned over documents. We—

Mr. ROSKAM. They have not been responsive.

Secretary BURWELL. So I would like to follow up with staff to understand. Our staffs need to get together to understand this.

Mr. ROSKAM. Great. It is a complete mystery, and time is short. So I want to move to another issue, but it is to the point of absurdity. So if you can intervene and get us the "big ugly table," which according to the briefing was critical to the decision making, along with the memorandum of understanding between CMS and IRS, that would be helpful.

Secondly, we heard testimony at the Oversight Subcommittee about the fraud and erroneous payment rate from CMS. The Deputy Administrator said the number is 12.7 percent. The remedy or part of a solution Mr. Blumenauer and I are working together for a common access card using the same technology that DoD uses and has used in the financial services arena.

We received some technical assistance, but it was like pulling teeth from CMS; had to get the Administrator personally involved to get this done. Okay. Because he is meeting people who do not want to change things.

But this, Madam Secretary, as we both know, is a system that desperately needs to change. Would you be willing to help Mr. Blumenauer and me, as we are trying to move forward, get the technical assistance and put together a common access card pilot program that we can see if it works and if it saves money?

We are persuaded it will do that, but we need your help and we need your personal help substantively because we are meeting a lot of passive-aggressive folks that do not want to be helpful.

Will you help us?

Secretary BURWELL. I will look into seeing what we can do in terms of whether we have—is it statutory? Is that why we are providing technical assistance?

Mr. ROSKAM. Yes.

Secretary BURWELL. Because it is statutory. Okay. Then let us look into it and understand because I think hopefully this is the kind of thing that will move us along the electronic health benefits end using technology and data to do delivery system reform. So I would like to understand it more fulsome and figure out if we can provide technical assistance if it is statutory.

Chairman BRADY. Thank you. All time has expired.

Mr. Doggett, you are recognized.

Mr. DOGGETT. Thank you, Mr. Chairman.

And, Madam Secretary, the President's budget indicates that, quote, "The Administration is deeply concerned about rapidly growing prescription drug prices."

Certainly that is a concern that is so real to many consumers who are basically faced with the choice: your money or your life.

While I am fully supportive of the Biden Cancer Moon Shot Initiative that you referred to to try to convert some of the pain and grief that he and so many families have, unless the Moon Shot addresses accessibility for so many of our neighbors, it will really be just a shot in the dark.

The one thing that we already know without any more research on drug effectiveness is that an unaffordable drug is 100 percent ineffective. I applaud each of the budget's legislative proposals that

you outlined to Mr. McDermott. Together they would save taxpayers over \$172 billion.

Republicans are always telling us about how entitlements need to be brought under control and Medicare is unsustainable. I think the place to begin is by cutting those who think they are entitled to charge the highest drug prices in the world to Medicare and Medicare consumers.

Clearly legislation is required, but you and I know that lightning could strike the Capitol dome in the same place not twice but ten times, and this Congress would not be willing to stand up to the pharmaceutical lobby. It is essential that the Administration use every tool at its disposal to prevent price gouging.

You are aware that 50 of our colleagues have asked that you and the NIH use existing authority to at least set some standards for prices when taxpayers paid for the research that led to a drug. Can you assure that our request is receiving your thorough consideration?

Secretary BURWELL. It is. It is. Your letter we have received. Thank you, and we are continuing to try and pursue every administrative option.

We have proposed legislative and statutory changes as part of the budget but are looking at a wide array, which we welcome your letter and your suggestion.

Mr. DOGGETT. I am pleased with your Dashboard, with your proposal on Part B payment models. I hope you can build on the oncology care model from the Innovation Center.

I believe that when you ask that we mandate pharmaceutical companies to provide certain information that is vital, that is a good idea, but I hope that you will consider requesting that they voluntarily provide that information this year and will continue to look for ways to bundle pharmaceuticals with other services, will implement your bio-similar reimbursement rule, and take every step you can, knowing this Congress will do little, but there are still steps you can take to help American families on pharmaceutical price gouging.

Thank you so much.

Chairman BRADY. Thank you. All time has expired.

Mr. Smith, you are recognized.

Mr. SMITH of Nebraska. Thank you, Mr. Chairman.

And thank you, Secretary, for your presence here today.

I do want to follow up on a characterization made earlier that it is Republicans' fault for removing some funds, therefore causing the co-ops, the Obamacare consumer oriented and operated plans to collapse.

I do want to add though that on April 11th, 2014, from a fact sheet from CMS they stated that, quote, "We anticipate that risk corridors' collections will be sufficient to pay for all risk corridors' payments." I just want the record to reflect that.

But certainly the collapse of CoOpportunity Health for Nebraska and Iowa has been a huge deal in Nebraska. Many Nebraskans are still smarting from it. Actually a constituent named Pam has lost her coverage three times, thanks to the Obamacare, the entire plan that certainly denied her the coverage she was told she could keep, that she could afford, that covered her preexisting condition.

And so I do have a question though. As it relates to the Administrators of CoOpportunity Health for Nebraska and Iowa, it is my understanding that they kind of saw trouble on the horizon. So they requested the opportunity to suspend enrollment, and that request was denied.

Can you speak to that?

Secretary BURWELL. We discussed this, I think, last year when I was before the committee, and I would like to follow up in terms of where they felt the request because we did not, when I followed up, feel that there was a request at all that came into us and that was denied.

So I would love to follow up because when I followed up on this before, we had not received that request.

Mr. SMITH of Nebraska. Okay.

Secretary BURWELL. And so let us understand because we work with all of the co-ops on this issue. Our number one priority is the consumer, as you are indicating. That is our priority as well. That is why, to be honest, a number of the co-ops came out before this open enrollment as we worked with the States that are their primary regulator. We worked with the States on that issue.

So the consumer is the number one concern. So if we can understand how they felt they did that because if there was a process that is unclear or something there, I think it would serve everyone else if we can learn from this example.

Mr. SMITH of Nebraska. Right. And overall, you know, we heard a couple of months ago I think it was that the co-op program is on sound footing, and yet we have now learned that Maine, I believe, who was the only one at one point turning a profit, is now beginning to lose money.

Where do we stand on that entire issue? Are they on as solid footing as we were told some weeks ago?

Secretary BURWELL. So with regard to that, as you know, at that point as when we came to open enrollment, we worked with all the States to make sure that the State Commissioners of Insurance and we felt they were.

With the facts that we have and had at that time, that is where we are. I think we also have taken steps to help the co-ops in terms of how they can access capital if they need it. That guidance was put out about two weeks ago as well.

We are going to continue to monitor closely with the States.

Mr. SMITH of Nebraska. Thank you.

Thank you.

Chairman BRADY. All time has expired.

Mr. Thompson, you are recognized.

Mr. THOMPSON. Thank you, Mr. Chairman.

Madam Secretary, thank you very much for being here and the outstanding work that you and your team do.

I've got a couple of issues I would like to get a response on. The first is the recovery audit contractors, the RACs. I have had dealings with these folks in my district, and I am assuming other folks on the committee have as well.

The idea that a provider would have to wait 800 days for a decision is just wrong, and I am hoping that you are going to be able to tell me that you are working on fixing that.

And I know that the Provider Relations Coordinator Program has done some good in this area. Are there plans to expand that so we can get this number down to let people in some cases stay in business?

And then also I want to talk to you a little bit about TeleHealth. Congressman Black and I have legislation that would expand TeleHealth. It is a way that you can accomplish two I think very important goals. One is to save money, and the other and most important is to save lives.

I know the President's budget has provisions in there to expand the venues whereby TeleHealth can be used, and also to allow it to be used in Medicare Advantage.

And I would be interested in knowing if you have some sort of means by which to collect data on the cost savings because if we can quantify that, I am sure it will help us expand TeleHealth even more.

Secretary BURWELL. With regard to the first issue in the RACs, we have made changes. And so if it goes beyond the 60 days, they don't get the money, in terms of the RACs. We've actually put in place changes with the feedback.

Mr. THOMPSON. With the contractors?

Secretary BURWELL. Yes. Yes. And so if it goes beyond that period of time, it doesn't. If at any point the decisions are overturned in the process, they don't get the money either. And so we put in place a number of steps in response to the criticisms that we have heard about RACs. With regard to the telemedicine issue, as you stated, we have several proposals in our budget. We think this is an important place to make a difference, both in terms of quality of care that we can provide, access in rural areas, particularly. It's very important.

And right now, we have, we have those numbers scored. And so we have been able to score the savings that we think can occur by using telemedicine. And so we can get to you all as you all are considering your legislation how we score those numbers. And there are two different provisions, both in terms of our federally qualified and rural health clinics being initiation sites for telemedicine, as well as making sure that in Medicare Advantage it can be paid for. Which is sometimes one of the prohibitive things with telemedicine.

Mr. THOMPSON. Well, we'd like to see those numbers and that methodology, and also would love a commitment from you to work with us to make sure we can further expand telemedicine. Because it does save lives and does save money.

Secretary BURWELL. Yes. And we'll probably come to it, I think, if we're going to talk about the Indian Health Service as well.

Mr. THOMPSON. Thank you.

Chairman BRADY. Thank you. Ms. Jenkins, you're recognized.

Ms. JENKINS. Thank you, Madam. Or, Mr. Chairman. Thank you, Madam Secretary, for being here. As many of my colleagues on this Committee have already mentioned, the President's health care law has continued to fail so many Americans. Over the past few weeks, I've hosted almost 20 town halls throughout Kansas. And folks back home often tell me how they face increased premiums with fewer options for care. 2016 premiums are expected to increase by 15 to 25 percent in my home state of Kansas. This sim-

ply is not right, especially in the face of a failed economic recovery. And I, along with my colleagues here, continue to work to replace Obamacare, repeal it, find proposals that drive competition, lower cost and improve health care quality for all Americans. One particular provision of Obamacare that's especially cumbersome and drives up healthcare costs for the everyday American is the requirement that individuals have a prescription from a physician in order to purchase over the counter medicine with their health savings accounts and flexible savings accounts. And I have worked on a bill, HR1270, the Restoring Access to Medication Act, which would eliminate this unnecessary requirement that's both confusing and frankly, it's just a waste of time for patients and physicians. And we've worked closely on this legislation now for three years, with my colleague, Representative Kind, from Wisconsin. When you testified in front of our committee last June, I asked if you would support us on this type of legislation. At the time you indicated you weren't familiar with the issue. Have you had a chance within the last year to review it now? And if so, would you support the legislation?

Secretary BURWELL. With regard to the issue in terms of driving down the costs on the over the counter prescriptions, I apologize in terms of the specifics of the legislation. We'll need to come back to you on that. In terms of the basic concepts of making things simpler and easier, we're working at that across the board. And whether it's the announcement that occurred yesterday with Walgreens about over the counter and Naloxone and other drugs like that. So the concept of this is something that I think we want to continue to work on. With regard to the specifics, I will need to get back.

Ms. JENKINS. Okay. Well, I believe this is just a few easy, common sense approach. It's bi-partisan. If the Administration will just take a look at it. It's kind of frustrating, year after year after year to have you come before us as if you're not interested in looking for some of these common sense solutions to help all Americans, especially when they do have bi-partisan support. So thank you. I yield back.

Chairman BRADY. Thank you. Mr. Paulsen, you're recognized.

Mr. PAULSEN. Thank you, Mr. Chair, and thank you Secretary. Secretary Burwell, Mr. Larson. Thank you, Secretary, Madam Secretary, for being here. Madam Secretary, several states have closed down their exchanges, and many other states are facing some challenging financial situations with self-sustainability. That includes MNsure, which is Minnesota's exchange in the program. And a new audit found out that over a five month period last year, MNsure repeatedly failed to properly determine the eligibility of enrollees, resulting in potentially 271 million dollars in overpayments. That's 271 million dollars of taxpayer money. And this is the headline from the Minneapolis Star Tribune, just a week and a half ago. I'd like to enter this for the record, Mr. Chairman. And these are overpayments that occurred despite the fact that a report a few months earlier had warned MNsure that it was not accurately applying eligibility requirements. Now, the President's health care law, it does require that state-based marketplaces, that they be self-sufficient. It requires that they follow the law. But HHS doesn't really seem

to be doing anything to enforcement it on the enforcement side. Instead, they've acknowledged or they've given more money, in terms of no-cost extension requests through the end of this year. And so it seems there's no gatekeeper. There's no enforceable plan.

And this is really not about being against Obamacare. It's about enforcing the law and making sure the taxpayers are protected, and continuing to hold these exchanges accountable is going to ensure that patients ultimately are not going to be hurt when there's a change in health insurance. So my understanding also is that after all these reports, after all these audits, throwing away millions of dollars in taxpayer money, HHS's own inspection, Inspector General, is also going to be coming out potentially with a report in a few weeks that will explore issues with MNSure's internal controls. So your own Inspector General is acknowledging some of these problems. So can you just share anything with us about the upcoming report that might be coming out? And more importantly, just can you give a little bit of plan of action for making sure that MNSure is following the law?

Secretary BURWELL. So with regard to the state based marketplaces, as you reflected, a number of them are in various states and have been able to achieve certain things and not. And when they're not, you know, the Administration has engaged. And HHS has engaged with them. And whether that's in Hawaii or security issues in other state exchanges. And so we do engage on that. The IG's report is something we look forward to, and will be a part of us determining what are the appropriate next steps for us in terms of that engagement.

But across the board, as different state based marketplaces have had different issues, I think you probably know we have engaged and at various points and times needed to switch them to the platform, if they aren't able to meet certain of the conditions that you articulated. That they are making sure that there are adequate networks. That there are different types of issues. Most have been technology related, but not all.

Mr. PAULSEN. Okay. So we'll see some enforcement mechanisms, some follow ups, some follow through?

Secretary BURWELL. We look forward to the IG's report, when we will receive it. I think you know; we work with the IG as part of program integrity across the Affordable Care Act. It's something we work for. But also we want to let them have their independent view. And then they come back and tell us what they have found.

[The information follows:]

Audit finds lax eligibility checks for public health programs in Minnesota

Overpayments could be as high as \$271 million in public health programs.

By Christopher Snowbeck
Star Tribune

JANUARY 28, 2016 — 9:31PM

A new audit suggests that many people who enrolled in public health insurance through MNsure last year might not have qualified, driving as much as \$271 million in overpayments during a five-month period. The report issued Thursday by Legislative Auditor James Nobles looked at a sample of cases from early 2015 and found errors in 38 percent of those who enrolled through the state's health insurance exchange in either the Medical Assistance or MinnesotaCare programs. Auditors applied the error rate to a larger group that enrolled through MNsure to project the potential cost.

"We all know there's going to be some error, but this is higher than an acceptable error rate," said Cecile Ferkul, the deputy legislative auditor. The state Department of Human Services (DHS), which uses the MNsure system to run the programs, said the report points to issues that it continues to address, although officials questioned whether the audit overstates the problem.

The auditor's report focused on the portion of MNsure used for the state's public health insurance programs, which generally provide coverage for lower-income Minnesotans.

As of March 2015, more than half of the 870,000 people enrolled in public health care programs had done so through the MNsure system, according to the audit.

It looked at a sample of 157 enrollments through MNsure between January and March 2015, and found that 59 of them were not eligible for the public program from which they were receiving coverage.

The projected overpayment by the state for these enrollees between January and May 2015 was about \$104,213 combined, according to the report.

Auditors applied the error rate to all people who enrolled through

MNsure during the first quarter, and estimated that somewhere between 80,902 people and 132,140 people were either ineligible for coverage or had been placed in the wrong program.

The projected overpayment by the state between January and May was somewhere between \$115 million and \$271 million.

“The Department of Human Services did not adequately verify that people who enrolled in public health care programs through MNsure were eligible for those programs,” the report concluded. “This is a repeat finding.”

Of the 59 people in the auditor’s sample who weren’t eligible for the coverage they were receiving, 44 of them weren’t eligible for any coverage, the report found.

DHS officials, however, questioned this finding. Using a different methodology, DHS audited 128 cases between October 2014 and March 2015 and found only one case in which an enrollee did not qualify for any public program, Deputy Commissioner Chuck Johnson said in an interview.

Plus, the audit covered a period during which the department didn’t have a process for renewing coverage that would effectively check eligibility, Johnson said. A process for handling renewals is now in place, Johnson said, although he acknowledged problems with attempts to use the system for 64,000 people last month.

‘We need to improve’

Even with those qualifiers, Human Services Commissioner Emily Johnson Piper said she took the findings of the audit seriously.

“We need to improve, and the need to improve is critical,” said Piper, who was named commissioner in December. “Not only our IT infrastructure needs to be improved, but also our business practices and customer service as we move forward.”

Minnesota launched the MNsure exchange in 2013 to implement the federal Affordable Care Act. It’s an option for individuals and families to buy private coverage, and also is the new eligibility and enrollment system for the state’s public health insurance programs.

In November 2014, Nobles released a report that found problems determining eligibility by DHS, which is a primary user of MNsure for

eligibility and enrollment in public programs.

The new report found that DHS did not fix nine of 11 problems detailed in the 2014 audit.

In a written response, Piper said the timing of the new audit did not allow DHS enough time to correct all problems from the earlier report. She pledged, however, that the department is working to make the system better.

Republicans who have been critical of the MNsure exchange, as well as the federal health law, jumped on the latest report.

“We’ve spent more than \$300 million on this failed Obamacare exchange, and it somehow still can’t figure out how to prevent hundreds of millions in benefits from going to those who aren’t eligible,” said Rep. Greg Davids, R-Preston, in a statement.

Sen. Michelle Benson, R-Ham Lake, said in a statement that “citizens who need assistance and taxpayers who provide that assistance have both been failed by MNsure.”

During a news conference Thursday morning at MNsure’s headquarters in St. Paul, Gov. Mark Dayton said he had not seen the audit report, but said the system has improved.

Dayton cited recommendations this month from a state task force that said Minnesota should stay the course with MNsure, rather than jump to the federal government’s HealthCare.gov exchange. The federal website would not handle determinations for Medical Assistance and MinnesotaCare.

“We’re better off having this program in our own hands, controlling our own destiny,” Dayton said during the news conference.

Enroll through Sunday

MNsure called the Thursday news conference to encourage Minnesotans to use the exchange to buy private coverage from now through Sunday, which is the close of the current open-enrollment period.

In general comments before being asked about the new audit, Dayton referenced how MNsure workers have struggled with the health exchange system since it was originally planned.

“I was part of those original decisions,” the governor said, “and I look back now and I realize that we just ... seriously underestimated the magnitude of this task.”



Chairman BRADY. Thank you. Mr. Larsen, you're recognized.

Mr. LARSON. Thank you, Mr. Chairman. And thank you for holding this hearing. And Secretary Burwell, it's always a pleasure to have you here. And I wanted to thank you sincerely for your continuing outreach. You are a model of how we believe that the relationship between the executive and legislative branches should work. And I want to thank you. I want to commend the President and you for the budget. And especially, as Mr. Neal has addressed already, the more than billion dollars that have been put forward to address this long term epidemic that we're facing with heroin overdoses and opiates. And I also want to commend Senator Shaheen and Congressman Courtney. The New England delegation has come together in looking head on at this epidemic. I think this is something that affects every member in this institution, in all states. There's nothing partisan about it. We are in the throes of an epidemic. And it is my hope that while I think the billion is appropriate, by the time that we get through sorting out and going to regular order, if in fact we do, that too many more people are going to have passed away. And so what we're hoping, in the New England delegation, I hope that Members of the Committee can join with us in sending a letter to the President. I think we need emergency supplemental funding now, along the lines of Senator Shaheen and Congress Courtney have called for, that would provide the 600 million dollars that could be used immediately by those on the front lines of trying to deal with this, this epidemic. I would note that just since January 28th in New London, Connecticut, 24 deaths occurred. The Zika virus is something certainly that needs our attention, et cetera. But I dare say that this is a far greater epidemic and needs our immediate attention. And for so long, has been swept under the floor. I commend Mr. Neal for bringing this to the attention of the entire New England delegation. It's my sincere hope that the committee can join together to see if we can't get supplemental funding. I hope you can join us in that effort.

Secretary BURWELL. We look forward to working with the Congress across the board in whatever appropriate way to get the funding that we need. We think the funding and moving it to communities is important, and we'll look forward to working with the Congress.

Mr. LARSON. Thank you.

Chairman BRADY. Thank you. Mr. Marchant, you're recognized.

Mr. MARCHANT. Thank you, Mr. Chairman. Ms. Burwell, one of the most significant things that's happened in Texas in this last year as far as health care was that at least one of the largest health care providers, it may be our largest, Blue Cross, Blue Shield, completely walked away from and abandoned its PPO program. And anybody that had an individual policy had to convert to basically their HMO plan. That's, that has basically created most of the calls about health care in my office this year.

You're proposing, and you've just given notice of a benefit and payment parameters regimen that's coming up. And my concern is, does this new regimen that you're laying out, force the private insurance companies more into abandoning their PPOs and more into

an HMO plan? Or will it provide them sufficient room to where they can actually operate a PPO model?

Secretary BURWELL. Well, with regard to the, the rule making and where that will go, I don't think it is something. I think there are a number of things that these companies are considering when they're making these decisions. And I think they are two different things. There's the marketplace, in terms of those folks who are going to the individual marketplace. And then there's the employer based market. And what we know in both of those marketplaces—and obviously the employer based market is separate from the marketplace that we see some narrowing of the networks.

One of the things in the marketplace though is that you must have an adequate network. That there's at least a test for that for the marketplace in terms of what we're doing. And so many companies are making these decisions. They're making the decisions. It is a private market. And they're following the consumer. In terms of what we saw statistically, what happened from 13 to 14 and 14 to 15, what we saw is the consumer actually making choices that they were choosing a narrower network and lower price versus a broader network and higher price. And I think we see the insurers responding to that in both the private market as well as the marketplace market, the employer based market. And so we want to do this to make sure that choice is available. And this year in the marketplace, in nine out of ten counties for most of the marketplace participants, there were three or more choices. And that's a part of getting to that space. And this comes back to the other question about the networks. What I think we believe is an important part of this is downward pressure on overall healthcare costs. Because that's what's driving insurer decisions. And that's why this concept of delivery system reform, an engaged, empowered, educated consumer at the center, where we pay for value, not volume, where we use data and information and where we change the way we deliver care, is the important when we think over the long term.

Mr. MARCHANT. Mr. Chairman, if I can just ask one final question. Is there a place that I can go—

Chairman BRADY. I'm sorry, Mr. Marchant. All time has expired. Mr. Reed, you're recognized.

Mr. REED. Thank you, Mr. Chairman. Welcome, Madam Secretary. Madam Secretary, a limited time, I'm looking for an area where we may be able to advance some legislation this year in regards to reform that we can agree upon. And one of those areas is welfare reform. And I read the budget in particular. And I was very interested in pages 55 through 59 of the summary of the budget, dealing with TANF, and the issue of flexibility and the Upward Mobility Project. Could you touch on what the Administration's looking at in regards to giving greater flexibility to local and state entities that you reference in the summary portion of the budget in regards to things like Upward Mobility and others?

Secretary BURWELL. I think this is something we'd want to work with the Congress on. And think as was indicated that there has been bi-partisan work in the space of what we need to do further. I think we're very focused on the work elements and making sure that the money goes, the TANF money. And our approach is

about that. And so this is a place where I think we welcome the opportunity to work with Congress.

Mr. REED. And are there any areas in particular you could identify for us in regards to greater flexibility, the Administration would be willing to engage in a conversation giving to local and state entities that are in this space doing this much needed work?

Secretary BURWELL. I think we'd like to come back and have that conversation. Is it all right if we follow up with staff? Because I think the bi-partisan effort that was moving last year had a number of these elements that I think we thought were, were good and positive and would like to support, if we can be specific.

Mr. REED. Are there any, any areas in particular you can identify?

Secretary BURWELL. I'd like to come back on the specifics.

Mr. REED. Well, we'd appreciate having that conversation and being involved in that conversation, as it's an issue that we're taking up in our office. As we want to reform this area. The other area that I'm looking at is if there is a better way that in your opinion, Madam Secretary, that we could measure the success of these outcomes? Often I find in this area measurement of the success is how much money we spend in this regard. Is there anything in your personal opinion you think we could do better, other than just measuring cash or dollars spent on these programs? That maybe we could have that conversation of changing the metrics. Is there anything you personally would like to work with us on in regards to changing those metrics from a cash basis?

Secretary BURWELL. I think one of the metrics that we all want is knowing how many people actually get into gainfully employed situations for an extended period of time.

Mr. REED. Oh, I so appreciate that.

Secretary BURWELL. That's not the only measure, in terms of—

Mr. REED. Are there any other measures you have?

Secretary BURWELL. But that is one that I do think is an important one. And why, we believe, the money should be more targeted than it currently is in terms of what it's being for in states.

Mr. REED. I so appreciate, commend to that metric change. Because I think it is much needed in this culture, to measure the outcome based on success in regards to people getting into a self-sufficiency mode, standing on their own two feet themselves. Is there any other metric you'd be willing to discuss personally that you think is a better metric, to see how these programs are doing?

Secretary BURWELL. I think when we come back on the specifics of the flexibility, let's have that conversation.

Mr. REED. I look forward to that. And I thank you always for your hard work, and appreciate working with your office in regards to the issues that we have addressed with you before. With that, I yield back.

Secretary BURWELL. Thank you.

Chairman BRADY. Thank you. Mr. Becerra, you are recognized.

Mr. BECERRA. Thank you, Mr. Chairman. Madam Secretary, thank you very much. And always a pleasure to have you with us. Ma'am, before I ask my question, can I just say thank you for what I know you had a hand in, in the President's proposed budget, to

try to deal with Medicaid reimbursement for citizens on the island of Puerto Rico. And the fact that right now Puerto Rico's going through a very difficult time financially, they're trying to right the ship. And one of the worst things that they can face is a situation where they are having a really difficult time funding the healthcare that their residents need. Which ultimately becomes an even worse crisis if people aren't getting care now, before things get really bad. So thank you for that proposal to try to balance the way we treat the U.S. citizen on the island of Puerto Rico.

I'm interested in, if you can give me comment on the Affordable Care Act's provision that expanded the use of Medicaid so that families that are working but earn very modest incomes can still qualify for healthcare through, if not the exchange, then the Medicaid Expansion Program. I know a number of states have incorporated that Medicaid Expansion Program. Others haven't. Those states that haven't, can you tell us how many states have not yet incorporated Medicaid? How many individuals including children are impacted by not having health insurance, as a result of states refusing to adopt Medicaid Expansion? And can you tell us what the impact has been for those states that have incorporated the Medicare—Medicaid Expansion Program into their healthcare?

Secretary BURWELL. So right now, 30 states plus the District of Columbia have done the expansion. And if all the rest of the states that aren't expanded did it, we estimate that there would be four million additional people who would no longer be uninsured. 3.1 million directly in terms of the individuals that would become eligible. But in all the states where expansion has occurred, there are portions of the population that were eligible but do not sign up, but as part of the expansion, come to sign up. So the total number becomes four million.

With regard to the proposal in our budget, in the conversations with many governors across the country that are not in, one of their concerns is, "Will the Federal Government stay and be a part?" That's a question that, that I am consistently asked. Our proposal gets to that fundamental of making sure they know for the first three years, they know what their budgeting will be, which is an important consideration for governors. In terms of the benefits we're seeing to the individual, the health and financial security that it means is something that I think everyone can understand. With regard to the economics, in Kentucky, we know that the estimates are 40,000 jobs created by 2021. 30 billion dollars into the state's finances. In addition, when we have analyzed those places where there are hospital closures—and we know that's happening across the country for a number of reasons. But in the states that have expanded, the hospital closures as a percentage are smaller. And we believe that's attributable to uncompensated care that is no longer occurring.

Mr. BECERRA. Thank you. Thank you, Mr. Chairman.

Chairman BRADY. Thank you. Mr. Young, you're recognized.

Mr. YOUNG. Thank you, Mr. Chairman. Madam Secretary, I appreciate being here. I, I came here a few years ago. I haven't spent a lifetime doing this. And I came here to solve problems. And I have to say I've been frustrated in the last few years. And frustrated because of what I hear back from my constituents. One of

the main things I hear from my constituents is that Obamacare isn't working. That they don't like it. That their costs are going up. They regard their health insurance as all but useless. Deductibles are skyrocketing. Premiums are going up. And there's, there's data to support these things. Premiums for example, CBO expects an increase in seven and a half percent. Cost of bench mark plan, across the 37 states that utilize the federal exchange. But you know, eyes start to glaze over, when I talk to my constituents about all of the specific numbers. They just want us to fix this thing. And you know, meanwhile it's been talked about, that availability of coverage continues to narrow. And you know, I came here to solve these problems. It doesn't seem like we have a functioning system when so many of my constituents decide instead to pay the IRS tax penalty instead of buying insurance. That seems like a real problem. It doesn't seem like we have a functioning system when costs continue to go up. When the American people are told that their premiums would instead go down or be the other direction.

It doesn't seem like we have a functioning system, when in the state of Indiana, one of our largest insurers, Assurant, a national carrier, left the exchange. And so forth. And so I guess in the interest of trying to solve problems, I've asked this before. It's become a big ideological totemic battle between Republicans and Democrats, conservatives and liberals. But are there mandates that you as Secretary would be willing to work with Congress on repealing, vis-a-vis Obamacare? If not all of them. Which has been the position of the Administration in the past. Are there specific mandates that you would be willing to work with us on repealing? And I'll give you the remaining 40 seconds to offer a response. And you can offer whatever else you might have in writing, please.

Secretary BURWELL. There are many things I think most people in America don't want to go back to a place where pre-existing conditions keep you off your healthcare. Where if your child had cancer at the age of 15, that they've reached annual and lifetime limits. And these are some of the important changes that—

Mr. YOUNG. Is Obamacare working? I guess I'll just interject here. And you can supplement it with written testimony.

Secretary BURWELL. Yes. So, yes. And I believe in the area of access we've seen strong improvements.

Mr. YOUNG. Because I'm not hearing that from Hoosiers. I am not hearing consistently that Obamacare is working.

Secretary BURWELL. I think the question is—

Mr. YOUNG. Do you have surveys that substantiate that?

Secretary BURWELL. Yes, in terms of actually people in the marketplace. We have seen the marketplace satisfaction—

Mr. YOUNG. I'm talking Americans more generally. Do they like Obamacare?

Secretary BURWELL. Americans more generally? But what Americans like is, that you don't have to worry about pre-existing conditions. Is that the question that's asked?

Chairman BRADY. Thank you. All time has expired.

Secretary BURWELL. That is a different question that he has asked?

Chairman YOUNG. We can deal with that issue together in a different way. Thank you. And I yield back.

Chairman BRADY. Thank you, Madam Secretary. I'm going to—

Secretary BURWELL. And I think there are places we can.

Chairman BRADY. Thank you. I'm going to recognize Mr. Kelly. And then we're going to back to one. I just wanted to make sure we can get everyone on. Mr. Kelly, you're recognized.

Mr. KELLY. Thank you, Chairman and Madam Secretary. I appreciate your being here. We talked before, on the side. My concern is, when it comes to the quality incentive payments in the Medicare Advantage Plan—this is what we were talking about—I don't expect you to be able to answer this now. I know you're going to get back to me about it. But those plans were set up to incentivize a more efficient operation. And under the rule-making process, Mr. Kind and I have a piece of legislation also with Mr. Doyle and Mr. Guthrie. And so it's bi-partisan. Under the bench mark caps, we're rolling the QIPs into that and saying, "This is the cap." So if you're a four or five star rated plan, there's no incentive for you to go beyond that. I mean, it just isn't reachable. So essentially you're being paid at the same rate. I mean, the cap sets a cap. You can get paid lower amounts but you can't get paid higher amounts. And the result of that—and I'm asking you—do you have to have legislation to do that, or can you do it internally? I think it's an interpretation of the benchmark cap.

Secretary BURWELL. And we will come back on whether or not we have the statutory authorities across the board in terms of the work that we're doing in the CMI, the Innovation Center, in terms of making sure you have that ability to have that upward movement for good, strong players. We have changed that. And so this is a particular case I just need to understand what we have. In the most recent proposals on our accountable care organizations, we use the logic that you just articulated and have made fixes. So in this particular area on the four and five stars, do we have those still?

Mr. KELLY. Yeah. And I appreciate it. Because I think the real issue is, how soon can we get this done? Because if it's an incentive, then it has to truly be an incentive.

Secretary BURWELL. For good behavior.

Mr. KELLY. It can't be a non-incentive that's described as an incentive.

Secretary BURWELL. Yes.

Mr. KELLY. So we will get that to you in writing. If you can get back to us quickly, I appreciate that. With that I yield back, Chairman.

Chairman BRADY. Thank you. Mr. Blumenauer, you are recognized.

Mr. BLUMENAUER. Thank you, Mr. Chairman. Madam Secretary, I'm going to send you a little note about end of life care. And I appreciate that I'm not talking to you about, "Can we make the change?" It's made. I'm interested in how we can implement it more effectively. And I would really appreciate a chance to visit with you about that at some point. But I want to pick up where Mr. Young left off. Because I feel sometimes like I'm in an alternative universe. I have roundtable discussion in Oregon repeatedly. And yeah, there are hiccups and problems. But it's an entirely dif-

ferent universe. Providers like what's going on. We've expanded service. We've put millions, hundreds of millions of dollars into the system. Now, my friend from Kansas talked about the problems. That's a state that didn't expand it. And the question I would ask to you is, gee, if Kansas had been one of the 30 states that had actually expanded the program and had hundreds of millions of dollars in their health care system, being able to take care of people who were too poor to qualify for the ACA, would it make a difference?

Or in the case of Indiana, which has sort of expanded it, but not in a clean, straight-forward way, it appears from an untrained eye to be kind of a jerry-rigged system that doesn't really work well in terms of the expansion. Can you talk for a moment about what difference that would make and why I'm getting almost universally positive reactions from hospitals, insurance providers and people on the street? None of the evil things that were rumored happened. Inflation is down. Premiums are not skyrocketing like they used to. I remember the debates we had. And my friends who are concerned have not been working over the five years to refine it. They're trying to blow it up or to chip away at it. What difference would it make if there was actual straight-forward expansion in states like Indiana and Kentucky?

Secretary BURWELL. I think the point you raised about the premium increases, it is one of the things that, as we look at historically what premium increases were before, in the individual market they were in the double digit space. In the employer based market right now, over time, for a family, what that, what we have seen is four out of the five years have been the four lowest on record since these records were kept in 1999. That is, that means things are increasing but they're increasing at a much lower rate, to your point.

I understand that still feels like increases for consumers, which is why we've got to move to delivery system reform. With regard to the issue of Medicaid Expansion, I think we do see in many of the states that have expanded, those benefits in terms of what it means in the community and the money. It's the money and the paid for services. In addition, for individuals, we see many more people being treated for diabetes. That leads to longer term reduction in cost if we can get ahead of diabetes.

Chairman BRADY. Thank you. Mr. Renacci, you're recognized.

Mr. RENACCI. Thank you, Mr. Chairman. Secretary Burwell, thank you for being here and thank you for reaching out to my office before the hearing. I'm sorry we were not able to connect, but I really appreciate you reaching out to all the committee members. I think that's important. You do not have an easy job. We all recognize that. So thank you for what you do. I'm hoping that as this year comes to an end, we can work on some things together. As you know, the ACA included a new program aimed at reducing hospital readmissions, called the Hospital Readmission Reduction Program. The goal of this program is one that I and many of my colleagues support. In fact it's estimated that nearly 18 billion per year is wasted on avoidable readmissions of Medicare patients alone.

Secretary BURWELL. Yes.

Mr. RENACCI. However, the implementation of this program has been problematic, especially for those hospitals serving low income populations. Evidence suggests that economically disadvantaged patients, especially patients eligible for both Medicare and Medicaid, are much more likely to be readmitted within 30 days of discharge, regardless of a physician's efforts to educate them on proper post-discharge care. This has also an effect of disproportionately harming hospitals that take care of those that need it most. I've said all along, this is not a Republican or Democrat issue. This is really an issue of fairness of service to those individuals. Do you believe that readmission program criteria can be improved by adding clear adjustments for dual-eligible status, as well as for other plan readmissions, such as those following trauma?

Secretary BURWELL. We do believe in our studying and we appreciate the money that the Congress gave us to do the actual analytics, which should be completed by October. In the space of dual-eligibles people with chronic conditions and the socio-economic issues that you're talking about, those things come together and they come together in high-cost people. And so we are doing the work to understand analytically. We had put out a proposal for some changes related to other areas where it has a negative impact if you are taking. We got comments back that people didn't like that as a solution.

So we we did not go forward with that as a change. But we do believe this is a space where we need to understand where it makes a difference and how our rules can help support those that are taking care of those that are difficult to take care of. You may also know about the piece we just announced, that the Center for Medicaid and Medicare Innovation, where we're actually funding the efforts to do support. So you connect those people with the right services. As a means by which we're going to test whether that improves quality and lowers cost. So there are a number of steps we're taking. We believe it's an issue that we are looking closely at.

Mr. RENACCI. Thank you. I have a bill that I know has 75 cosponsors, Republicans and Democrats. So I hope we can work together on fixing this issue. Thank you, and I yield back, Mr. Chairman.

Chairman BRADY. Thank you.

Mr. Kind in the corner you're recognized.

Mr. KIND. Thank you, Mr. Chairman.

Madam Secretary, thanks for your testimony today and for the job that you're doing. See, I want to direct your attention. Chairman Brady and I have been working on legislation reform in the post-acute care setting for increased efficiency, better outcomes, cost savings. So we'd like to engage your office to make sure we're heading in the right direction so we can get moving on that legislation.

Secretary BURWELL. We look forward to engaging.

Mr. KIND. Also, as you know, I've been a real stickler when it comes to payment reform in the healthcare system, trying to drive the system to more quality value outcome-based payments. And there's a lot churning right now. I just want to give you some time today to give us an update and what's been going on to get to a

value-based reimbursement system and if we're starting to see some cost savings as a result.

Secretary BURWELL. Yes. So the commitment that we made last January for the first time I committed that Medicare payments, 30 percent of them would be in value, not volume. It was the first time we'd made that sort of commitment for Medicare, and I am hopeful and expecting that we will meet our 2016 goal of reaching that. We hope that by 2018 it will be 50 percent. Obviously I will not be here, but we'll be here to make sure that we are on that trajectory. And in terms of what that does in terms of the savings, we believe that those are real.

The other place where we're actually starting to see numbers and dollars in terms of the savings is in the accountable care organizations, and we have done the models and the demonstrations. You statutorily gave us standards that had to be met. Quality could not be decreased and we had to have savings in order for them to scale. The actuaries have scored these, and we are able to meet that test. We've seen several hundred million in just a one- and two-year period of time, and so we are starting to see that.

We have taken the input and have rolled out an additional group of the ACOs, the accountable care organizations, and actually just today you saw the governor of Alabama speak because we're working with him on Medicaid in this space as well, and those are regional accountable care organizations.

Mr. KIND. We've also been seeing in recent years some remarkable cost savings on a per capita basis in the Medicare program in particular, but without a reduction in benefits for the services that our seniors are receiving. Can you give us an update on that?

Secretary BURWELL. Yes. We are in terms of those per capita costs, and that's what we have to focus on. Because we have a growing population in Medicare, focusing on the per capita is where we're keeping our eye on the ball. And that's everything from reducing those costs to making sure they're going into the prevention and getting those free preventative services that help us save costs over time. We're seeing some increase, we'd like to see more.

Mr. KIND. I think if we keep setting those financial incentives to value quality, we're going to see a lot of innovation, a lot of reform by our providers themselves. We're going to work very hard to hit the mark. So I encourage you to keep your eye on the ball in that regard. I think it's one of the keys to how successful healthcare reform is ultimately going to be in the future.

Thank you, Mr. Chairman.

Chairman BRADY. Thank you.

Mr. Meehan, you're recognized.

Mr. MEEHAN. Thank you.

Secretary, I was appreciative of your commentary regarding the over-prescription of the opioids and the tremendous precursor implications of that with the heroine problem. We have a group of former prosecutors working on a comprehensive approach. I would really enjoy if you would communicate back with us while we're looking at this so we can collaborate on this issue rather than discovering later what the intentions are. Can I switch my comments for a moment?

And I appreciated your opening with the idea of a patient-centered delivery model. You opened with discussions about bringing healthcare to children at home, and the value of the home now in a changing healthcare perspective in creating not only just efficiency, but you know yourself when you can deliver healthcare personnel into that setting, the observations they make with respect to the patient and the environment, support of the family, ability to maintain their drug regimen, things of that nature have so many other benefits.

And yet we're seeing a recommendation by the budget to reduce compensation for copays, introduction of copays for home healthcare that isn't generated after a hospital stay, home-infusion therapy, another thing in which we can take an opportunity for a patient to not have to go to a more expensive setting for that same kind of service. These are examples and ways in which I think we can find that home-centered care as a way to drive down health costs as well as continue to see real quality enhanced.

And I hope you can work on that and give me a sense why would we be looking at copays when Congress actually in the 1970s found that that was counterproductive.

Secretary BURWELL. I think the overall concept is what we're moving towards generally, and so with those specific examples that you've given you need to understand why those specific examples. Because the general premise in terms of the demonstrations, the funding that we're doing is all about that home-based care because we do believe it can both increase quality and reduce price. And so most of the changes are going in that direction. So I don't know if there are exceptions to the—

Mr. MEEHAN. I know you've got the data exclusivity from biologics and I know we're looking at that seven-year standard. I have real concerns about what it's going to do for innovation, and I hope that you will be able to characterize what it is going to do. I mean we are all working on the reduction of costs, but there's also going to be an impact. That number of 12 years was reached for a reason, and it wasn't something that was arbitrary.

And so the concern we have with a seven-year standard is what it will mean and particularly as we're looking at new challenges from Zika viruses to great new pathways to deal with cancer. But that's an issue for another moment, and I thank you, and I yield back.

Chairman BRADY. Thank you.

Mr. Pascrell, you're recognized.

Mr. PASCRELL. Thank you, Mr. Chairman.

Secretary Burwell, thank you for being here today. You've been an outstanding secretary, and you've got a year to go. I don't know who's going to take your place. Maybe Dr. Kevorkian, who knows.

Last year at this very budget hearing, you pledged to work with the Congress to find a solution to incorporate unique device identifiers, UDIs, and to health insurance claims to help improve patient safety and quality of care. I'm reading and hearing day after day from all over the country about a major problem which we are not addressing.

CMS has put forward no solution. CMS has indicated that it would support pilot programs to demonstrate the feasibility of UDI

in claims. But to my knowledge, no such pilot has been launched. CMS has not taken any steps to ensure that such a pilot gets off the ground. Even if one were to launch today, results would be back for years, and we would miss our opportunity to implement this important policy that can help save lives.

Quite frankly, the time is up. CMS has failed to come up with a solution to incorporate UDI in its claims databases as recommended by the FDA. Device safety experts have recommended it and even you during your confirmation hearing. As you know, CMS works for you, so what steps do you plan to take to ensure that the agency starts to proactively support UDI in claims using every tool at their disposal. And I would claim before you answer the question that the industry itself, the industry itself, it's looked at very, very carefully at chapter and verse about this industry.

Madam Secretary.

Secretary BURWELL. With regard to UDIs since our last conversation about this, we have made progress in terms of what we've done on the Office of the National Coordinator's side and actually put out guidance that says that the UDIs will be a part of the electronic health records. And when we think about why we want the UDIs in terms of having a place where one can go and find out if someone had something—if we need to track back, having that be a part of the individual's record we think moves a long way with regard to the questions of ensuring and using this tool as a tool for safety. And so have taken steps in that particular space.

With regard to those who make—we have external guidance that comes from external boards on when we make differences and changes in the claims and what we do in terms of claims records. At this point they have not come to making a recommendation. We still continue to engage and have those conversations. But with regard to getting to the safety—

Chairman BRADY. Madam Secretary, I apologize. The time has expired.

Ms. Black, you're recognized.

Mrs. BLACK. Thank you, Mr. Chairman.

Secretary, thank you for being here today. These are a lot of topics, and I'd like to say that these are topics that are certainly important to our taxpayers, they're important to our patients as well, and I appreciate you being here to answer these questions.

I want to hold up a report that just came out yesterday, the Senate report that there were illegal benefits benefitted from \$750 billion in Obamacare subsidies. And the report goes onto talk about how there is not a coordination between HHS and the IRS on these subsidies. The report says that there were over 500,000 immigrants that got these tax credits, but there wasn't verification and never was there verification sent in to show even after the tax credits went out that these folks were here legally in the country.

And so what we've seen in other programs where the money goes out the door, it's very difficult to get that money back again. So there seems to be a lack of coordination in verifying that these folks are here in the country legally, and this is hard-earned taxpayer money that is going out the door. And so I want to know what your plan is to make sure that before these dollars go out the

door that we can verify someone's status because we know that once the IRS has to go back and try to chase the money, very little of that money comes back. So do you have a plan for making sure that this does not occur?

Secretary BURWELL. So with regard to one of the things I think that was important in the report is it did reflect that we don't know whether they were illegal or not. What we know is they didn't provide the documentation. And as we—

Mrs. BLACK. And so how long a time period would you have let go by with these tax credits going out before there was a verification.

Secretary BURWELL. With regard to that, we follow the statutory guidelines, and that's about 90 days. And so last year 470,000 folks were cut off within that approximately 90-day timeframe. And the thing that I think is also important to recognize in terms of the connects that you're talking about is those individuals that did not have verification will not be able to get the tax credits. And the other thing is the IRS will follow up in terms of their filing.

Mrs. BLACK. But the tax credits already went out the door.

Secretary BURWELL. For the period of time that is—

Mrs. BLACK. Yes. For that period of time, so—

Secretary BURWELL [continuing]. We follow the statutory—we follow the statutory guidelines, and we don't know if there—

Mrs. BLACK. \$750 million went out the door.

Secretary BURWELL. But we do not know that they weren't supposed to receive them. Many of the people that go through the process of verification actually have the right documentation.

Mrs. BLACK. Excuse me. I'm running out of time, but I want to tell you I do have a bill that says no subsidies without verification whether that's in the self-cessation, verification needs to be done before the money goes out the door. We have seen this in so many of the entitlement programs where the money goes out, we can't verify and there are billions—literally billions of dollars that are going out in these programs, and I just don't understand why someone can't come up with their verification. I mean if I make out an application for something and it's not complete, then I don't get whatever service it is that I'm applying for. I think that's really the direction we have to go.

Chairman BRADY. Thank you. Whole time has expired.

Mr. Davis.

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

There are many things that I really like about this proposed budget, especially the continuous support for federally qualified health centers, home visiting, the addressment of behavior health, issues relative to substance abuse prevention and treatment. But I also have some serious concerns about the proposed funding for graduate medical education.

Madam Secretary, I noticed that your budget once again calls for a 10 percent cut in indirect medical education payments to teaching hospitals. Yet my teaching hospitals tell me that the cost of these programs are significantly greater than the direct and indirect GME payments they receive.

In fact, most of the major teaching hospitals in Chicago are training an excess of 100 doctors over the residency cap and we

still face significant access to care problems in my community. I'm concerned that these cuts that are proposed would result in fewer doctors being trained. That will heighten the access to care problem. Wouldn't it make more sense or be better to lift the cap and train more rather than fewer physicians?

Secretary BURWELL. I think the changes that we propose on both sides, on the Medicare side as well as the children's GME side, are about trying to make sure that we do get the right numbers of physicians and types of physicians. And so the proposals that we put forth are both about targeting in terms of higher need, higher-need communities as well as primary care and the specialties where we don't. And that's what are changes are targeted towards in terms of making sure that we are in the Medicare space paying for those physicians that will do Medicare and Medicare hospitals and making sure that we're targeting the right things. And that's the objective of the proposals.

Mr. DAVIS. And I note that you're also seeking authority to kind of move more towards primary care.

Secretary BURWELL. That's correct.

Mr. DAVIS. Position training and I'm certainly in agreement with that. But when I look at the aging of our population with 10,000 new seniors every day, don't we also need specialists, cardiologists and neurologists to deal with the needs of this population group?

Secretary BURWELL. Yes, we are targeting both primary care underserved, getting positions to go to underserved as well as the issue of specialties where we are short. And so we are trying to have all of this assistance in the medical education be more targeted to those areas. It is—

Mr. DAVIS. Thank you very much. I thank you for doing a great job and I yield back the balance of my time.

Secretary BURWELL. Thank you.

Chairman BRADY. Thank you.

Ms. Noem, you're recognized.

Mrs. NOEM. Thank you, Mr. Chairman.

Secretary Burwell, I wanted to draw attention today to an emergency situation I have in South Dakota with my Native American constituents that aren't getting healthcare. And I certainly know you're aware of the situation, but I want to hear today how you plan to fix it.

The Federal Government has a responsibility to our tribes to provide for their healthcare because of treaty obligations. And frankly they failed to follow through on their promise to do so. In fact, in the Great Plains area, we have reports of inappropriate conduct including nepotism, favoritism in hiring practices, reassignment of employees who are underperforming or have been poorly trained as well all leading to very low quality delivery of healthcare.

In fact, a bombshell 2010 Senate report laid out a lot of these allegations, and these problems have been going on for long before I've been in Congress, for a decade or more. And the fraud, the abuse, the waste is rampant in the Great Plains area.

And since then, even since that 2010 report, little has changed within IHS. And I know you'll speak to funding levels, but, before a Senate committee last week, your acting deputy secretary specifi-

cally stated that there has been an increase of 43 percent in funding into IHS in recent years. So we know we can't simply throw more money at the problem, that there has to be a whole culture change at IHS that has to happen.

And what I'm concerned about is that last year CMS inspections of the facilities in Rosebud and Pine Ridge showed that it was a dangerous situation. In fact, what was so ironic was that CMS said that it was going to terminate its provider agreements to IHS and the irony of that is that we have one federal agency saying it won't make federal payments to another federal agency when they're both housed within the same department. And it shows the bureaucratic absurdity of the situation we have going on in South Dakota.

And at this very minute, my Rosebud tribal members are driving over an hour to get emergency healthcare services because the IHS's hospital ER was closed due to dangerous care being provided there. So it's not necessarily just funding; there's other issues as well. The mismanagement, the misconduct in the Great Plains area needs to be dealt with and frankly it goes from one administrator to the next. I know that one has recently been reassigned, but then I also hear that he's come to Washington D.C. to a different position, wasn't necessarily penalized for his lack of doing his job in South Dakota and in the Great Plains area.

I want to hear your strategies for how you're going to implement change in culture in this Great Plains region. But I also believe that buried within your IHS budget justification this year you have a paragraph that says IHS places a high priority on corrective action in the Great Plains area. The problem is that this paragraph appears to be literally copied and pasted from the justifications over the last four years.

So there's nothing that indicates to me that we're going to have a change. It tells me that, yes, you're aware of the problem, but I don't know that you have a plan to fix it. And frankly we're putting people's lives in jeopardy in South Dakota. And we have emergency rooms that are closed down and an agency that will not reimburse another agency because we have people addicted to drugs and alcohol doing procedures on people, sterilization of utensils that's happening by handwashing.

So I need your answers, probably written, because I'm out of time. I hope you know how serious I am about this. But if you'd respond to me in written form, I would be eternally grateful.

Secretary BURWELL. Yes, and I would just say this is a place where I think we may need your help as well.

Mrs. NOEM. I will help.

Secretary BURWELL. Because I am committed but I don't have a year—I have 11 months and days left.

Mrs. NOEM. Yeah.

Secretary BURWELL. But I believe we need to get a different answer and outcome. And so this is a place where I may come back to you for help and assistance.

Mrs. NOEM. I'm there. Thank you.

Secretary BURWELL. Because changing culture is both the relationships on the ground. You know better than I do being from the region. It's going to take a lot, but Dr. Wakefield and I are committed.

Chairman BRADY. Thank you.

Mrs. NOEM. Thank you.

Chairman BRADY. Madam Secretary, thank you.

Mr. Crowley, you're recognized.

Mr. CROWLEY. Thank you, Mr. Chairman.

Madam Secretary, welcome. I, too, think you're doing a great job. I'm pleased to see the Administration's initiative to improve funding for mental and behavioral healthcare issues. One of the often overlooked benefits of the Affordable Care Act is that it's extending insurance coverage to millions of Americans. It also has improved access to previously unavailable or unaffordable mental health treatments.

For example, a recent GAO examined six of the states that adopted the ACA's Medicaid expansion and found improved access to behavioral healthcare. There is more work that needs to be done in this area. Which the fiscal year 2017 budget highlights. Can you talk generally about the changes we face in expanding access to treatment for mental and behavioral healthcare and how the President's budget proposed to address some of those changes?

Secretary BURWELL. It's on a number of fronts, this money will be used, and I think one is about actually supporting the access to care in communities. And that's a big part of what the money is about is making sure that we have the access to care. The other is for providers, and this gets back to the issue we were just discussing. The IHS is an incredible example of this in the tribes in terms of making sure we have the right providers.

Parts of this money actually will be directed towards the IHS and other places to make sure we have enough providers that can provide the care. The final element of the strategy is about making sure for those who have severe mental illness that we get them into care early. That's about connecting to them and having places for them to go.

Mr. CROWLEY. One of the other areas that I'm very excited about that you address in the budget is the issue of child care. It's so critical to a child's development for school and for life and it's also critical to helping working families, minimum—who are trying to get into the workforce and stay in the workforce, to make sure the child is taken care of in an enriching environment, a loving environment. Can you discuss very quickly or briefly the Administration's proposal to improve access to the quality of child care in this country?

Secretary BURWELL. There are two elements to it. It is, one, the implementation that we have been given in terms of improving childcare and direction. We've been given discretionary funding that will be used to implement what the Congress has given us. But I think you also know we have a large mandatory proposal that would be about expanding childcare so that people could have that access and go to work and do the things that they want to do as a family in terms of young children and having care for them as they go to work. And that is a large proposal that's on the mandatory side that would be quality, but expansion in terms of those served.

Mr. CROWLEY. I'm very familiar with it because I'm working with Senator Casey and with Congressman Frankel on this very issue itself and sponsoring it——

Secretary BURWELL. We're excited about that legislation.

Mr. Crowley [continuing]. Here in the House. But thank you for the proposal within the budget and for the great work that you're doing. So with that, Mr. Chairman, I yield back the balance of my time.

Chairman BRADY. Thank you.

Mr. Rice, you're recognized.

Mr. RICE. Thank you, Mr. Chairman.

And thank you, Secretary Burwell, for being here. I appreciate you reaching out to me earlier in the week. Very thoughtful, and I appreciate the information you provided to the Committee. I have a couple of questions, one with respect to the Medicaid expansion and the 20 states that haven't expanded.

I don't know if you heard, but the United States has \$18 trillion in debt and both the Office of Management and Budget and the Congressional Budget Office, they don't agree on many things, but they agree we're on an unsustainable path. So let me ask you: If you had a wonderful uncle who loved you so and said, look, if you'll buy a house, maybe a more expensive house that you can afford, I'll make the payments for you. And let's say that uncle was just going into bankruptcy. Would you take him up on his offer?

Secretary BURWELL. The question of the analogy, I would just recognize that we've reduced the deficit in this country by \$4 trillion. And the budget that's before us right now has an additional \$2.9 trillion over a period in terms of reduction. And so I think in terms of the accuracy of the analogy in terms of where we are as a nation, in the President's budget, we will keep the deficit-to-GDP ratio—will get down to that 2.7 level which we haven't been in many years.

Mr. RICE. I served on the Budget Committee for three years, and every official from OMB and CBO that I talked to that entire time said that we are on an unsustainable path.

Let me ask you this: The South Carolina Exchange was the ninth Obamacare exchange to close. It closed in December out of 23 that were formed nationwide. Twenty-two of the twenty-three lost money in 2014. Nineteen of the twenty-three had claims in excess of premiums. Why is that?

Secretary BURWELL. With regard to the issue of the co-ops, when we think about the co-ops entering and we think about business, often stable players that have been in a business enter new spaces. Or sometimes what we have is a situation where you have new players entering an old business. In the case of the marketplace——

Mr. RICE. Why are they losing money? Is it because our government is inept to run the healthcare system, or is it because we just did really bad projections and we didn't know that we were going to actually pay out more in claims that we collected in premiums? How could we have missed it that bad?

Secretary BURWELL. The co-ops are private businesses. I think you're referring to the co-ops, not——

Mr. RICE. Yeah, I——

Secretary BURWELL. The co-ops are private companies. And with regard to the decisions of those companies, you're right. Those are business decisions that a company is making that we the government do not have control over.

Mr. RICE. Weren't they created with government money, taxpayer money?

Secretary BURWELL. They were created with government loans, loans that were cut in terms of—

Mr. RICE. Let me ask you this.

Secretary BURWELL [continuing]. The support that they were going to get.

Mr. RICE. I'm running out of time, but let me ask you this: Eight million people in 2014 paid a penalty for not signing up for Obamacare. How many were enrolled?

Secretary BURWELL. In terms of the enrollment?

Mr. RICE. Yeah.

Secretary BURWELL. Last year at the end of open enrollment it was about 11.6 million folks.

Mr. RICE. So almost as many chose to pay a penalty rather than sign up. Why is that?

Secretary BURWELL. Many people are making—

Chairman BRADY. Madam Secretary, if you would answer that in writing, I apologize. All the time is expired. I know your hard stop was 4:30. We have two members who have waited patiently. Can we finish these out? And we understand your schedule is—

Secretary BURWELL. Okay. I actually can delay the—yes, let's stay.

Chairman BRADY. Great.

Mr. Smith, you're recognized.

Thank you, Madam Secretary.

Mr. SMITH of Missouri. Thank you, Mr. Chairman.

Ms. Secretary, 37 percent of Medicare Advantage beneficiaries have annual incomes below \$20,000 annually. I represent one of the poorest congressional districts in the country. So protecting the Medicare Advantage program for low income beneficiaries is extremely important to my constituents. The Medicare Advantage program offers extra financial protection such as maximum out-of-pocket limits, extra benefits and care coordination activities.

If plans are focused to restrict some of these benefits as a result of the funding cuts in the President's budget of roughly \$77 billion, do you believe that these cuts could result negatively, impact low income beneficiaries who may then face higher cost out of pocket?

Secretary BURWELL. So what we've seen in terms of the changes that we've done to date in Medicare Advantage, the program continues to grow and grow in a healthy pace. We've seen premiums not have great increases and 99 percent of folks have access and coverage. And so in terms of what we've done to date, we have tried to take steps that are in ways that will not have the kind of impact that you've described. We believe what we're proposing won't.

We also know that when we compare—and this gets to the entitlement issues that we began this hearing with, and it's appropriate to end here, is the issue of in a world where we know that the fee for service Medicare recipients on a per capita basis are

paying much less than these Medicare Advantage. And MedPAC and other have analyzed that there are changes that are important to saving the taxpayer money.

And so we're trying to get that balance so we don't have the outcome you described. We don't want that. But also make sure that as the taxpayers' money is being used in Medicare Advantage that it's being used wisely.

Mr. SMITH of Missouri. So, yes or no, do you think the \$77 billion cut is going to affect my constituents on Medicare Advantage?

Secretary BURWELL. No, we think that what it will do is create many of the changes we're proposing about competition coming back to the earlier point about markets. And so we believe that what we're proposing will not have those negative impacts.

Mr. SMITH of Missouri. Okay. Thank you.

Chairman BRADY. Thank you.

Mr. Dold for the final question.

Mr. DOLD. Thank you, Mr. Chairman. Madam Secretary, first of all, thank you so much for reaching out to our office. I certainly appreciate that. And I also want to thank you for being willing to work with the Committee. And I think that some of the things that we want to do is we want very much the same things. We want to access to quality care at an affordable rate, and that's certainly what I'm hearing from my constituents. That's what we're looking for.

Unfortunately, as you may know, we had some market disruptions in Illinois in the fall of 2015. One of the most popular PPO plans basically said we're not going to offer the PPO. 173,000 Illinoisans were forced to scramble to find a new plan in a much narrower network. And ultimately we heard—I heard on a regular basis that moms would have to choose between their oncologist or the pediatrician that they take their kids to or those types of things.

The other interesting part of is that is that since open enrollment has closed, several of those insurance companies have expressed their concerns about remaining in the exchanges for 2017. So the question I have for you is: What are you doing or is the agency doing to help prevent market disruptions going forward?

Secretary BURWELL. With regard to that in terms of the marketplace, the two things are, one, is it a product the customer demands, and, two, the issuers in the marketplace. We just ended with 12.7 folks in. The issue of market stability, we saw nine out of ten folks in the marketplace be in counties where there are three or more issuers, which is about choice and competition.

We know we have more work to do, though, to your point. And we are taking those steps. We announced that there would not be a special enrollment period for tax issues this year, and we did that before December 15th to get people to come in before January 1st. We've eliminated a number of special enrollment periods. I'm sure you've heard this from a number of the issuers. That's one of the things that they think will contribute to stability.

The other thing they asked us for is estimates of their risk adjustment numbers early. So there are a series of steps that we're taking to continue to promote a stable marketplace.

Mr. DOLD. I appreciate that. A couple things with regard to the budget. I want to thank you on the mental health side of things, and there's a lot more work that needs to happen there. But I also want to share my concerns with my good friend from Illinois on the funding for graduate medical education, and I also want to make sure I'm raising a concern on the biologics. Taking it down to seven years I think is an enormous concern with regard to innovation, and I think, again, signals something that we have a 12-year date exclusivity right now. To take it to seven is problematic in my view.

Finally, I wanted to just talk to you about something that I think is important as we talk about waste fraud with in Medicare, and that's the Medicare Common Access Card, something I've worked with Congressman Blumenauer on, Congressman Roskam. We're losing approximately \$60 billion in fraud admittedly by CMS. And what the Medicare Common Access Card would do is have a chip in it. Right now we've got identity theft running rampant. This is an issue for seniors. Would CMS be interested or at least open to a pilot program doing a Medicare Common Access Card?

Secretary BURWELL. As I mentioned when Mr. Roskam asked about it, I want to look into figuring out what are our authorities and how this would work.

Mr. DOLD. I certainly appreciate that. Thank you, Madam Secretary.

Chairman BRADY. Thank you all. Time has expired. We had an earlier discussion about the comparisons between Part D and the VA. Without objection, I'll submit for the record a letter from CBO outlining their reasons why it would simply not result in savings. So ordered.

[The information follows:]



CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Peter R. Orszag, Director

April 10, 2007

Honorable Ron Wyden
United States Senate
Washington, DC 20510

Dear Senator:

You asked a number of questions relating to the Medicare drug benefit and options for allowing the Secretary of Health and Human Services (HHS) to negotiate over the prices paid for drugs under that benefit. The Medicare Modernization Act contained a provision that prohibits the Secretary both from interfering in the negotiations between drug manufacturers and the prescription drug plans (PDPs) that deliver the Medicare benefit, and from requiring a particular formulary or instituting a price structure for the reimbursement of covered drugs.

Responses to the questions you raised are below.

Could negotiating by the Secretary over drug prices obtain savings for the Medicare program if those negotiations were limited to selective instances?

As the Congressional Budget Office (CBO) indicated in a previous letter, negotiations limited to a few selected drugs or types of drugs could potentially generate cost savings.¹ For example, negotiations could be focused on drugs with no close substitutes or those with relatively high prices under Medicare. In such cases, CBO assumes that the effect of the Secretary's actions—if he or she took advantage of the new authority—would primarily reflect the use of the “bully pulpit” to pressure drug manufacturers into reducing prices.

Although cost savings might be possible in selective instances, the impact on Medicare's overall drug spending would likely be limited. Bully pulpit strategies would probably be effective only if they were constrained to a small number of drugs; otherwise, the pressure of the spotlight would be dissipated. Consequently, spending on the small number of affected drugs would likely account for only a small fraction of expenditures under the Medicare drug benefit. Furthermore, even if the Secretary focused on a select number of drugs, the effect might be limited because pressure from PDPs and public relations concerns already affect pricing—so the incremental effect of giving HHS additional options for exerting pressure would generally be small. Finally, drug manufacturers could seek to limit the impact of the Secretary's actions by setting higher initial prices for their drugs, to offset any potential price concessions from negotiations with the Secretary. As a result, CBO expects that the overall impact on federal spending from

¹ See Congressional Budget Office, Letter to the Honorable Ron Wyden regarding the authority to negotiate prices for single-source drugs for Medicare beneficiaries (March 3, 2004).

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negotiations targeted at selected drugs would be modest. Beyond that general conclusion, the precise effect of any specific proposal would depend importantly on its details.

Recent negotiations over Cipro and FluMist showed significant savings relative to prevailing commercial prices, but several factors substantially limit their relevance to Medicare negotiations. In the case of Cipro, which can be used to treat anthrax, the relevant negotiations were conducted in the climate of a national emergency immediately following the attacks of September 11th and deaths from anthrax-laced letters. Furthermore, Cipro's patent protection was close to expiring and several manufacturers were poised to produce that drug once the patent expired. That set of circumstances gave particular force to the threat issued by Secretary Thompson to seek authority for generic production of Cipro, which was apparently instrumental in bringing the negotiations to a close. FluMist, a nasal form of flu vaccine, was relatively new at the time of the relevant negotiations. The manufacturers of that product apparently overestimated demand for it and therefore had large stockpiles on hand that would have little or no use once the flu season ended. Although HHS was able to negotiate price reductions for FluMist in December 2003, its manufacturer chose soon thereafter to give away a substantial quantity of the vaccine free of charge—and even then demand apparently remained low. The exceptional circumstances associated with those two examples limit their applicability to the case of drugs covered by the Medicare benefit.

If the Secretary were given authority to negotiate by Congress and used that authority, would it be possible to obtain savings to Medicare?

The key factor in determining whether negotiations would lead to price reductions is the leverage that the Secretary would have to secure larger price concessions from drug manufacturers than competing PDPs currently obtain.² When several drugs are available to treat the same medical condition, PDPs can secure rebates from selected drug manufacturers by giving their drugs preferred status within formularies. Because enrollees are encouraged to use such preferred drugs (through lower cost-sharing requirements), manufacturers are willing to offer price concessions to the PDPs in order to give their drugs preferred status and thereby increase their market share.

By itself, giving the Secretary broad authority to negotiate drug prices would not provide the leverage necessary to generate lower prices than those obtained by PDPs and thus would have a negligible effect on Medicare drug spending. Negotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. The authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions could give the Secretary the ability to obtain significant discounts in negotiations with drug manufacturers. In the absence of such

² See Congressional Budget Office, Letter to the Honorable William H. Frist, M.D., regarding CBO's estimate of the effect of striking the "noninterference" provision as added by P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (January 23, 2004); and Congressional Budget Office, cost estimate for H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007 (January 10, 2007).

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authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited. Broad negotiating authority would not necessarily result in the type of targeted approach that could produce savings. CBO thus estimates that providing broad negotiating authority by itself would likely have a negligible effect on federal spending.

Since 2003, has anything changed—other than the Secretary saying he would not negotiate—that would indicate whether such negotiation would be successful?

Since the enactment of the Medicare Modernization Act, HHS has issued certain regulations to implement the drug benefit that suggest a reluctance to limit the availability of drugs to enrollees, even if the result is somewhat higher drug spending.

Under the act, PDPs are required to cover at least two drugs in each therapeutic class of drugs that treat the same condition. Because a common definition of therapeutic classes did not exist, the law also provided for U.S. Pharmacopoeia, a private standard-setting entity, to establish a model set of classes, which PDPs were encouraged but not required to follow. In its regulations, HHS required PDPs to cover all or substantially all drugs in several important classes, including antipsychotic medications. (That requirement was established on the grounds that failure to cover such a broad set of medications would discourage individuals from enrolling in the benefit or in a drug plan that provided less extensive coverage.) In addition, those regulations encouraged PDPs to cover at least one drug in each subclass of drugs that U.S. Pharmacopoeia specified, even though that was not required under the legislation. The regulations reduced the rebates that PDPs can secure and raised the cost of the drug benefit.³ The motivations affecting those regulations would presumably also affect the negotiating stance of the Secretary, limiting the likelihood that the negotiations would yield lower drug prices. At the same time, the regulations have reduced the rebates obtained by PDPs and thus created some potential for additional savings.

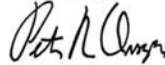
The current HHS Secretary has indicated that he would not pursue drug price negotiation if given the authority to do so, and it is difficult for CBO to predict what actions future HHS Secretaries might or might not take. Simply put, it may be difficult through legislation to force a Secretary to pursue negotiations aggressively if he or she is reluctant to do so.

³ See Congressional Budget Office, *An Analysis of the President's Budgetary Proposals for 2006* (March 2005), Appendix A, and Congressional Budget Office, Letter to the Honorable Joe Barton and the Honorable Jim McCrery regarding potential effects of disclosing price rebates on the Medicare drug benefit (March 12, 2007).

Honorable Ron Wyden
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I hope this analysis is helpful to you. If you would like additional information on this subject, CBO would be pleased to provide it. The staff contacts for this analysis are Tom Bradley and Philip Ellis.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter R. Orszag".

Peter R. Orszag
Director

cc: Honorable Max Baucus
Chairman
Committee on Finance

Honorable Charles E. Grassley
Ranking Member

Chairman BRADY. Madam Secretary, I want to thank you for appearing for us and extending your time. While we have disagreements, you have been very professional, very responsive and clearly dedicated to your job. So thank you very much for being here today. Members may submit written questions be answered later in writing. Those questions and your answers will be made part of the formal hearing. With that, to Madam Secretary and others, the Committee stands adjourned.

[Whereupon, at 4:42 p.m., the Committee was adjourned.]

[Questions for the record follow:]

Secretary Burwell's Hearing on
 "The President's Fiscal Year 2017 Budget"
 Ways & Means Committee
 February 10, 2016

All responses are accurate as of February 10, 2016

Questions for the Record: Secretary Burwell

Questions from Representative Tiberi of Ohio:

Secretary Burwell, as you well know, Obamacare's CO-OP program has been a disaster. After using the American taxpayer as a piggybank, more than half of these entities have failed. I know many of my colleagues share my concerns, and I want to highlight a recent incident with a CO-OP in Ohio, InHealth. Press reports have indicated that InHealth is under enhanced oversight, which means CMS is concerned about its financial stability and is closely monitoring its operations. About 9,000 Ohioans are enrolled in InHealth, and they recently got some surprising news: at the last minute, InHealth decided to drop most OhioHealth hospitals and doctors from their provider network leaving them with few options now that open enrollment has passed. Now, I understand that this Obamacare CO-OP is struggling— that's what happens when Washington thinks it knows best and engages in crony capitalism. And I understand that they are just one of many issuers forced to narrow provider networks because of Obamacare's mandates and regulations.

But what I don't understand is how an Administration that crows about consumer and patient protections in the President's health care law can allow a CO-OP it is so closely monitoring to pull the wool over people's eyes and not announce major changes to provider networks until after the open enrollment period has passed.

1. Secretary Burwell, is monitoring decisions about providers networks part of CMS's enhanced oversight of the CO-OPs? Will there be recourse for enrollees who feel tricked?

Answer: We are focused on monitoring and supporting the remaining CO-OPs and making sure that consumers whose CO-OPs will not offer coverage for 2016 retain access to high-quality, affordable health insurance.

There are inherent risks in any start up; the insurance market is especially challenging. Each CO-OP is different and faces its own unique challenges. CO-OPs entered the health insurance market with a number of challenges, including: building a provider network

and no previous claims experience on which to base pricing, while facing competition from larger, experienced issuers.

Provider networks are established via private contracts between health care providers and insurers, including CO-OPs, who frequently negotiate about the terms of such agreements, and frequently change from year to year. We continue to monitor network adequacy to determine whether networks meet requirements, and will work with state departments of insurance to resolve consumer complaints.

While I understand the disruption a decision like this can cause for consumers, it is important to note that plans still must maintain adequate networks that meet federal and state standards. If consumers are concerned that their plans aren't meeting these standards, they should contact their state Department of Insurance, which has primary authority for overseeing network adequacy.

2. Secretary Burwell, I was intrigued by the statement in the budget that the Administration believes it has increased the solvency of the Hospital Trust Fund by 15 years.

Can you provide the Committee with a detailed breakdown of the policies that yield enough savings to gain 15 years?

Answer: The proposed changes in health and tax policies included in the FY 2017 budget would help extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years. These changes are outlined in the second response below.

3. Specifically, can you highlight the Medicare Part A savings and the increased taxes the Administration has identified to achieve this outcome?

Answer: Budget proposals that generate significant Part A savings and thereby help extend the life of the Trust Fund include proposals that support delivery system reform, promote efficient care, and align payments more closely with costs of care in both traditional Medicare and Medicare Advantage.

In addition, the revenue proposal, "Rationalize Net Investment Income and Self-Employment Contributions Act (SECA) Taxes," will also help extend the life of the Medicare Trust Fund. The proposal would ensure that all business income of high-income taxpayers is subject to the 3.8 percent net investment income tax (NIIT), while dedicating all new and current tax revenue from the NIIT to Medicare's Hospital Insurance Trust Fund.

4. How much, in total and year-by-year, is needed to extend solvency for 15 years?

Answer: During the 10-year budget window, the FY 2017 Budget's Medicare legislative proposals will save a net \$419 billion (over a third of which would impact spending from the Hospital Insurance Trust Fund), while the net investment income tax proposal would dedicate over \$500 billion to the Hospital Insurance Trust Fund. While the Budget projects savings over a 10-year period, savings from these proposals would grow over time and would be sufficient to extend solvency of the Part A Trust Fund by over 15 years.

(Dollars in Millions, negative numbers reflect savings)

	FY 2017	5 Years FYs 17-21	10 Years FYs 17-26
Total Medicare Legislative Savings Proposals (Parts A, B, C, and D)	(3,729)	(98,215)	(419,438)
Rationalize Net Investment Income and Self-Employment Contributions Act Taxes (Effects on the Hospital Insurance Trust Fund)	(389)	(194,215)	(524,774)
Total	(4,118)	(292,430)	(962,212)

Questions for Representative Holding of North Carolina:

Secretary Burwell, I understand that you heard from North Carolina's Insurance Commissioner earlier this month. According to Commissioner Goodwin's letter to you, he is ¹highly concerned² that ³insurers may withdraw from the individual market in North Carolina altogether.² In North Carolina, there are only three Qualified Health Plans (QHPs), with the largest covering over two-thirds of the market. They have been approved for an average rate hike of 32.5 percent for 2016.

1. As insurers privately discuss whether to continue to raise rates another 30% or pull out of the market entirely, how would you explain to North Carolinians that the market is working for them?

Answer: HHS' priority is to provide Marketplace customers with access to quality, affordable coverage. In the years since the passage of the Affordable Care Act, we have seen increased competition among health plans and more choices for consumers.¹ During the third Marketplace Open Enrollment, nine out of ten returning customers were able to choose from three or more issuers for 2016 coverage, up from seven in ten in 2014. In North Carolina specifically, 74 percent of consumers had the option to purchase coverage for \$75 per month or less after the advance premium tax credit².

¹ www.hhs.gov/about/news/2015/07/30/competition-and-choice-in-the-health-insurance-marketplace-lowered-premiums-in-2015.html

² <https://aspe.hhs.gov/sites/default/files/pdf/172176/2016HealthInsurance.pdf>

At the end of open enrollment in January, about 12.7 million Americans, including 613,487 North Carolinians, selected or were automatically reenrolled in affordable, quality health plans for 2016 coverage through the Marketplaces.³ Based on analysis through late December 2015, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit for the 2016 plan year.

As for the rates in North Carolina, ACA Marketplaces help consumers shop around for the best deal. Marketplace consumers can purchase any available plan regardless of health conditions, and tools such as the doctor lookup and out-of-pocket cost calculator help them find the plan that meets their needs. Last year, 2.39 million returning HealthCare.gov consumers, more than 40%, switched plans. They saved an average of \$42 per month, or about \$500 annually.⁴ In contrast, average rate changes reported in rate filings assume that all consumers stick with their current health insurance plan. In particular, they assume that no consumers enroll in any new plans offered for 2017, even though new plans frequently offer lower prices. This doesn't reflect reality, given that a large share of returning Marketplace consumers switched plans last year.

In addition, preliminary rates are not final rates. Preliminary rates often change significantly before being finalized. In particular, they are subject to state regulator review, which led to \$1.5 billion in savings for consumers in 2015. Last year, final rates in some states were below proposed rates. Lastly, it is important to remember that tax credits go up along with premiums. 85% of Marketplace consumers receive tax credits, which are designed to protect consumers from premium increases and help make coverage affordable. Tax credits increase if the cost of the second lowest-cost silver, or benchmark, plan goes up. So if all premiums in a market go up by similar amounts, 85% of Marketplace consumers in that market will not necessarily pay more because their tax credits will go up to compensate. Rate increases reported in the rate filings do not account for tax credits.

Moving forward, HHS is eager to build on the progress in reducing the number of uninsured Americans – an estimated 17.6 million Americans gained coverage as the Affordable Care Act's coverage provisions have taken effect,⁵ and the Nation's uninsured rate is below 10 percent for the first time since data collection began over five decades ago. And because of the ACA, Americans across the country have access to better insurance, no matter where it's purchased.

Six years ago, if you were one of America's 13.7 million cancer survivors, or the millions living with a chronic disease, it was almost impossible to get health insurance. Today, no one can be denied coverage because of a pre-existing condition.

³ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-04.html>

⁴ <http://www.hhs.gov/blog/2016/04/12/premiums-last-year-much-lower-than-initial-rates-suggested.html>

⁵ <https://aspe.hhs.gov/health-insurance-coverage-and-affordable-care-act-aspe-issue-brief-september-2015>

Six years ago, having insurance didn't necessarily mean you would get any help paying for basic care. Today, 137 million Americans with private insurance have preventive care at no extra cost.

And six years ago, families had to worry that their insurance would stop paying claims when they needed it most. Even if you never missed a premium payment, a major illness could mean bankruptcy. Today, annual and lifetime caps on most benefits are gone and families are protected.

As you know, individuals are able to purchase health insurance outside of the annual open enrollment period if they prove to HHS that they have experienced a ³qualifying life event.² Insurers have told HHS that consumers enrolled through special enrollment periods are utilizing up to 55 percent more services than those consumers that enrolled during the open enrollment period. I have heard from insurers in my state that these special enrollment periods are ³being gamed.² Without confidence that HHS will properly process or deny special enrollment period applications, insurers may choose to not offer their products on the exchange.

2. What actions is HHS taking to prevent individuals from ³gaming the system² and what actions is the agency taking to reassure insurers that this is not taking place?

Answer: 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.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- clarifying language to make the rules of the road are clear to everyone,
- reviewing all SEPs and eliminating those that are no longer necessary, such as:
 - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy
 - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
 - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
 - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
 - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
 - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and

- providing stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes.

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

Question from Representative Dold of Illinois:

Secretary Burwell, I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk products consumed by young children up to three years of age. My understanding is that this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the U.S. dairy industry that need to be further examined.

- **Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?**

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,⁶ and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical

⁶ As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf (Accessed March 14, 2016).

comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

Questions from Representative Meehan Pennsylvania:

President Obama promised that Obamacare will be affordable. The fact is that individuals and families have been subject to double-digit increases in premiums and deductibles. The premiums for the second-lowest priced silver plan increased by nearly 11% in Pennsylvania between 2015 and 2016. This is consistent with the average national premium increase of 11.3% for a silver tier plan. Nationally, the average deductibles for the lowest-cost Obamacare plans increased from 2015 to 2016 by 10.6% for individuals and 10% for families. A higher deductible means higher out-of-pocket expenses for individuals and families. And as a result, individuals are putting off medical care. Republicans are working on delivering on the promise of expanding access to affordable health care insurance coverage.

1. What am I supposed to tell my constituents about why Obamacare is increasingly unaffordable?

Answer: The Affordable Care Act takes significant steps towards expanding coverage and improving access to health care while also improving the quality and affordability of health care for all Americans. It strengthens the private health insurance market and extends financial assistance to moderate-and low-income Americans to help make health insurance coverage more affordable. For example, for consumers in the 38 states using the healthcare.gov platform, more than 8 in 10 individuals who enrolled in a 2016 Marketplace plan qualified for an advance premium tax credit with an average value of \$294 per person per month⁷. In fact, most people can find monthly premiums for \$75 or less, after financial assistance.

ACA Marketplaces help consumers shop around for the best deal. Marketplace consumers can purchase any available plan regardless of health conditions, and tools such as the doctor lookup and out-of-pocket cost calculator help them find the plan that meets their needs. Last year, 2.39 million returning HealthCare.gov consumers, more than 40%, switched plans. They saved an average of \$42 per month, or about \$500 annually.⁸ In contrast, average rate changes reported in rate filings assume that all consumers stick with their current health insurance plan. In particular, they assume that no consumers enroll in any new plans offered for 2017, even though new plans frequently offer lower prices. This doesn't reflect reality, given that a large share of returning Marketplace consumers switched plans last year.

⁷ <https://aspe.hhs.gov/pdf-report/health-insurance-marketplaces-2016-average-premiums-after-advance-premium-tax-credits-38-states-using-healthcaregov-eligibility-and-enrollment-platform>

⁸ <http://www.hhs.gov/blog/2016/04/12/premiums-last-year-much-lower-than-initial-rates-suggested.html>

Lastly, it is important to remember that tax credits go up along with premiums. 85% of Marketplace consumers receive tax credits, which are designed to protect consumers from premium increases and help make coverage affordable. Tax credits increase if the cost of the second lowest-cost silver, or benchmark, plan goes up. So if all premiums in a market go up by similar amounts, 85% of Marketplace consumers in that market will not necessarily pay more because their tax credits will go up to compensate. Rate increases reported in the rate filings do not account for tax credits.

I am concerned that HHS is proposing Medicare policies that are not patient-centered and would likely drive up Medicare spending. For example, the Administration proposes to implement a \$100 per episode co-payment for home health services that are not preceded by an inpatient hospital stay for all new beneficiaries. Despite the Administration's estimate of cost savings, the Medicare Payment Advisory Commission (MedPAC) has highlighted that a disadvantage of requiring beneficiary cost-sharing for home health is that it could encourage Medicare beneficiaries to use more expensive post-acute care settings. In the 1960s, Medicare required a co-payment for home health services. In repealing the co-pay in 1972, Congress recognized that the co-payment resulted in shifts to more costly settings.

2. Why would the Administration propose a policy that Congress has already rejected?

Answer: Thank you for raising this important issue. This proposal is consistent with Medicare Payment Advisory Commission (MedPAC) recommendations to introduce a copayment for these services. MedPAC notes that beneficiaries without a prior hospitalization account for a rising share of home health episodes and that adding beneficiary cost sharing for home health care could be an additional measure to encourage appropriate use of home health services. Since many of these services are funded by Medicare Part B, MedPAC notes that decreases in home health spending growth would reduce Part B premiums.

While home health utilization and spending have grown over the past decade, home health services represent one of the few areas in fee-for-service Medicare that does not currently include beneficiary cost-sharing. Adding cost-sharing is expected to encourage beneficiaries to consider the appropriate use of home health services.

This proposal has appropriate safeguards to make sure that its implementation will not unfairly burden beneficiaries or restrict access to care. We appreciate your concern and would be happy to answer additional questions or provide a staff-level briefing.

The 12 years of data exclusivity for biologics may be among the few areas of bipartisan agreement in the Affordable Care Act. I am disappointed that the Administration undercut U.S. law by negotiating data exclusivity of less than 12 years in the Trans-Pacific Partnership and is now proposing to reduce the market

exclusivity period to 7 years. While the Administration suggests that reducing exclusivity prevents high drug prices, the Administration fails to acknowledge the reduction's potential effect on innovation.

3. Why does the Administration reject the ACA's carefully negotiated 12 years of data exclusivity and what calculation has HHS made as to the impact on the innovation of novel biologics?

Answer: The budget proposal to reduce the exclusivity period to 7 years in the United States is one of several proposed reforms designed to increase access to generic drugs and biologics.

With regard to the Trans-Pacific Partnership (TPP) Agreement, the U.S. opening proposals on pharmaceutical intellectual property provisions were based on existing U.S. law, under which the current standard for market exclusivity for biologic drugs is 12 years. Biologics exclusivity was one of the most challenging issues in the TPP negotiations. The Administration fought hard for an outcome as close to U.S. law as possible. The result was a negotiated compromise that guarantees 8 years of protection for biologics by our TPP partners. This level of protection for biologics still spurs innovation in biologic medicine, which offers great potential for new treatments and cures.

I am concerned that the ACA's reduction in Disproportionate Share Hospital (DSH) payments minimizes the correlation between participation in the Medicare DSH program and higher Medicare costs for urban hospitals with more than 100 beds like those that serve and employ individuals in my District. The problem is further exacerbated by CMS' switch to using the S-10 worksheet to calculate uncompensated care. My understanding is that the S-10 is not consistent with how hospitals report data. One analysis finds that Pennsylvania hospitals in the aggregate would see a 43.6% loss in payments as a result of the switch to S-10. If CMS is interested in capturing data more broadly, the Agency must ensure that it does not cherry pick data points to paint the picture it wants to see. In seeking to know what supplemental payments a hospital receives, CMS should not be blind to a hospital's Medicare losses.

4. What is the status of CMS' efforts to implement the S-10?

Answer: The Affordable Care Act modified the method for computing Medicare DSH adjustments, beginning in 2014, and for each subsequent fiscal year. Under this provision, hospitals eligible to receive Medicare DSH payments receive 25 percent of the amount they would have received under the statutory formula for Medicare DSH payments previously in effect. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid to Medicare DSH hospitals based on their share of the total amount of uncompensated care for all Medicare DSH hospitals for a given time period. In addition, the Secretary has the

authority to estimate uncompensated care based on appropriate data, including alternative data where the Secretary feels that proxy data is a better estimate for the costs of treating the uninsured.

In FY 2014, CMS determined that Worksheet S-10 of the Medicare cost report could potentially provide the most complete data for Medicare hospitals. For a full report on the potential data sources considered, please visit: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html>. At the time, CMS also noted that Worksheet S-10 is a relatively new data source that has been used for specific payment purposes only in relatively restricted ways (for example, to provide a source of charity care charges in the computation of EHR incentive payments).

Because of concerns regarding variations in the data reported on Worksheet S-10 of the Medicare cost report and the completeness of these data, CMS did not propose to use data from the Worksheet S-10 to determine the amount of uncompensated care for FY 2014. However, since FY 2014 hospitals have been on notice that Worksheet S-10 could eventually become the data source for CMS to calculate uncompensated care payments. CMS continues to believe reporting on Worksheet S-10 will improve over time particularly in the area of charity care reporting, which is already being used and audited for payment determinations related to the EHR Incentive Program.

CMS has stated that they may proceed with a proposal to use data on the Worksheet S-10 to determine uncompensated care costs in the future. The Worksheet S-10 could ultimately serve as an effective source of more direct data regarding uncompensated care costs for purposes of determining the allocation of uncompensated care payments once hospitals are submitting accurate and consistent data through this reporting mechanism. In the interim, CMS is committed to taking steps such as revising and clarifying cost report instructions, as appropriate.

As you know, 43 colleagues joined me in sending a letter to CMS outlining concerns with the way the Agency is implementing Medicare payment reform for clinical laboratories as required by the Protecting Access to Medicare Act of 2014. We are currently awaiting a response from CMS. I'm hoping you can address several concerns.

5. Why did CMS exclude a number of laboratories from the reporting process? Wouldn't you expect this exclusion to skew the market data resulting in Medicare rates that are not reflective of market rates?

Answer: We appreciate your concerns. As CMS's January 8th response noted, we are in active rulemaking on this topic and cannot provide much comment, but will be sure your comments are considered as CMS prepares the final rule. If you did not receive the letter, please let us know and we would be happy to send you a copy. In October 2015, CMS published a proposed rule to implement section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare

payment rates. In the proposed rule, CMS proposed to define the term “laboratory” according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. We also addressed how to meet the statutory requirement that an “applicable laboratory” receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, we proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

We are currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an “applicable laboratory”. We will carefully consider those comments in developing a final rule implementing PAMA.

6. In light of clear statutory language, why did CMS exclude “proteins” from the biomarkers that an Advanced Diagnostic Laboratory Test must be able to analyze? What is the status of implementation and has the Agency made any adjustments to the implementation timeline?

Answer: The Protecting Access to Medicare Act of 2014 (PAMA) defines an Advanced Diagnostic Laboratory Test (ADLT) as “a clinical diagnostic laboratory test covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner)”. To qualify as an ADLT (which receives special treatment under the new payment system established by PAMA), the test must also meet one of three additional criteria, including (as one option) that the test is “an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.”

In its proposed rule published in October 2015, CMS considered how best to operationalize this complex statutory definition. CMS subsequently received many comments on the proposed rule including comments on the proposed definition of an ADLT. We are currently reviewing those public comments and we will carefully consider them in developing a final rule implementing PAMA.

Rep. Diane Black and I introduced legislation, the Federal Exchange Data Breach Notification Act of 2015 (H.R.555), last year to require the government to notify consumers if their information is compromised on the Obamacare exchanges. We remain concerned about the potential for breaches.

7. Could you provide an update regarding any improvements that the Department of Health and Human Services (HHS) has made to the security and privacy controls for the Obamacare Federal Data Hub?

Answer: The privacy and security of consumers' information is a top priority. When consumers fill out their online health care Marketplace applications, the information they are providing is protected by stringent security controls. While no system is immune from attempted attacks or intrusions, CMS continually maintains and strengthens the security of HealthCare.gov and its supporting systems. HHS conducts continuous monitoring using a 24/7, multi-layer IT professional security team, third-party penetration testing, and a change management process that includes ongoing testing and mitigation strategies implemented in real time. To date, no person or group has maliciously accessed personally identifiable information through HealthCare.gov or supporting systems.

HHS has taken significant steps and implemented robust security controls to protect the security and privacy of the systems and connections supporting HealthCare.gov, including the Hub. HHS developed these systems consistent with federal statutes, guidelines, and industry standards that help safeguard the security, privacy, and integrity of the systems and the data that flow through them. HealthCare.gov and the Hub have been determined to be compliant with the Federal Information Security Modernization Act of 2014 (FISMA), based on standards promulgated by the National Institute of Standards and Technology (NIST). Marketplace systems are also in compliance with all the relevant privacy and security statutes, including the Privacy Act of 1974.

The Hub and its associated systems are protected via layered security (i.e. Defense in Depth) to mitigate information security risk, including penetration testing, which happens on an ongoing basis using industry best practices to appropriately safeguard consumers' personal information and agency data. As part of the ongoing testing process, and in line with federal and industry standards, any open risk findings are appropriately addressed using risk mitigation strategies and implementing compensating controls. The security of the system is also monitored by sensors and other tools to deter and prevent unauthorized access.

8. What funding does HHS devote to cybersecurity protection for the exchanges and more broadly?

Answer: The Department dedicates resources to support the responsibility of securing millions of individuals' personal health information, conducting highly sensitive biodefense work, reviewing new drug applications and clinical trial data, and issuing more grants than any other federal entity. In FY 2016, HHS is dedicating a total of \$51 million to support cybersecurity activities to ensure that the program has resources to appropriately plan, mitigate, and address cyber threats. The FY 2017 President's Budget maintains these investments. In addition to these resources, HHS agencies request additional support for cybersecurity through their programs. In the FY 2017 President's Budget, CMS requested funding to enhance cybersecurity by completing a transition to an enterprise approach for managing information security and privacy.

Health Insurance Marketplace cybersecurity is part of CMS' overall investment in Information Technology for the Marketplaces. The FY 2017 Budget requests a Marketplace IT program level of \$657 million. This investment supports systems integration, testing, and security across the Marketplaces to ensure integration and testing of new code, and security standards for consumer and issuer data. CMS has implemented

security controls and reviews, including ongoing penetration testing and automated scanning, consistent with FISMA requirements and industry best practices. As part of the ongoing testing process, and in line with federal and industry standards, any open risk findings are addressed with risk mitigation strategies and compensating controls. Marketplace IT systems are continuously monitored by sensors and other tools to deter and prevent unauthorized access.

The Centers for Medicare and Medicaid Services (CMS) finalized its Medicare Part B reimbursement policy for biosimilars to combine all biosimilars into one average sales price calculation and payment code. Effectively, the payment policy treats biosimilars as if they are generics. Biosimilars are not copies of one another like generics.

9. What is CMS' rationale for the blended payment rate for biosimilars?

Answer: Biosimilars hold great promise for all Americans, including Medicare beneficiaries, and CMS is committed to a payment approach that will provide a fair payment in a healthy marketplace. Competition fosters innovations that redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries – improving quality, price, and access.

While we appreciate that there are differences between multiple source drugs and biosimilars, from a payment policy perspective, it is reasonable to treat them similarly. They both have significant similarities with their predecessor product (a reference product for biosimilars and an innovator product for generics) and they are both approved through an abbreviated pathway. Further, we believe that biosimilars and multiple source drugs will have similar marketplace attributes; like generics, biosimilars will compete for market share with each other as well as with the reference product.

Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. To the contrary, we believe there is a strong need for lower cost alternatives to high cost biologicals, and the statute provides an incentive for the development of the biosimilars market by providing for reimbursement that includes a 6 percent add-on of the reference product's Average Sales Price.

Questions from Representative Price of Georgia:

MACRA Implementation

Secretary Burwell, in a review of the proposed FY 2017 Budget for the Centers for Medicare and Medicaid Services (CMS), I didn't see any discussion regarding how CMS will be distributing to medical societies the resources provided in MACRA for quality measure development and other quality related activities. I believe that

Congress provided \$15 million per year starting in FY 2016 and to date none of that money has been made available.

1. Can you share with the Committee HHS' plans for getting this money to the provider community for measure development activities?

Answer: MACRA provides CMS with \$15 million annually from FY 2015 to FY 2019 to develop a framework for future clinician quality measurement development to support the Merit-based Incentive Payment System and Alternative Payment Models. To meet the requirements of the statute, CMS posted the draft Measure Development Plan on December 18, 2015, with a public comment period through March 1, 2016. Per the statute, the final plan will be posted in May, followed by updates thereafter as appropriate. This plan will be used to guide the priority areas for measure development.

CMS recognizes the importance of measure development as we work to implement the provisions of MACRA. The process of preparing a measurement proposal concept, seeking bids, and assessing competitive bids will soon be underway. CMS has actively engaged with specialty societies to learn about their interests in the funding, and is synthesizing the results of these engagement sessions in order to spend contract dollars in a way that meets the needs of these organizations.

2. The President's Budget discusses the implementation of MACRA and alternative payment models being developed. What plans do HHS and CMS have in place to ensure that every alternative payment model developed by a medical society that meets the criteria for being a qualified alternative payment model gets implemented and is ready for physicians to participate in starting January 1, 2019?

Answer: MACRA established a new independent advisory committee, the Physician-Focused Payment Model Technical Advisory Committee (PTAC). The PTAC meets on a periodic basis to review physician-focused payment models submitted by individuals and stakeholder entities and prepare comments and recommendations on proposals that are received, explaining whether models meet criteria for physician-focused payment models.

We look forward to receiving recommendations for new physician-focused payment models. We will need stakeholder engagement with the PTAC, including physicians and other clinicians, to suggest well designed, robust models that could meet the statutory criteria to be an eligible APM.

The PTAC currently anticipates meeting on a quarterly basis to assess physician-focused payment model proposals, but the frequency of meetings may change depending on the number and complexity of proposals received. All meetings will be public, with timely, advance notice of meetings provided through the Federal Register. We encourage stakeholders to attend these meetings and provide comments and input to the PTAC on

the proposals; remarks may be made during the public comment portion of the meetings or comments may be submitted in writing.

After reviewing proposals, the PTAC will prepare comments and recommendations regarding whether the models meet the physician-focused payment model criteria established by HHS. The PTAC will submit its comments and recommendations to the Secretary, who will then review them and post a detailed response to them on the CMS website.

3. How is the money available under the Centers for Medicare and Medicaid Innovation (CMMI) being used to provide technical assistance, data support, and review opportunities for physician societies that are developing alternative payment models for MACRA?

Answer: Congress provided funding in MACRA for CMS for technical assistance to small practices, rural practices, and practices in medically underserved health professional shortage areas. This technical assistance could be provided by entities such as regional extension centers and regional health collaboratives to offer guidance and assistance to physicians and other clinicians.

The technical assistance is to focus on the performance categories under the Merit-based Incentive Payment System (MIPS), helping to make it as seamless as possible for these clinicians and practices to comply with MIPS requirements and helping interested practices transition to implementation of and participation in an alternative payment model (APM).

We requested feedback from the physician and broader clinician community last year on how best to implement this technical assistance. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community, including discussing the role that the Centers for Medicare and Medicaid Innovation (CMMI) can play in developing alternative payment models for MACRA. Currently, in developing and testing payment and service delivery models, CMMI is providing opportunities for stakeholders, including members of physician societies, to gain experience with new payment models and to participate in forums like the Health Care Payment Learning and Action Network.

4. Is CMMI working to develop APMs under MACRA? Will the Comprehensive Care for Joint Replacement Model (CJR), a new episode-based payment model for lower extremity joint replacement, be considered an APM under MACRA?

Answer: MACRA established a particular definition of alternative payment models (APMs) and established what qualifies as an “eligible APM,” for purposes of evaluating whether an EP is a qualifying APM participant (QP) for a year. QPs receive a payment incentive and are exempt from the Merit-Based Incentive Payment System for the year.

While creating this new category of eligible APMs provides for promising incentives for a growing number of EPs in the future, we expect the initial years to be ones of development as we apply lessons learned and continue to refine the program. The statute creates a high bar for eligible APMs. Many currently existing APMs – at the Innovation Center and in the private sector – are not likely to meet all these requirements, but some will. We will continuously search for opportunities to expand the range of options for participation in eligible APMs within the contours of the statute. In keeping with the statute, it is our intent to align the MIPS and the APM incentives to the extent feasible, thus allowing maximum flexibility for physicians and other clinicians who are not yet ready to participate in eligible APMs to participate in MIPS and then migrate to eligible APMs when they are ready.

As we move forward with MACRA implementation, we will continue to gather and incorporate feedback from stakeholders as we promote additional physician-focused APMs and work to define the details of the eligible APM criteria contained in statute. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

CMMI

- 5. It should come as no surprise that we take issue with CMMI's broad interpretation of authority. Are we to anticipate that CMMI will continue to exploit the authority granted under Section 1115A by promulgating additional mandatory demos where patients are thereby used as test subjects? How will CMMI identify the patient population and services to be targeted in future demos?**

Answer: Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. While I appreciate your concern, the statute does not require that models be voluntary, but rather gives the Secretary discretion to design and test models that meet certain requirements as to spending and quality.

Models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. In addition, the Secretary must focus on models expected to reduce program costs while preserving or enhancing the quality of care. All models include monitoring and evaluation of patient care. Section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, but the Secretary is not limited to those models. The Innovation Center will continue to use these statutory criteria, including input from interested parties, for selecting and designing future models.

Section 1115A requires that models which fail or are expected to fail to improve the quality of care within current spending or reduce spending while maintaining the quality of care be terminated or modified.

6. What exactly are the processes used by CMS to evaluate and modify models, and how does CMS deem a model to be worthy of termination?

Answer: Every 1115A model has a rigorous, rapid-cycle, evaluation conducted by an independent team that unfolds concurrently with model implementation. In every model evaluation, we strive to determine the impact of the innovation on patient and provider experiences, outcomes and quality of care, and program expenditures. While each model is different and requires a customized evaluation approach, common components include: regular surveys of beneficiary experience of care, analysis of claims-based utilization and quality of care outcomes, and qualitative data collection, such as patient and caregiver focus groups. We make sure that our models are well designed – and we use all appropriate scientific and statistical methods to study the impact of the model test relative to what would have happened in the absence of that model test.

We are required to terminate or modify an Innovation Center model unless the model is expected to improve the quality of care without increasing spending, reduce spending without lowering the quality of care, or both improve the quality of care and reduce spending. CMS uses these criteria to determine if a model should be terminated or modified based on the data available from the model evaluations and other sources.

CJR-Focused Questions:

7. The Comprehensive Care Joint Replacement model is expected to capture nearly 800 acute care hospitals with at least 120,000 joint replacements a year. What data did CMMI rely on in developing the CJR model in order to conclude that the CJR model will lead to improved care?

Answer: The CJR model is informed by other models and demonstrations currently and previously conducted by CMS and will explore additional ways to enhance coordination of care and improve the quality of services through bundled payments. Medicare tested innovative approaches to paying for orthopedic services in the 3-year Medicare Acute Care Episode (ACE) demonstration. CMS is currently testing additional approaches under the Bundled Payments for Care Improvement (BPCI) initiative. Both of these models informed the design of the CJR model.

CMS will provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Furthermore, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the

hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period.

In addition, because we are proposing to incorporate regional pricing data in the creation of prices for the CJR model, we will provide comparable aggregate expenditure data available for all claims associated with MS DRGs 469 and 470 during an episode period for the census region in which the participant hospital is located. We believe that making these data available will enhance participating hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model.

8. How will CMMI monitor the effects of CJR throughout the duration of the program?

Answer: As with all Innovation Center models, during the CJR model, CMS will monitor and evaluate the impact of the model to guard against any unintended consequences that might negatively impact beneficiaries. With respect to monitoring for access to care, CMS will apply their existing authority and tools to monitor for overutilization and underutilization of care under the CJR model. These tools include data analysis, the process of tracking patterns of utilization and trends in the delivery of care, and medical review, a clinical audit process by which we verify that services paid by Medicare were reasonable and necessary. With respect to monitoring for quality of care, CMS will use their existing authority to audit claims and services, use the Quality Improvement Organizations to assess for quality issues, use CMS authority to investigate allegations of patient harm, and to monitor the impact of the quality metrics for the model. Beneficiaries also have the ability to report concerns about the model to Quality Improvement Organizations and through 1-800-MEDICARE. Finally, CJR model participants will also be monitored for compliance with all existing rules and regulations.

The evaluation will include both quantitative and qualitative data and will use a variety of methods and measures in assessing quality. This will include claims based measures such as increases in readmissions and ER visits, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) satisfaction and care experience measures, and functional performance change scores from the required patient assessment instruments in Home Health Agencies (HHAs) and Skilled Nursing Facilities (SNFs). In addition, CMS plans for the evaluation to include a beneficiary survey that will be used to assess the impact of the CJR model on beneficiary perceptions of access, satisfaction, pain, mobility, and other relevant functional performance measures.

9. Will CMMI be able and ready to halt the demo immediately if shown to reduce the quality of care?

Answer: As concerns are identified, CMS can initiate audits and corrective action under existing authority. In addition, under Section 1115A(b)(3)(B) of the Social Security Act, the Secretary is required to terminate or modify an Innovation Center model unless the model is expected to improve the quality of care without increasing spending, reduce

spending without lowering the quality of care, or both improve the quality of care and reduce spending. If during the course of testing the CJR model it is determined that termination or modification is necessary, such actions will be undertaken through rulemaking as necessary.

10. Current information from conversations with several BPCI conveners for hospitals and hospital awardees indicates a large number of hospitals, or systems, have not realized favorable reconciliations for CY2014 or Q1-Q2 2015. Given the rapid pace of the CJR start date and the extremely limited time participating hospitals have to obtain, analyze, decipher, and make decisions from the historical data, how do you expect the CJR model to be a success?

Answer: The CJR model has the potential to improve quality in four ways. First, the model adopts a quality first principle where hospitals must achieve a minimum level of episode quality before receiving reconciliation payments when episode spending is below the target price.

Second, higher episode quality, considering both performance and improvement, may lead a hospital to receive quality incentive payments based on the hospital's composite quality score, a summary score reflecting hospital performance and improvement on two measures: one related to the complication rates for elective hip or knee replacements and the other measuring patient experience of care.

The composite quality score also takes into consideration a hospital's submission of patient-reported outcomes and limited risk variable voluntary data.

Third, in addition to quality performance requirements, the model incentivizes hospitals to avoid expensive and harmful events, which increase episode spending and reduce the opportunity for reconciliation payments.

Fourth, CMS provides additional tools to improve the effectiveness of care coordination by participant hospitals in selected Metropolitan Statistical Areas. These tools include: 1) providing hospitals with relevant spending and utilization data; 2) waiving certain Medicare requirements to encourage flexibility in the delivery of care; and 3) facilitating the sharing of best practices between participant hospitals through a learning and diffusion program.

The CJR model includes certain financial safeguards for participant hospitals. There is no repayment responsibility in performance year 1, a stop-loss limit of 5 percent in performance year 2, a stop-loss limit of 10 percent in performance year 3, and a stop-loss limit of 20 percent in performance years 4 and 5 for participating hospitals other than rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals. The stop-loss limit for these hospitals will be at 3 percent in performance year 2 and 5 percent in performance years 3 through 5. A parallel approach has been finalized for the stop-gain limits to provide proportionately similar protections to CMS and

hospital participants, as well as to protect the health of beneficiaries. The CJR model also gradually phases in repayment responsibility with a reduced discount percentage for repayment responsibility in years 2 and 3.

CMS will also provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Moreover, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period. In addition, because we are proposing to incorporate regional pricing data in the creation of prices for the CJR model, we will provide comparable aggregate expenditure data available for all claims associated with MS DRGs 469 and 470 during an episode period for the census region in which the participant hospital is located. We believe that making these data available will enhance participating hospitals' ability to identify existing care patterns that need to be changed or strengthened as well as the kinds of strategies needed to improve their care practices so that they can be most successful under the model.

11. Performance estimates of hospitals in CJR markets (using available data from CMS and BPCI historical and performance period data from the same or similar markets and estimates of trend factors) indicate that nearly 75% (579 of 794 hospitals) will show annual losses under CJR (many in the millions of dollars) if they are unable to dramatically affect post-acute care service utilization and achieve provider alignment across the entire care continuum, a function not traditionally performed by hospitals or physicians. Given the complexity of implementing effective care redesign under CJR, do you anticipate a percentage of hospitals to stop providing hip and knee replacements because this mandatory program has the potential to create a cataclysmic financial downfall?

Answer: The model's goal is to give hospitals a financial incentive to work with physicians, home health agencies, skilled nursing facilities, and other providers to make sure beneficiaries get the coordinated care they need. Patients, hospitals, physicians, and post-acute care providers all stand to gain from the successful implementation of the CJR model. By improving care coordination throughout the episode, unnecessary care can be reduced, and quality outcomes improved. There will be an opportunity for hospitals to earn more through partnerships with physicians and post-acute care providers as care coordination is improved, and opportunities for hospitals to share these funds with physicians and post-acute care provider collaborators in care redesign. We anticipate hospitals will continue to serve patients needing hip and knee replacements and improve collaboration with other post-acute providers in the community leading to improved outcomes for beneficiaries.

Furthermore, the CJR model includes certain financial safeguards for participant hospitals. There is no repayment responsibility in performance year 1, a stop-loss limit of 5 percent in performance year 2, a stop-loss limit of 10 percent in performance year 3, and a stop-loss limit of 20 percent in performance years 4 and 5 for participating hospitals other than rural hospitals, Medicare-dependent hospitals, rural referral centers, and sole community hospitals. The stop-loss limit for these hospitals will be at 3 percent in performance year 2 and 5 percent in performance years 3 through 5. A parallel approach has been finalized for the stop-gain limits to provide proportionately similar protections to CMS and hospital participants, as well as to protect the health of beneficiaries. The CJR model also gradually phases in repayment responsibility with a reduced discount percentage for repayment responsibility in years 2 and 3. CMS will also provide technical assistance to hospital participants in the CJR model through educational webinars and other tools. Moreover, in response to a hospital's request and in accordance with our regulations and applicable privacy laws, we will provide beneficiary claims information (1) in summary format, (2) as raw claims line feeds, or (3) both, depending on the hospital's preference. These data will encompass the total expenditures and claims during the acute hospitalization and the 90 day post-discharge episode for the hospital's beneficiaries whose anchor diagnosis at discharge assigned the hospital stay to MS DRG 469 or 470. We will make these data available for both the hospital's baseline period and no less often than on a quarterly basis with the goal of making these data available as often as on a monthly basis if practicable during a hospital's performance period.

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CMMI and ACOs

12. The Pioneer ACO program appears to be your most "successful" program judging by the fact that it was the only program you chose to expand. Albeit there is no indication that the Pioneer ACO model met the statutory criteria for expansion. Nonetheless, 13 of 32 ACOs, approximately 40%, dropped out of Pioneer after just one year. Is this a program capable of sustaining itself?

Answer: The Pioneer ACO Model is the first model designed and tested by CMMI to be certified for expansion by the CMS Office of the Actuary and the Secretary of HHS. Under the Affordable Care Act, the Secretary has the authority to expand an Innovation Center model in duration and scope for Medicare if: 1) an expansion is expected to reduce spending without reducing the quality of care or improve the quality of care without increasing spending 2) the CMS Chief Actuary certifies that an expansion would

reduce or maintain net program spending and 3) an expansion would not deny or limit the coverage or provision of benefits to Medicare beneficiaries. The CMS Office of the Actuary has reviewed the Pioneer ACO Model's early independent evaluation results, as well as conducted its own additional analyses, and concluded that an expansion of the Pioneer ACO Model as it existed in the first two performance years would reduce net program spending under Medicare. The Secretary has also determined that an expansion of the Pioneer ACO Model would maintain or improve quality and would not deny or limit coverage or provision of benefits, thereby allowing the Secretary to expand this model.

In terms of sustainability for the Pioneer ACO Model, the model began on January 1, 2012 as a five-year model developed by CMMI to test whether alternative design elements might enhance ACO effectiveness and ultimately inform policy changes to improve the Shared Savings Program by means of future rulemaking. The model concludes in 2016. Regarding the Pioneer ACOs that chose to leave the model, CMS always expected that a subset of Pioneer ACOs would leave the model over time. CMS respects the need for individual organizations to make decisions that are most appropriate for their circumstances but we are encouraged that several of the Pioneer ACOs transitioned to being participants in the Medicare Shared Savings Program and the Next Generation ACO Model. These developments bolster CMS' confidence that incorporating elements of the Pioneer ACO Model into the Shared Savings program will help those alternative payment arrangements improve outcomes for beneficiaries and Medicare, as well as increase provider participation in them. As we learn through demonstrations and stakeholder comment what works well in the model= subsequent rulemaking for the Shared Savings Program will be informed by lessons learned from our experience.

13. Total spending on all CMMI experiments to date has amounted to \$4.335 billion. Only one program has been selected for expansion, yet it generates minimal savings. How do you justify wasting billions of taxpayer funds?

Answer: In 2014 alone, Medicare ACOs improved quality of care and saved an estimated \$411 million. From 2010 to 2014, there was a 17 percent decline in patient harm resulting in an estimated 2.1 million fewer hospital-acquired conditions, an estimated 87,000 fewer patients dying in hospitals and nearly \$20 billion in health care costs saved — likely the result of various programs that support and incentivize hospitals to share best practices for reducing avoidable harm. While there's still more work to do, the new programs implemented and models being tested are providing the tools needed to sustain the historic slowdown in health care cost growth we've seen since 2010.

The Innovation Center's portfolio of models has attracted participation from a broad array of health care providers, states, payers, and other stakeholders, and serves Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries in all 50 states, the District of Columbia and Puerto Rico. Over 4.7 million Medicare, Medicaid, and CHIP beneficiaries are or soon will be receiving care furnished by the more than 61,000 providers participating in Innovation Center payment and service delivery models. Beyond the impact for these beneficiaries, Innovation Center models

are impacting tens of millions of additional Americans by engaging thousands of other providers, payers, and states in model tests and through quality improvement efforts that extend across the country. Innovation Center models are making important contributions towards building a health care delivery system health care system that leads in innovation, delivers affordable, high-quality medicines, and results in healthier people. CBO recently estimated in a report dated July 30, 2015 that the work of the Innovation Center would yield \$38 billion in savings over the next ten years (2016 to 2025).

Problems with EHRs

14. How much federal money has been used to invent implementation of EHRs?

Answer: The American Recovery and Reinvestment Act (ARRA) appropriated \$2 billion to the Office of the National Coordinator for Health Information Technology (ONC) to implement the HITECH Act. ONC used its ARRA funds to support the development of a national health IT infrastructure that enabled providers to leverage health information to improve the quality and efficacy of the care they deliver to their patients. The \$2 billion was a one-time influx of funding. Outside of this funding, ONC's annual budget has been approximately \$60 million since 2007. The Center for Medicare and Medicaid Services (CMS) EHR Incentive Programs provided payments to eligible professionals and hospitals to adopt, implement, and demonstrate meaningful use of certified EHR and have paid approximately \$33.6 billion in incentive payments. As with all our funding, we are committed to proper stewardship of taxpayer dollars.

15. Did we invent behavior that deployed EHRs before we had the right architecture to deliver on digital healthcare? Aren't we backtracking now to create the sort of interoperability and data liquidity that we should have developed as initial standards?

Answer: The EHR Incentive Programs rule and the ONC certification program have been successful in driving adoption and use of EHR technology. In the seven years since the HITECH Act was enacted, the nation has seen dramatic advancement in the use and adoption of health IT. Specifically, nearly all (97%) acute care hospitals have adopted certified health IT and three-quarters (74%) of physicians have adopted certified health IT.

ONC recognizes that collaborative commitments across government and industry are needed to address challenges for the U.S. to realize the full benefits and potential of a secure, interoperable electronic health information infrastructure that seamlessly supports the health system and provides individuals with safe, person-centered care. As adoption increases, ONC and CMS have worked together to advance standards-based interoperability, including through provisions in the fall 2015 release of the latest health IT certification rule and EHR Incentive Programs rule.

16. Aren't we challenged to get the EHR vendors to cooperate to the level beyond their own self-interests and acting toward better a national architecture that serves not only the Medicare beneficiaries, but all patients?

Answer: In its Shared Nationwide Interoperability Roadmap, ONC identified near-term actions and roles that health IT stakeholders should perform to make immediate progress and impacts with respect to interoperability. The Roadmap is a shared, industry wide set of milestones, calls to actions, and commitments that lays out a focused series of steps and activities that we need to collectively undertake to achieve interoperability and enable a learning health system. Though ONC defines a path to short term success, the Roadmap is also designed to lay out a long-term vision and was developed with extensive input from federal agencies, Congress, and health IT stakeholders, including consumers, healthcare providers, health IT developers, and public health. It provides an opportunity to improve coordination and includes a set of milestones by which we can judge progress.

The Roadmap specifically called out three specific principles: 1) supporting consumer access, 2) not blocking information, and 3) implementing federally recognized, national standards around interoperability so all products speak the same language. In February 2016, Secretary Burwell announced at the Healthcare Information and Management Systems Society (HIMSS) meeting that companies providing electronic health records to 90% of hospitals agreed to take action to implement those three commitments. Additionally, hospitals including the five largest and many others that span a total of 46 states also stepped up and agreed to these commitments. We are optimistic about this unparalleled public-private sector collaboration on interoperability.

A New Approach to Meaningful Use

17. Most everyone agrees we need to move away from the current way of doing things – both in MU and EHR certification. Our patients and physician colleagues have joined in unison to call for serious reform. Given Administrator Slavitt’s recent comments admitting that the Meaningful Use program needs reform, how specifically has ONC been advising CMS in rethinking the MU program?

Answer: ONC and CMS have been working side by side to update the Medicare and Medicaid EHR Incentive Programs, advance the certification of health IT towards care delivery goals, and to implement MACRA.. In addition, we have been working with physician and consumer communities and have listened to their needs and concerns. For Medicare physicians and other practitioners, we will be sharing details and inviting comment on our proposal to implement the EHR requirements in MACRA as we roll out our proposed regulations this spring.

Several critical principles inform the important work of both agencies. First, we aim to reward providers for the outcomes technology helps them achieve with their patients. Second, we want to allow providers the flexibility to customize health IT to their individual practice needs. Technology must be user-centered and support physicians. Third, we need to level the technology playing field to promote innovation, including for start-ups and new entrants, by unlocking electronic health information through open APIs – technology tools that underpin many consumer applications. This way, new apps, analytic tools and plug-ins can be easily connected to so that data can be securely accessed and directed where and when it is needed in order to support patient care.

Finally, we aim to prioritize 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.

ONC and CMS will continue working together to prevent information blocking, improve the EHR Incentive programs, and support a health IT environment that rewards innovation and user-centered technology.

18. In March, your agency will release guidance for a new MIPS program. What impact do you expect this will have on MU? What other impacts are you anticipating as a result of MIPS?

Answer: The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), through the Merit-based Incentive Payment System (MIPS), considers quality, resource use, clinical practice improvement activities, and meaningful use of health IT in calculating how Medicare physician and practitioner payments are determined. While MACRA continues to require that Medicare physicians and practitioners be measured on their meaningful use of certified EHR technology for purposes of determining their Medicare payments, it provides new flexibility to determine how to measure that use.

CMS is working closely with provider groups, the consumer community and other important stakeholders to ensure we release an effective proposed rule this spring. The law requires that we continue to measure the meaningful use of ONC Certified EHR Technology under the existing set of standards. While MACRA provides an opportunity to adjust payment incentives associated with EHR incentives, it does not eliminate meaningful use. In addition, the MIPS only addresses Medicare physician and practitioner payments; the EHR incentive programs for Medicare hospitals and Medicaid have a different set of statutory requirements.

The process is ongoing, and we are committed to learning and improving and collaborating on the best solutions. Ultimately, we believe this is a process that will be most successful when physicians and innovators can work together directly to create the best tools to care for patients. We look forward to working collaboratively with stakeholders, including Congress, on advancing MACRA implementation and working to ensure this change is successful in the months ahead.

The Viability of the Health Care Exchanges:

19. On November 19 of last year, United Healthcare, one of the country's largest insurers, reported that it was scaling back advertising of individual plans for this year due to a reduction in expected earnings of \$425 million. The company also reported that it saw no reason to expect an improvement in the current climate and that it was considering not offering an exchange plan in 2017. Another large national insurer, Aetna, has made similar undertones. A third large national insurer, Humana, is also terminating several of the large

health plans it offers on the exchanges. Secretary, what do these announcements suggest about the viability of the healthcare exchanges?

Answer: The Marketplace is strong and growing. During the third Marketplace Open Enrollment nine out of ten returning customers were able to choose from three or more issuers for 2016 coverage, up from seven in ten in 2014. During this same period, 12.7 million Americans selected affordable, quality health plans for 2016 coverage through the Marketplaces. In fact, this year 60 percent of our new enrollees signed up in time to have coverage by January 1, compared to about 40 percent of new enrollees last year.

Health plans are learning how to price and how to offer competitive products that consumers want. We also know that the Marketplace created one of the largest pools of new customers for insurance companies in years. Even as the market meets today's needs and signs millions of new consumers up in record numbers, we also pay attention to adjustments that are needed as the Marketplace matures— whether that's creating new decision support tools for consumers, or strengthening risk adjustment, or clarifying the rules of the road on Special Enrollment Periods. We have full confidence that the Marketplaces will continue to thrive for years ahead.

Insolvency of the Medicare Hospital Insurance Trust Fund:

20. Last year, Medicare's trustees projected the date of exhaustion for the Medicare hospital insurance trust fund at 2030. CBO has accelerated that date by 4 years – to 2026 which is within the budget window. This is so even though the large Medicare spending cuts included in Obamacare – allegedly used to offset the huge costs of that new entitlement – were also supposed to extend the life of Medicare. Given this imminent date of 2026, what are you doing to ensure the long-term viability of the Medicare program?

Answer: The FY 2017 Budget includes a package of Medicare legislative proposals that will save a net \$419 billion over 10 years by supporting delivery system reform to promote high-quality, efficient care, improving beneficiary access to care, addressing the rising cost of pharmaceuticals, more closely aligning payments with costs of care, and making structural changes that will reduce federal subsidies to high-income beneficiaries and create incentives for beneficiaries to seek high-value services. These proposals, combined with tax proposals included in the FY 2017 President's Budget, would help extend the life of the Medicare Hospital Insurance Trust Fund by over 15 years.

Competitive Bidding:

21. The current competitive bidding system is failing patients, why do you think further expansion of a broken program is a good idea?

Answer: The Durable Medicare Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program is an essential tool to help Medicare set appropriate payment rates for DMEPOS items by replacing the existing, outdated, excessive fee schedule amounts with market-based prices. The program has resulted in reducing beneficiary out-of-pocket costs, providing significant savings to the Medicare program and taxpayers, and reducing over-utilization and fraud. It has also achieved

billions in savings for Medicare and beneficiaries. Additionally the program has ensured continued beneficiary access to high quality items and services without compromising beneficiary health and safety.

- 22. Starting on January 1, 2016, CMS has significantly reduced reimbursement rates for DME items in non-competitive bid areas. Secretary Burwell, can you give me specific details (other than using claims data) how you are monitoring the impact that these cuts are having on patient access to DME items in non-competitive bid areas?**
- 23. If you determine that there are access problems with DME items in non-competitive bid areas because of the recent cuts, how you will remedy these problems and how long the process will take? Can you stop the second cut due to take effect on July 1, 2016?**

Answer to 22-23: CMS has been using a real-time claims analysis to monitor health status results in the DME competitive bidding program and other Medicare payment systems. The analysis for the DME competitive bidding program includes key indicators of the health status of beneficiaries and their access to DMEPOS items and services such as deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. We also monitor beneficiaries who no longer have claims for a competitively bid item after the program began, beneficiaries who may at some point need the item, and beneficiaries who currently have claims for competitively bid items. CMS is doing a similar type of analysis and monitoring for the adjusted DME fee schedule rates during the 6-month transition period and after this transition period. In addition, CMS will be monitoring assignment rates of suppliers. Assignment means that the suppliers have agreed to accept Medicare allowed rate as full payment for the DME item. If there are any issues identified through our monitoring, we will take appropriate actions depending on the situation.

Local Coverage Determinations (LCDs)

- 24. Can you explain the agency's views on the recent increase of LCDs that are being adopted across the country on a national scale, and what your agency is doing to ensure that Medicare coverage for precision medicine appropriately fosters innovation and patient care?**

Answer: Local coverage determinations (LCDs) are authorized by statute to allow the Medicare Administrative Contractors (MACs) flexibility in creating innovative and effective coverage policies to meet the needs of beneficiaries in their regions. The LCD process may also provide more expeditious coverage for new technology than may be available at the national level. In creating local policies, the MACs must follow the LCD development process established by CMS, including opportunities for public comment and input from the local medical community through a Contractor Advisory Committee (CAC). In some cases, the MACs may draw upon specialized expertise available at another MAC or may work together to develop more consistent policies. However, if a MAC proposes to adopt a draft policy developed by another MAC, it must still follow all

the required procedural steps, including solicitation of public comments and presentation to the CAC, within its own jurisdiction. More information on the LCD process is available in Chapter 13 of the Medicare Program Integrity Manual at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>.

The promise of precision medicine is delivering the right treatments, at the right time, to the right person. It is through this promise that we are given one of the greatest opportunities for new medical breakthroughs that we have ever seen. Payment decisions for individuals' care will come under the same processes as all items and services coverable under Medicare Fee for Service. These include coverage by claim by claim adjudication, local coverage determination or national coverage determination. For drug coverage under Part D, plan sponsors' formularies must include adequate coverage of the types of drugs most commonly needed by Part D enrollees, all new drugs must be reviewed by the plan for inclusion on the formulary, and sponsors must have procedures in place that ensure enrollees have access to Part D drugs that are not included on its formulary.

Questions from Representative Jenkins:

Madame Secretary, as I discussed during the hearing, one particular provision of Obamacare that is especially cumbersome and drives up health care costs for everyday Americans is the requirement that individuals have a prescription from a physician in order to purchase over-the-counter medicine with their health savings accounts and flexible spending accounts. I have worked on bill H.R. 1270 – the Restoring Access to Medication Act –which would eliminate this unnecessary requirement that is confusing and a waste of time for patients and physicians. I have worked closely on this legislation for over three years with my colleague, Representative Ron Kind from Wisconsin. When you testified in front of this committee last June, I asked if you would support this type of legislation. At the time you indicated you were not familiar with the issue.

- 1. After having time to review H.R. 1270, would you support this bi-partisan legislation?**

Answer: Thank you for raising this issue. As I have said before, we are willing to work with Congress on any proposal that improves access, affordability, quality, and health of the economy. This proposal could have substantial revenue effects and does not meet this test without including an offset. I would defer you to my colleagues at the Department of Treasury for specifics around their regulations.

- 2. In addition, the Program of All-Inclusive Care for the Elderly (or PACE) has a proven track record of providing the highest quality of care to some of our most vulnerable seniors - those who need a nursing home level of care but wish to continue living in the community. However, the program only serves**

35,000 people and PACE organizations say they could serve many more. What is the administration doing to build on this successful program?

Answer I share your support for the PACE program, and CMS is taking steps to modernize and streamline PACE enrollment and services.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services. In addition to updating PACE regulations, we are working to implement the PACE Innovation Act of 2015, which expanded the department's authority to allow waivers in order to conduct demonstration projects that involve PACE. CMS is actively working with stakeholder and advocacy groups to determine how the PACE comprehensive care approach can be combined with community care models and expanded to reach a broader population. We will keep your staff apprised of the status of the pilot.

3. Currently Medicare beneficiaries who enroll in the Program of All-Inclusive Care for the Elderly (or PACE) do not have the option to keep the Part D plan of their choice. For many, this is a disincentive to enroll in PACE. What steps would CMS require to allow Medicare beneficiaries to have a choice in the Part D plan they enroll in if they choose to enroll in PACE?

Answer: Beneficiaries who join a PACE program get Part D-covered drugs and all other necessary medication from the PACE program. Similarly, in most cases, beneficiaries who choose to join a Medicare Advantage Plan that includes prescription drug coverage must take the drug coverage that comes with the Medicare health plan if it's offered. While we believe coordination between medical and drug benefits under the current system is beneficial, we would be happy to provide technical assistance on any proposals you may have in this area.

Questions for Representative Black of Tennessee:

Last September, the Chairman and members of the Ways and Means Committee sent a letter to CMS asking for critical information on the oversight of the CO-OP program. In their response, CMS states that the agency took assertive actions towards the failing CO-OPs, including placing many on Corrective Action Plans or Enhanced Oversight Plans.

1. Can you tell me whether CMS required New York to submit to them a corrective action plan?

CMS provided the Committee with the letters they sent to specific CO-OPs asking for corrective actions, but the Health Republic Insurance of New York was not sent a letter.

2. It seems unbelievable CMS would overlook the largest CO-OP, covering by far the most enrollees, in their corrective action plans. How was it that this was missed?

Answer: No. CMS did not issue a corrective action plan to New York prior to the decision to wind down the CO-OP. However, CMS regularly uses enhanced oversight plans (EOPs) and corrective action plans (CAPs) as part of our CO-OP monitoring and oversight process, as laid out in the CO-OP loan agreements and recommended by the HHS OIG. CMS places a CO-OP on an EOP or CAP when it identifies an issue that can be resolved through corrective action.

CMS ordered an independent audit of Health Republic in summer 2015 based on early warning signs about the CO-OP's finances. This independent auditor found higher losses than the CO-OP had expected or projected in its financial reporting to CMS. In this case, the financial problems confronting Health Republic appeared to be too severe to address or correct through a CAP. In the interests of consumers and taxpayers, CMS worked with the State Department of Financial Services, which is the primary insurance regulator, to wind down the CO-OP and to ensure that consumers would have coverage through the end of the year.

3. How did CMS prioritize their oversight actions for various CO-OP's, if, evidently, this was prioritized not by size, scope, or cost?

Answer: CMS is committed operating as a proper steward of the taxpayer dollars issued through the loan program and to administering the CO-OP Program for the benefit of consumers. Since awarding both start-up and solvency loans, CMS has been closely monitoring and evaluating the CO-OPs to assess performance and compliance, and has engaged regularly with state DOIs, which are the primary regulators of insurance issuers in the states.

All CO-OPs are subject to standardized, ongoing reporting to and interactions with CMS that include weekly, biweekly, or monthly calls to monitor goals and challenges; periodic on-site visits; performance and financial auditing; and monthly, quarterly, semi-annual,

and annual reporting obligations. Since March 2015, CMS has conducted site visits of CO-OPs in 15 states. We believe these visits are a benefit to plans, consumers, and taxpayers. These visits provide CMS with an opportunity to verify whether and how a CO-OP meets its obligations. During these visits, CMS reviews management structure and staffing, financial status, business strategy, the policies and procedures of the CO-OP, marketing and sales information, and operations, including vendor management and oversight. CMS also reviews whether a CO-OP is meeting their obligations for medical management and member relations. CMS also collaborates with DOIs concerning each CO-OP loan recipient.

CMS prioritizes its oversight efforts based primarily on the financial reporting and regulatory reporting it receives from the CO-OPs on an ongoing basis. CMS monitors the CO-OPs' overall financial condition using several factors of the Federal Deposit Insurance Corporation's Uniform Financial Institutions Rating System. CO-OPs have monthly, semi-annual, and annual reporting requirements, including financial statements, balance sheets, income statements, statements of cash flow, and enrollment statistics. Last year, CMS increased the data and financial reporting requirements for CO-OPs. Each CO-OP is required to provide a semi-annual statement of its compliance with all relevant State licensure requirements, and, if necessary, an explanation of any deficiencies, warnings, additional oversight, or any other adverse action or determination by DOIs received by the CO-OP. If the CO-OP is experiencing compliance issues with State regulators, the CO-OP is required to describe the steps being taken to resolve those issues. CMS meets monthly with the state insurance regulators regarding each CO-OP. This additional financial data collection has helped CMS to identify underperforming CO-OPs and gives CMS the opportunity to work with the CO-OPs and DOIs to help correct issues that are identified.

4. Are you similarly looking into whether Health Republic misrepresented their finances to you?

Answer: As a normal course of action, in any of the situations where a CO-OP is no longer operating, CMS is conducting financial reviews and audits to ensure that funds were spent appropriately. After a CO-OP has been placed in receivership, CMS is limited in its ability as a creditor to control or investigate a CO-OP that has gone into supervised liquidation under state law. However as called for in statute, once a CO-OP loan agreement (like other Federal loans) is terminated, the loans become due as present debts, and CMS is obligated by statute to refer those debts to the Civil Division of the Department of Justice for collection.

The changes necessary to implement Section 2 of the Patient Access and Medicare Protection Act could be accomplished through the use of a billing modifier and a fee schedule update. In the past, CMS has used this method to address situations similar to the one we are discussing today. Further, modifiers and fee schedules are routinely updated as need.

5. **Keeping that in mind, I am having difficulty understanding why CMS is insisting that the law requires a non-routine update that cannot be implemented until July?**
6. **What sort of advanced planning is usually necessary for CMS to implement these types of changes in its system? I would like to know how often CMS updates its fee schedules for products and services, on average, each year.**

Answer: We are aware of and appreciate your concerns regarding this issue. CMS began working on implementation of the Patient Access and Medicare Protection Act of 2015 (PAMPA) when it first passed Congress in late December. Since PAMPA was signed into law at the end of December, it would not have been feasible for CMS to implement it on January 1, 2016. Given the amount of system changes required and the testing involved, the soonest they are able to implement this change is July 1, 2016. Until these changes are implemented, payments for these items will be based on the adjusted DME fee schedule amounts. The DME adjusted fee schedule rates are currently in a 50/50 blend during this 6 month transition period. The average reductions for these Group 3 complex rehabilitative wheelchair accessories are about 10 percent. On or after July 1, 2016, suppliers will receive the full fee schedule amount.

To ensure beneficiary access to these accessories particularly for these vulnerable populations, advance payment may be available for suppliers. According to our regulations, an advance payment means a conditional partial payment made by the contractor in response to a claim that is unable to process within established time limits. Suppliers are able to submit a single advance payment request to their Medicare Administrative Contractor for multiple claims during this period. These advance payments may be issued if certain regulatory requirements are met.

CMS will be monitoring beneficiary access closely during this time to ensure they receive the wheelchairs and accessories that they need.

In Medicare, Medicaid and the private sector, health care delivery and payment systems are seeing significant and accelerating change. Yet the Program of All-Inclusive Care for the Elderly (or PACE), which pioneered so many of the features we now seek to build into our health care system, is being constrained by regulations that are almost a decade old.

7. **What is the administration doing to update these regulations and provide more flexibility to PACE so that our seniors can have greater access to its gold-standard, proven and replicable model of integrated, community-based and person-centered care?**

Answer: I share your support for the PACE program, and CMS is taking steps to modernize and streamline PACE enrollment and services.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services.

I am concerned that recent news indicates too much instability in the individual market. Although you are highlighting a 90 percent coverage rate, enrollment expansions in the individual market are far below initial projections. Consumers who are willing to do their part by paying a full year of premiums are paying higher rates because the exchanges allow people to sign up for “just-in-time” medical services during what are designated as “special enrollment periods (SEPs).”

I’ve heard you talk about the “strength of the marketplace” but I also hear about the millions of dollars in issuer losses coming in a significant proportion from these SEPs, and I’m concerned about the long-term sustainability of the market. I recognize your agency recently announced the elimination of 7 SEPs, but my understanding is that three of them were already expired, and the other four do not address the problem in a significant manner. I also find it ironic that days later your agency announced a brand new SEP for delinquent tax filers.

I am also concerned about the ever moving and expanding open enrollment (OE) period. The original ACA regulations had OE periods that ended in early December. Allowing individuals to continue to enroll after the current policy year can encourage anti-selection and letting purchasers pay for only a partial year of coverage, while still receiving a full year of coverage.

8. Does HHS plan to significantly eliminate more SEPs in the near future, and will there be any attempt to enforce or attest the existing ones?

Answer: 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.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- clarifying language to make the rules of the road are clear to everyone,
- reviewing all SEPs and eliminating those that are no longer necessary, such as:
 - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy
 - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
 - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
 - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
 - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
 - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program.

We have also provided stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes. For example, we will conduct an assessment of plan selections that are made through certain special enrollment periods to evaluate whether consumers properly accessed coverage.

Our program integrity team will pull samples of consumer records nationally and may request additional information from some consumers or take other steps to validate that consumers properly qualified for these special enrollment periods. The findings from the assessment will help us to inform future policy and operational improvements to enhance program integrity. We will continue to monitor how special enrollment periods are used and we anticipate that we may make changes in the future.

9. Does HHS plan to limit or expand the open enrollment period?

Answer: As you may know, each year CMS releases a Proposed Notice of Benefit and Payment Parameters, in which we detail certain proposed policies for the upcoming plan year. In the 2017 payment notice, CMS proposed dates for the individual market annual open enrollment period for the 2017 benefit year. For 2017, we proposed to maintain the same open enrollment period we adopted for 2016—that is, November 1, 2016, through January 31, 2017. The rule also noted that we are considering defining the open enrollment period for coverage year 2018, and sought comment on what that period should be.

10. The Healthcare.gov website has a tab front-and-center that asks users to see if they can get coverage outside the open enrollment period. Do you keep track of who is getting coverage through SEPs and exactly for what reasons, such as giving birth, moving, etc., or are they just all lumped together?

11. If they are lumped together, why can't you keep track of what SEPs are being used, in order to ensure federal dollars are being spent appropriately?

12. If you are not able to keep track of SEPs, how will you carry out back end enforcement?

Answer: 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.

We continue to review the rules around SEPs in order to keep them fair for issuers and for consumers. We have announced several changes including:

- clarifying language to make the rules of the road are clear to everyone,
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 - Consumers who enrolled with too much in advance payments of the premium tax credit because of a redundant or duplicate policy
 - Consumers who were affected by an error in the treatment of Social Security Income for tax dependents
 - Lawfully present non-citizens that were affected by a system error in determination of their advance payments of the premium tax credit
 - Lawfully present non-citizens with incomes below 100% FPL who experienced certain processing delays
 - Consumers who were eligible for or enrolled in COBRA and not sufficiently informed about their coverage options
 - Consumers who were previously enrolled in the Pre-Existing Condition Health Insurance Program; and
- providing stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes.

We have also provided stronger enforcement so that special enrollment periods serve the purpose for which they are intended and do not provide unintended loopholes. For example, we will conduct an assessment of plan selections that are made through certain special enrollment periods to evaluate whether consumers properly accessed coverage.

Our program integrity team will pull samples of consumer records nationally and may request additional information from some consumers or take other steps to validate that consumers properly qualified for these special enrollment periods. The findings from the assessment will help us to inform future policy and operational improvements to enhance program integrity.

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

13. Does HHS plan to limit or expand the open enrollment period?

Please see response to Question 9.

Questions from Representative Kelly of Pennsylvania:

Despite support from both parties and from the Administration for Quality Incentive Payments in Medicare Advantage, those payments have been reduced or eliminated for many 4 and 5-star plans because of the ACA MA benchmark cap. Madame Secretary, I recently introduced legislation - HR 4275, along with my colleagues Ron Kind, Mike Doyle and Brett Guthrie - that would solve this problem.

1. But we believe that HHS has the authority to make the change WITHOUT legislation. A strict reading of the law undermines the intent of the ACA to pay for value in Medicare Advantage. Will you ask your lawyers if they can re-examine their interpretation to find a way that you can exclude the quality payments from the calculation of the cap?

Answer: We appreciate your interest in this area and your support of the Agency's efforts to pay for value. We do not believe we have the discretion to eliminate application of the pre-ACA rate cap or exclude the bonus payment from the cap calculation. The bonus payment is based on an increase to the 'applicable percentage' which is a component of the benchmark calculation itself.

The Budget includes a proposal to reform Medicare Advantage payments to improve the efficiency and achieve sustainability of the program for all Medicare beneficiaries. This proposal has four components that better incentivize Medicare Advantage plans to submit cost-effective bids while preserving beneficiary supplemental benefits and enhancing quality incentives. As part of the balanced and comprehensive approach, the proposal would standardize quality bonus payments across counties by removing the doubling of the quality bonus payment which is only available in certain areas and lifting the cap on benchmarks for plans that are entitled to receive a quality bonus payment. I look forward to working with the subcommittee to enact reforms to Medicare Advantage payments.

Questions from Representative Smith of Nebraska:

As you know, I continue to be concerned about the solvency of the remaining Consumer Oriented and Operated Plans (s), and whether the taxpayer dollars loaned to the CO-OPs will ever be repaid.

In a January 6, 2016, letter, CMS Acting Administrator Andrew M. Slavitt stated "CMS will use every available tool to recoup loan funding" from CO-OPs which are wound down. Please provide an update on recovery of funds from CO-OPs which have been or are being wound down.

1. Has HHS or CMS estimated how much money will be recovered from the failed CO-OPs? If so, what is that estimate and how was it calculated?

Answer: CMS takes our obligation to taxpayers very seriously. While it is too early to tell how much money can be recovered, CMS will take aggressive steps to recover all the money we can. Providers can still submit claims after the date of a service, meaning that it will take time to develop a full picture of a CO-OP's finances. Collection efforts will be dictated by the terms of the loan agreement, and state and federal laws. We have begun the formal process of recovering funds by terminating loans for many CO-OPs and notifying them of their obligation to repay the loans. We are working in close collaboration with the US Department of Justice and will use all available tools to recover loan funds owed by these companies.

2. What is the financial status of the remaining CO-OPs? Do you expect additional CO-OPs to suspend operations in 2016? If so, how many?

Answer: CMS is closely monitoring the eleven remaining CO-OPs. Each of these CO-OPs were approved by their State Department of Insurance to offer coverage for the 2016 plan year. We will continue to work closely with the Departments of Insurance to protect consumers and taxpayers.

3. Do you project the remaining CO-OPs will repay their loans on time, under the terms of their contracts with CMS? What is the basis for that determination?

Answer: As you know, the CO-OP loans are not due to be repaid until 5 to fifteen years after the date funds are disbursed under the loan. We will continue to work with the remaining CO-OPs so that they are best positioned to fulfill their obligations under the terms of the loan agreements.

Questions from Representative Kind of Wisconsin:

I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk consumed by young children. My understanding is this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the US dairy industry that need to be further examined.

1. Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,⁹ and presented it to the WHO Executive Board (EB) for potential

⁹ As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/EB138_8-en.pdf (Accessed March 14, 2016).

endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

Questions from Representative Rangel of New York:

Madame Secretary – I want to ask you a question about third-party premium assistance programs that are operated by non-profits. Some of these programs have existed prior to the passage of the Affordable Care Act and many for decades.

Since CMS released an Interim Final Rule in March 2014, raising the issue of third-party payment of health insurance premiums, a growing number of insurance carriers are refusing to accept third party payments from non-profit organizations. These non-profit organizations have a long and proven track record of helping people with chronic conditions maintain affordable health coverage. I understand that there are certain statutory provisions related to premium assistance provided through the Ryan White Care Act and for our tribes.

1. Can you explain why HHS does not require insurance companies to accept third-party payments from non-profits on behalf of insured people with chronic conditions? Is there anything in the statute that bars you from doing so? Isn't it appropriate to consider applying the same protections to people battling kidney disease as those you've applied to people with HIV? Do you

agree that both groups should be protected from discriminatory insurance practices?

Answer: Thank you for raising this important issue. In the Interim Final Rule, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because federal or state law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

For example, section 402 of the Indian Health Care Improvement Act and the relevant regulations, which implement the Affordable Care Act, provide that Marketplaces may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, subject to terms and conditions determined by the Marketplace.

In addition, the Ryan White HIV/AIDS Program has been authorized to provide insurance assistance for low-income people living with HIV since 1990 under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. States have the authority to use AIDS Drug Assistance Program grant funds to purchase or maintain health insurance or plans when the coverage includes the relevant therapeutics and the cost of such coverage does not exceed the costs of otherwise providing the therapeutics directly. This provision was added in 2000 by the Ryan White CARE Act Amendments of 2000.

As noted in the November 4, 2013 FAQ, it has been suggested that hospitals, other health care providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an uneven field in the Marketplaces.

Issuers may still choose to accept third party payments from non-profits, and in an FAQ published in February 2014,¹⁰ CMS noted that it does not believe this creates adverse risk selection so long as the criteria for premium assistance is based on financial need, not health status, and that the assistance continues through the entire plan year.

I would like to paint a picture for you of the type of people charitable premium-assistance organizations are trying to help. These are people with very significant health care needs, but very little in terms of financial resources. For example, the American Kidney Fund (AKF) provides charitable assistance to disabled individuals who are on dialysis. These patients tend to be older – 48 percent are older than 60. They're also disproportionately minority when compared to the U.S. population; 38 percent of AKF grant recipients are African American and 15 percent are of Hispanic ethnicity. Fully 70 percent of the patients AKF helps are unemployed, while another 20 percent work only part-time. To qualify for assistance from AKF

¹⁰ <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-payments-of-premiums-for-qualified-health-plans-in-the-marketplaces-2-7-14.pdf>

for health insurance premiums, patients must have extremely low-income relative to expenses. Sixty percent of the patients AKF assists have annual household incomes under \$20,000. At the same time, they have average annual out-of-pocket medical expenses of close to \$7,000.

This is an economically and physically fragile population. When insurers refuse third-party payments from a non-profit like the AKF, this jeopardizes patients' access to appropriate coverage.

In my congressional district, I have around 100 patients who received assistance from AKF. And across the state of New York, we have over 2000 patients who have received assistance in 2015.

1. Do you think that insurers may be engaging in discriminatory practices? One of the goals of the ACA was to prohibit discrimination against people with pre-existing conditions? Do you agree this policy undermines that goal and encourages discriminatory practices by insurers to occur?

Answer: The Affordable Care Act reformed the health insurance marketplace to ensure that individuals with pre-existing conditions are able to access care by prohibiting insurance plans from discriminating against consumers with pre-existing conditions or charging them more because they got sick or lifetime limits on their insurance. In addition, with respect to the Marketplace specifically, the ACA provides for both tax credits to help consumers afford their premiums, and reduced cost-sharing for consumers who qualify. These market reforms and financial assistance work together to ensure access to care.

As noted in the HHS Notice of Benefit and Payment Parameters for 2017 proposed rule, HHS is considering whether to expand the list of entities from which issuers are required to accept payment to include not-for-profit charitable organizations in future years. If such not-for-profit charitable organizations were included, HHS would also intend to include guardrails aimed at minimizing the impact on the risk pool, such as limiting assistance to individuals not eligible for other Minimum Essential Coverage and requiring assistance until the end of the calendar year.

Question from Representative Davis Illinois:

Madame Secretary - I want to ask you a question about third-party premium assistance programs that are operated by non-profits. Some of these programs have existed prior to the passage of the Affordable Care Act and many for decades.

Since CMS released an Interim Final Rule in March 2014, raising the issue of third-party payment of health insurance premiums, a growing number of insurance carriers are refusing to accept third party payments from non-profit organizations. These non-profit organizations have a long and proven track record of helping people with chronic conditions maintain affordable health coverage. I understand

that there are certain statutory provisions related to premium assistance provided through the Ryan White Care Act and for our tribes.

1. Can you explain why HHS does not require insurance companies to accept third-party payments from non-profits on behalf of insured people with chronic conditions? Is there anything in the statute that bars you from doing so?

Answer: In the Interim Final Rule, CMS required QHP issuers to accept payment from entities such as the Ryan White HIV/AIDS Program, tribes, tribal organizations and urban Indian organizations, in part because federal or state law authorizes, or policy specifically envisions third party payment of premium and cost-sharing amounts by these entities.

As noted in the November 4, 2013 FAQ, it has been suggested that hospitals, other health care providers, and other commercial entities may be considering supporting premium payments and cost-sharing obligations with respect to qualified health plans purchased by patients in the Marketplaces. HHS has significant concerns with this practice because it could skew the insurance risk pool and create an uneven field in the Marketplaces.

CMS later clarified that the concerns addressed in the November 4, 2013 FAQ would not apply to payments from private, not-for-profit foundations if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status. CMS noted that it does not believe this creates adverse risk selection so long as the criteria for premium assistance is based on financial need, not health status, and that the assistance continues through the entire plan year.

Questions from Representative Pascrell of New Jersey:

In your response to my question about how HHS will work to support incorporating UDI into health insurance claims, you stated that there are external boards that provide recommendations on changes and additions to the claims form. However, as you know, those organizations take guidance from health plans, including Medicare, and CMS plays a substantial role in developing those recommendations. The decision to incorporate UDI into the claims form has implications for other agencies within HHS. FDA has repeatedly expressed support for UDI in claims to bolster its ability to conduct post-market surveillance of medical devices. The major problem with duodenoscopes shed light on a number of deficiencies in the current post-market surveillance system and highlighted the need to provide FDA with additional tools to perform this essential agency function.

1. As the head of the department that oversees both of those agencies, how do you plan to ensure that CMS' participation in that process adequately accounts for implications for other agencies, particularly FDA?

Answer: We share the important goal of improving patient safety through post-market

surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC's approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, having UDIs incorporated into EHRs will allow the use of a device to be linked with a patient's experience with that device, thereby generating better information for patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

2. The Centers for Medicare and Medicaid Services (CMS) has made investments totaling more than \$2 billion to pilot new delivery and payment system models. While many of these are promising, further experience and evaluation will be needed to know what works and what can be replicated. At the same time, CMS can build on existing models that have already stood the test of time, including the Program of All-Inclusive Care for the Elderly. How is CMS balancing its investment in new models with its investment in expanding existing, proven models?

Answer: I share your support for the PACE program, and agree that it is important to build on successful existing models as we test other delivery system reforms.

While PACE has proven successful in keeping frail elderly individuals in the community, we agree that we should revise certain regulatory provisions to afford more flexibility as a means to encourage the expansion of the PACE program to more states, increase access for participants, and further enhance the program's effectiveness at providing care while reducing costs. CMS is proposing to revise and update policies to reflect subsequent changes in the practice of caring for PACE participants and changes in technology based on our experience implementing and overseeing the PACE program. CMS continues to receive numerous suggestions from PACE organizations, beneficiaries, Members of Congress, and other stakeholders and looks forward to working with stakeholders throughout the rulemaking process.

CMS is dedicated to continuing to explore new opportunities and ideas to further strengthen PACE programs and services.

At the same time, the Innovation Center looks forward to building on its existing work while testing new models. The Secretary has the authority to expand the duration and scope of a model through rulemaking if certain statutory criteria are met: (1) an expansion is expected to reduce spending without reducing the quality of care, or improve the quality of care without increasing spending (2) the CMS Chief Actuary certifies that an expansion would reduce (or would not result in an increase in) net program spending and (3) an expansion is expected to not deny or limit coverage or benefits. The Innovation Center conducts an independent evaluation of each payment and service delivery model tested. Using these evaluation results, as well as other available data, the Innovation Center makes decisions regarding expansions in accordance with the statutory requirements and each model's unique elements.

The Innovation Center is also committed to developing and testing new models. New models are developed in accordance with the Innovation Center's purpose to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, or Children's Health Insurance Program (CHIP) beneficiaries. Moreover, in accordance with section 1115A(b), models to be tested under section 1115A must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. During the development of models, the Innovation Center builds on ideas received from stakeholders and consults with clinical and analytical experts, as well as with representatives of relevant federal and state agencies. Through these efforts, the Innovation Center balances investment in expanding existing models and testing new initiatives.

3. CMS is long overdue in finalizing regulations to adopt a standard claim attachment. Once CMS adopts and implements a standard claims attachment, how does the agency intend to integrate this information into databases that also contain information from claims? Does the agency intend to provide FDA, researchers, innovators and registries with access to claims attachment data in the same manner that the agency has provided access to claims data? If so, how, and if not, why not?

Answer: The Secretary is required to promulgate a final rule to establish a transaction standard and a single set of associated operating rules for health claims attachments. In 2005, HHS issued a proposed rule which would have established both transaction and content standards for claims attachments. Due to stakeholder comments, that rule was never finalized. HHS is closely tracking the work of the standard setting organizations on the development of claims attachment standards. In fact, in February 2016, the National Committee of Vital Statistics (NCVHS) has scheduled hearings from stakeholders on claims attachments. CMS looks forward to future recommendations from NCVHS on this topic.

4. Section 2 of the Autism Collaboration, Accountability, Research, Education, and Support Act of 2014 (Public Law 113-157) requires the Secretary of HHS to designate an official to oversee national autism spectrum disorder research, services, and support activities. It also directs the official to

implement such activities taking into account the strategic plan developed by the Interagency Autism Coordinating Committee and ensure that duplication of activities by federal agencies is minimized. What is the status of the designee?

Answer: The Department looks forward to announcing this spring a designee to (1) oversee national autism spectrum disorder research, services, and support activities, (2) implement autism spectrum disorder activities, taking into account the strategic plan developed by the Interagency Autism Coordinating Committee and (3) ensure that autism spectrum disorder activities of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative. In addition to their existing duties, this designee will serve as Autism Coordinator for the Department. We expect this appointment in the near-term, and will keep your office apprised.

5. A number of hospitals in my state of New Jersey have expressed concerns about the change to the Hospital outpatient reimbursement included in the Bipartisan Budget Act of 2015 (Public Law 114-74). Can you please clarify whether the Hospital Outpatient Departments that are currently grandfathered will be able to relocate and add services without losing their status as a Hospital Outpatient Department?

6. New Jersey Hospitals have asked that the regulatory guidance on the Hospital outpatient reimbursement policy included in the Bipartisan Budget Act of 2015 (Public Law 114-74) be issued as soon as possible. Would CMS be willing to issue proposed regulations on this policy before it issues the Outpatient Prospective Payment Rule, such as part of the Inpatient Prospective Payment proposed regulation to be issued in the Spring session of 2016?

Answer: CMS has posted publicly that this provision will be addressed through rulemaking in the CY 2017 Hospital Outpatient Prospective Payment System (OPPS) proposed rule which is generally issued in the summer. Here is the link to the notice: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Note-Regarding-Implementation-of-Section-603-of-the-Bipartisan-Budget-Act-of-2015.pdf>.

If there is a scenario regarding implementation of Section 603 that you are concerned about and want to call attention to it for the proposed rule, CMS would be happy to review any comments you would like to submit. In addition, the public will have the opportunity to comment on the proposed rule per the standard notice and comment rulemaking process. Additionally, please feel free to reach out to Jim Esquea on my staff to discuss any specifics.

7. CMS has launched unprecedented new initiatives to release Medicare claims data on procedures, medications and some medical supplies. CMS last year even expanded access to Medicare claims data to researchers and manufacturers of medical products. And, just last month, CMS issued regulations that will enhance the use and availability of Medicare data in implementing legislation that was championed in a bipartisan way and advanced by the former chairman of this committee, who now also happens to be the Speaker of the House. In implementing all these policies, CMS has described claims data as an “essential ingredient to building a better, smarter, healthier system” that would help “make smarter and more informed healthcare decisions”. The most common Medicare hospital procedure involves hip and knee implantation procedures, affecting 400,000 seniors per year and accounting for \$7 billion in spending. And that doesn’t even count the millions of patients with cardiac stents and other implanted devices. Adding the unique device identifier to claims data would ensure that this information can be just as valuable for implants as they are for drugs and other medical interventions. Given that CMS believes that Medicare claims data are critically important to improve patient care and reduce costs, why is it different for medical implants used in the most common Medicare procedures? Why does CMS believe claims data are essential to our learning healthcare system, just not for medical implants?

Answer: Congressman, we share the important goal of improving patient safety through post-market surveillance and adverse event reporting for medical devices with UDIs. Because the Department firmly believes that post-market surveillance for medical devices is critical, we are moving forward with the incorporation of UDIs into electronic health records. ONC’s approach is a strong step towards incorporating UDI into electronic health record technology and making that information ready and accessible for patients and clinicians to use at the point of care. Additionally, having UDIs incorporated into EHRs will allow the use of a device to be linked with a patient’s experience with that device, thereby generating better information for patients and providers to make well-informed decisions, and facilitate medical device innovation and safety surveillance.

In the meantime, CMS and the FDA look forward to continuing to explore options that would improve surveillance in a timely and effective manner. Both agencies are committed to capturing appropriate data and sharing information transparently to improve the quality and safety of care delivered to people across the nation. FDA and CMS also support the recommendation by the National Committee on Vital and Health Statistics to consider conducting voluntary pilot tests of the benefits, costs, and feasibility of UDIs in claims reporting. Voluntary pilots should address key challenges to adding UDIs to claims, including significant technological hurdles and costs (for providers, payers and others), as well as difficulties in validating UDIs reported on claims.

Questions from Representative Crowley of New York:

For over 10 years, HRSA has been overseeing a process at UNOS to revise the organ donation system so that it is more needs-based rather than solely geographic-based. As this process has continued, stakeholders in New York State and other states impacted by the current process are eagerly awaiting resolution, as are the many patients who remain on the organ transplant wait list.

1. Can you provide information about the timeline for a decision and an update on what progress HRSA and UNOS are making with these deliberations?

Answer: Any change in the OPTN liver allocation policy must be consistent with the requirements and principles of the OPTN final rule, which articulates the goals to be achieved through OPTN organ allocation policies. These policies must, among other factors, be based on sound medical judgment and seek to achieve the best use of donated organs, be designed to avoid the wastage of organs, avoid futile transplants, promote patient access to transplantation, promote the efficient management of organ placement, and not be based on a candidate's place of residence or listing (except to the extent necessary to satisfy other requirements).

Consistent with OPTN processes and requirements for the development of changes to the liver allocation policy, several key activities and policy changes have been completed in the last several years. Since 2014, the following steps have been taken to inform discussions of potential changes to the liver allocation policy regarding geographic challenges and alternative approaches to liver allocation.

HRSA anticipates that the Liver Committee will publish on the OPTN web site a policy proposal for public comment (60-day comment period) by January 2017, then subsequently review the feedback. Next, the OPTN Board will vote on a policy proposal.

Questions from Ways and Means Committee:

1. Does the Administration plan to use physician developed AUC in the ordering of advanced imaging studies instead of the ongoing prior-authorization policies? Please explain to the Committee why the Agency will not meet the implementation deadline of January 2017 and please tell the Committee a date certain as to when this program will be implemented.

Answer: CMS is required to adhere to rapid timelines for establishing a new Medicare Appropriate Use Criteria (AUC) program for advanced imaging services. The number of clinicians impacted by the scope of this program is significant as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast. We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and Clinical Decision Support mechanism developers. It is for these reasons we proposed a stepwise approach,

adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

2. **In order to improve patient outcomes and enhance quality of care, the new formula by which Medicare will reimburse physicians will incorporate patient engagement features. As structured, the beneficiary engagement subcategory within the Merit-Based Incentive Payment System (MIPS) references beneficiary self-management training and recognizes that to achieve successful beneficiary self-management training, the patient's self-management capabilities must first be assessed. The tool providers use to assess patient self-management capability makes a difference.**
3. **As CMS develops MIPS, will it direct providers to rely on an empirically validated, interval level, patient self-management assessment tool to determine a beneficiary's self-management capabilities? The use of measures that are validated and proven reliable through extensive peer-reviewed studies, national and international usage and that have empirically validated interval level measurement have proven capabilities to be acted upon - through intervention by patients and providers - in order to improve self-management and reduce unwarranted utilization.**

Answer to 2-3: As laid out in statute, the Merit-based Incentive Payment System (MIPS) is a rigorous value-based purchasing program for physician and practitioner services. EPs will be scored under MIPS based on a single composite performance score, which will factor in performance in four weighted categories: quality, resource use, clinical practice improvement activities, and meaningful use of certified electronic health record technology. We are working hard to establish the proposed measures and activities that will fall under each of the four MIPS categories and appreciate the feedback we have received from stakeholders, particularly regarding areas that are new to CMS, such as clinical practice improvement activities. We are committed to building a program that fulfills the goals of advancing quality and value, while being adaptive to the needs of each clinician's individual practice and patient population. We anticipate releasing a proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

4. **What is the status of CMS's efforts to stop improper payments before they are made? What impediments exist, if any, for using recovery auditor to execute pre-payment reviews of Medicare payments?**

Answer: CMS' program integrity strategy is moving beyond the reactive "pay and chase" method toward a more effective, proactive strategy that identifies potential improper payments before they are made, keeps unscrupulous providers and suppliers out of Medicare and Medicaid at the outset, quickly removes wrongdoers from the programs

once they are detected, and corrects improper payments as quickly as possible. CMS uses many tools as part of this strategy, such as prior authorization. CMS believes using a prior authorization process will help ensure that all relevant coverage, coding, and payment requirements are met before the service is rendered and the claim is submitted for payment.

CMS also uses prepayment reviews as part of this proactive strategy. CMS' Medicare Administrative Contractors, which process Medicare Part A and Part B medical claims or DMEPOS claims for Medicare Fee-For-Service (FFS) beneficiaries, may conduct prepayment reviews after the service is provided and the claim is submitted for payment but before the claim is paid. CMS continues to focus on prepayment reviews of claims that have historically resulted in high rates of improper payments. This will help stop improper payments before the claims are paid, and as a result, reduce the improper payment rate.

CMS also utilizes a sophisticated predictive analytics technology, called the Fraud Prevention System (FPS), to prevent and detect fraud, waste, and abuse in the Medicare FFS program. The FPS provides a comprehensive view of Medicare FFS provider and beneficiary activities in order to identify and analyze provider networks, billing patterns and beneficiary utilization patterns, and detect patterns that represent a high risk of fraudulent activity. Over the first three years of implementation, FPS identified or prevented \$820 million in inappropriate payments.

The statute specifically authorizes CMS to make payment to Recovery Auditors only from amounts recovered. However, in September 2012, CMS allowed Recovery Auditors to review claims before they are paid as part of the Recovery Auditor Prepayment Review Demonstration. The demonstration was conducted in seven states with high incidences of improper payments and fraud, as well as four states with the high numbers of short hospital stays. As part of the close-out process for the existing Recovery Auditor contracts while CMS worked to procure new contractors, the prepayment demonstration was paused and remains on hold while CMS assesses its options regarding the procurement of the next Recovery Auditor contracts.

5. What is the timeline HHS/CMS expects to adhere to in terms of finalizing the procurement for the next round of Recovery Audit contracts?

Answer: The current Recovery Auditors are under contract to continue their active recovery auditing work through July 2016 to allow completion of the new procurement process. In November 2015, CMS posted the Request For Proposal (RFP) for the new Medicare Fee-for-Service Recovery Auditor contracts. CMS is actively engaged in the procurement process for the next round of Medicare Fee-for-Service Recovery Auditor contracts.

I have become aware of a measure moving through the World Health Organization that seeks to prohibit the marketing of any milk consumed by young children. My understanding is this was developed with little or no public input. This measure carries significant public health, trade and economic implications for the US dairy

industry that need to be further examined.

6. Will you commit to working with this Committee and all impacted stakeholders to halt this process until these implications are fully understood?

Answer: At the request of Member States, the World Health Organization (WHO) developed draft guidance on ending the inappropriate promotion of foods for infants and young children,¹¹ and presented it to the WHO Executive Board (EB) for potential endorsement. This draft guidance aims to support countries in protecting and promoting optimal nutrition for children during the first three years of life, a critical window for health and nutrition outcomes.

WHO developed the draft guidance using a Scientific and Technical Advisory Group (STAG) process. The STAG was convened in 2013 and produced several reports, including a draft of the guidance that was presented to WHO in 2015. WHO held online and in-person public consultations in August 2015, revised the guidance, and presented it to Member States for the WHO Executive Board (EB) meeting in January 2016. During the EB meeting, WHO agreed to hold an additional consultation from 1-29 February 2016 to allow time for further Member State comment. The guidance is not binding on Member States.

The WHO draft guidance advises Member States on ending inappropriate promotion to consumers of foods for infants and young children, not to limit product availability. The draft does not seek to prohibit the marketing of all milk products consumed by young children, or to revise recommendations for optimal infant and child feeding practices. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to three years of age.

HHS is working with other relevant Federal agencies (including Department of State, Department of Commerce, USTR, USAID, USDA, among others) to prepare a technical comment submission to WHO, and has had multiple conversations with stakeholders on the matter. HHS will continue to work with the other agencies and discuss remaining concerns with stakeholders.

The Office of Civil Rights (OCR) is seeking a \$3.6 million increase in funding for fiscal 2017, \$1.36 million of which it would use to enforce the ACA's non-discrimination provision, which is expected to increase the OCR's workload by 25 percent as it reviews cases on whether insurers' specialty drug cost-sharing or medical service exclusions are discriminatory. Discriminatory practices related to the disproportionately high cost-sharing required for drugs for the treatment of HIV have been widely reported in the media. However, increasingly there have been reports about such treatment in other chronic diseases, such as rheumatoid arthritis, psoriasis and psoriatic arthritis, multiple sclerosis and even some types of

¹¹ As presented in report EB138/8: Maternal, infant and young child nutrition. Available at http://apps.who.int/gb/ebwha/pdf_files/EB138/B138_8-en.pdf (Accessed March 14, 2016).

cancer. One way to ensure appropriate access and sufficient patient protections is to have robust oversight prior to plan marketing, so beneficiaries are not forced to the last resort of the office of civil rights.

7. How does HHS intend to ensure that benefit designs, including the use of high cost sharing tiers, and the utilization management practices like step therapy/fail first protocols are used appropriately and don't inhibit access to medications for chronic diseases for beneficiaries?

Answer: As detailed in the Draft 2017 Letter to Issuers in Federally-Facilitated Marketplace, non-discrimination in benefit design with respect to EHB is a market-wide consumer protection that applies inside and outside of Marketplaces for non-grandfathered health insurance plans offered in the individual and small group markets. An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

As part of that guidance CMS cautioned issuers to avoid discouraging enrollment of individuals with chronic health needs. For example, CMS noted that if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal (such as a substantial difference in the cost of the two regimens), such a plan design might effectively discriminate against, or discourage enrollment by, individuals who would benefit from such innovative therapeutic options. As another example, if an issuer places most or all drugs that treat a specific condition on the highest cost formulary tiers, that plan design might effectively discriminate against, or discourages enrollment by, individuals who have those conditions.

The enforcement of this standard is largely conducted by States. CMS has encouraged States that are enforcing the Affordable Care Act to consider a number of strategies for assessing compliance with this standard including, but not limited to, analysis of information entered in the QHP Plans and Benefits Template.

8. How will HHS ensure that both plans participating in the Exchanges, as well as plans participating in MA-PD are offering robust formulary access for medications that treat chronic diseases?

Answer: CMS has policies to promote access to medications for consumers enrolling in coverage through the Marketplace and for Medicare beneficiaries. With regard to the Marketplaces, Qualified Health Plans must offer a range of benefits including benefits in at least ten broad categories, including prescription drugs. As noted in the answer to question # 8 below, as part of the certification process, CMS reviews data submitted by plans to ensure non-discrimination in QHP prescription benefit design.

Part of this review includes reviews for adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

For Medicare, CMS encourages Part D sponsors, including MA-PD sponsors, to submit formularies similar to those in widespread use today. CMS reviews the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor's categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary.

A Health Business Daily article, "CMS Might Take Deeper Dive Into Outlier Drug Costs to Find Discriminatory Designs" (June 29, 2015), states, "Although the issue of discriminatory plan design is on the radar of the National Association of State Insurance Commissioners, few, if any, states have the qualitative rigor needed to conduct a sophisticated analysis of benefit designs. Moreover, they generally don't have clinicians, pharmacists or statisticians on staff. Identifying outliers might be easier for states where only a few carriers compete."

9. What steps are being taken by CCHIO and CMS to analyze the prevalence of these aggressive tactics, including specialty tiers and the frequent use of step therapy/fail first protocols and the potential health outcome impact on patients in the exchanges and Medicare?

Answer: Thank you for raising this important issue. It is critical that patients are able to access the care they need when they need it and I look forward to working with you broadly on these issues. In addition to the reviews for non-discrimination in EHBs as part of the 2017 QHP Certification process, CMS has proposed to review QHP's formulary drug list to ensure non-discrimination in their prescription benefit design. CMS has proposed to perform an outlier analysis that compares seeking certification to be offered through an FFM and flag those identified as outliers based on both includes both State-level and national lower threshold values. QHPs that are outliers have an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia category and class. CMS requires that QHPs meet or exceed both threshold values. CMS also encourages States performing plan management functions to implement this type of review.

In addition, as we have in prior years, CMS will review each QHP's prescription drug coverage to determine that it meets applicable standards laid out in regulation. Based on data submitted by issuers in the prescription drug template, this review will analyze the availability of drugs recommended by nationally-recognized clinical guidelines used in the treatment of specific medical conditions. The medical conditions included in the

review include the following: bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia. In addition to analyzing the appropriate coverage of drugs recommended by the clinical guidelines, the review will also analyze cost-sharing requirements associated with these drugs so that they are not used to dissuade consumers with such conditions from enrolling in the QHP. This portion of the review will identify QHPs that are outliers based on the presence of unusually high cost-sharing requirements for specific drugs. Other additional medical conditions may be considered as part of future reviews.

Finally, CMS will conduct a review of each QHP's coverage of standard treatment protocols for the treatment of certain chronic and high-cost medical conditions which includes the associated medical services and drug coverage for first and second line therapies as recommended by nationally-recognized clinical guidelines. CMS is also concerned about adverse tiering, which occurs when a formulary benefit design assigns most or all drugs in the same therapeutic class needed to treat a specific chronic, high cost medical condition to a high cost-sharing tier. Since adverse tiering is potentially discriminatory, this review may examine the tier placement of prescription drugs to determine whether QHPs are also consistently placing drugs used to treat these medical conditions on a high cost-sharing tier.

With regard to monitoring the use of utilization management tools and specialty tiers in Medicare Part D, as a part of formulary review, CMS will look to existing best practices to check that Part D sponsors' use of prior authorization, step therapy, and quantity limits is consistent with such practices. CMS will look to current industry standards as well as appropriate guidelines that might be found from expert organizations and to the use of such standards in existing drug sponsors that are widely used by seniors and people with disabilities. CMS will ensure that sponsors' use of such tools is consistent with best practices. CMS will also compare formularies among the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. In cases where a sponsor may fall outside of best practices, the sponsor will be asked to provide a reasonable justification for its practices. CMS' expectation is that formulary benefit management tools will be used in Part D formularies consistent with the way they are applied in existing formulary systems.

CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the standard deductible and before the initial coverage limit (or up to 33% for sponsors with decreased or no deductible under alternative prescription drug coverage designs). When applying a reduced deductible, sponsors are limited to the maximum specialty coinsurance levels as defined each year in the Bid User Manual. The deductible applied to the non-specialty tiers may not exceed the deductible that is applied to the specialty tier.
- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty

tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar per-month threshold and are intended for inclusion in the specialty tier.

- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

10. Moreover, CMS has proposed in the most recent draft Notice of Benefit and Payment Parameters ways to standardized benefit designs. While standardization has some benefits for consumers, some of the agency's of proposed designs would perpetuate the discriminatory nature of what we're seeing in the exchanges. Some states have taken action to address this discrimination through legislation (e.g., Capping monthly out of pocket pharmacy costs); what steps is the agency to support these state efforts and ensure that it doesn't take steps to actually hurt those efforts?

Answer: Standardized plans would be optional for issuers, meaning health plans would not be required to offer them. However, we believe that standardized options would allow consumers to more easily compare plans offered by different issuers within each metal level and thereby simplify the consumer shopping experience by allowing them to focus their selection on other factors like networks, premiums, and quality. Each of these options is standardized in terms of in-network cost-sharing: deductible, annual limitation on cost-sharing, and copayment or coinsurance for a key set of EHBs that comprise a large percentage of the average enrollee's total spending.

With respect to prescription drugs, we proposed that standardized options have the four drug tiers currently utilized in our consumer-facing applications at this time—generic, preferred brand, non-preferred brand, and specialty drug tiers. However, we proposed to allow issuers to offer additional lower-cost tiers if desired. Slightly more than half (56 percent) of the proposed 2016 FFE QHPs have more than four drug tiers. We believe that standardized options would be a valuable consumer tool that allows consumers to more easily compare plans. However, as noted above, CMS also plans to conduct rigorous review for potentially discriminatory benefit design during the certification process, including specific reviews for prescription drugs.

11. The Medicare Part D Program has continued to come in under cost estimates, but also has in place important patient protections. For instance, Part D plans are required to provide a 3 month transition supply for beneficiaries who are stable on medication, but have lost formulary access to the medication or are subjected to new fail first policies. No such protections are in place for beneficiaries receiving benefits through the Exchange. Why has HHS not provided protections consistent with those provided to Medicare beneficiaries for enrollees in Exchange plans?

Answer: The Marketplace and Medicare are different programs with different authorizing statutes.

As you may know, marketplace plans must have processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing.

In addition, as noted earlier, CMS has proposed to review QHPs' formulary drug list to ensure non-discrimination in QHP prescription benefit design. CMS has proposed to perform an outlier analysis where plans are compared to other plans seeking certification to be offered through an FFM and flagged when identified as outliers. The outlier calculation includes both State-level and national lower outlier threshold values. CMS requires that QHPs meet or exceed both threshold values. QHPs that are outliers have an unusually high number of drugs that are subject to prior authorization and/or step therapy requirements in a particular United States Pharmacopeia (USP) category and class. CMS also encourages States performing plan management functions to implement this type of review.

12. Non-medical switching is defined as, “when patients that are stable on a medication are switched for non-medical reasons for the purpose of controlling costs to the insurer/payer.” As a result of these medication switches, patients may suffer negative side effects and/or may not longer respond to treatment even if returned to their original medication. In fact, patients who are switched may increase utilization costs due to unintended medical consequences of the switch. Data on this type of activity is critical to protect patients and track the cost of switching. How will the agency collect data and monitor this issue on behalf of beneficiaries to ensure NMS does not lead to problems with adherence to medication or changes in utilization costs as a result of the switch?

13. Are you aware of any instances where plans have passed on additional costs to patients or forced patients to switch from one medication to another in order to facilitate increased cost-savings? Are the health and safety consequences of this activity well known and/or understood?

Answer: From the Marketplace perspective, CMS does not have access to or track individual patient data – such data resides with private Marketplace issuers. However, as described in greater detail above, all Marketplace plans must provide essential health benefits (EHB), including prescription drugs. Marketplace regulations contain a prohibition on discrimination and provide that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an

individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

14. Given the recent release and retraction of a proposed Part B drug demo project within CMML, can you inform us of the status of this project and whether this project will be subject to public review and comment?

Answer: Last fall, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from state and federal government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation while protecting access and affordability. We came away with feedback to address these challenges in a holistic fashion addressing three important areas: (1) increasing access to information to support better health care decisions, (2) driving innovation that improve and save lives, (3) and strengthening incentives in the delivery system to reward quality care to patients and encourage value-based and outcomes-based decision making.

Coming out of that forum, we have identified several areas of potential opportunity for consideration and collaborative policy development. The need for better information about drug prices and impacts on patients and providers in making better health care decisions was one theme that we heard across multiple panels. To that end, in December, we took a first step forward by providing more detailed information on Medicare spending on prescription drugs, for both Part B (primarily drugs administered in doctors' offices and other hospital outpatient settings) and Part D (primarily drugs patients take themselves) to better inform decision making. The Medicare Drug Spending Dashboard provides important information to the public in an accessible format, but, more important, it served as a first step to provide other information that can enrich the picture.

We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. We continue to look at a number of options in this area.¹²

15. Increasingly, we have been made aware of regulatory and legal barriers that prevent drug manufacturers and health plans from adopting value-based or risk-based contracting concepts. What regulatory options (if any) does HHS/CMS have or is it considering to mitigate government price reporting barriers that impede flexibility for innovative models in drug pricing?

Answer: As part of its effort to provide additional information, increase transparency, and address the affordability of prescription drugs, CMS has released an online dashboard to look at Medicare prescription drugs for both Part B and Part D. These categories include drugs with high spending on a per user basis, high spending for the program overall, and those with high unit cost increases in recent years. Having this information available to the public in an accessible format should inform health care decisions, policy considerations and encourage collective problem solving around these

¹² All responses are accurate as of February 10, 2016

important issues. We believe that, by sharing this information and allowing people to analyze the data, we can increase the knowledge around drug spending and support efforts that are evaluating whether public dollars are being spent most effectively.

Notably, the dashboard does not provide the net prices paid to manufacturers or the rebates to plans and prescription benefit managers. In the Part D program, we are not permitted to disclose the rebates paid by manufacturers to Part D plan sponsors. And for Part B, Medicare does not receive a rebate, but pays 106 percent of the estimated average sales price of each drug, which reflects the average prices paid by physician offices and hospital outpatient departments net of discounts and rebates.

In addition to these efforts related to transparency, we are working to encourage innovation. On September 1, 2015, the Center for Medicare & Medicaid Innovation (CMMI) announced a program to test Value-Based Insurance Design (V-BID) in Medicare Advantage (MA) plans. The program will examine the utility of structuring patient cost-sharing and other health plan design elements to encourage patients to consume high-value clinical services, thereby improving quality and reducing costs. Under this model, organizations can choose to reduce or eliminate cost-sharing for items or services, including covered Part D drugs, they have identified as high-value for a given target population.

On Friday, October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) released the Calendar Year (CY) 2016 Medicare Physician Fee Schedule (MPFS) Final Rule for public review. Within this rule were provisions finalizing Section 218(b) of the Protecting Access to Medicare Act (PAMA) (PL-113-93) relating to mandating the consultation of appropriate use criteria (AUC) by ordering physicians prior to referring Medicare patients for select advanced diagnostic imaging services. In the final rule, CMS has announced that they will not be able to meet the January 2017 implementation deadline and in fact, stated that they will not commit to any date-certain for implementation of this Congressional policy. Importantly, this policy, which passed the Energy and Commerce Committee, Ways and Means Committee, and the Finance with unanimous support and then the Congress with strong bipartisan support and is viewed as an important “down payment” for payment reforms in Fee for Service (FFS) program.

16. In light of the fact that CMS has already informed stakeholders that a statutory deadline will not be met, please provide a detailed plan for when CMS intends to fully implement the program and come into compliance with the statute.

Answer: The Protecting Access to Medicare Act includes rapid timelines for establishing a new Medicare Appropriate Use Criteria (AUC) program for advanced imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite

vast. We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDS mechanism developers. It is for these reasons we proposed a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

17. Advancements in personalized medicine are becoming even more critical in our pursuit to prevent as well as cure the toughest diseases. Diagnostics are a key component of personalized medicine and are becoming more complex and sophisticated in the information they provide. As a result, the laboratories which perform these personalized diagnostics are increasing in importance. What is the Agency doing to ensure that health plans offered through the Affordable Care Act are ensuring comprehensive laboratory in-network options with ample choices for patients and their providers?

Answer: As you know, the Affordable Care Act requires all health insurance issuers in the individual and small group markets to offer a core set of benefits called the essential health benefits (EHB). Plans must offer benefits in at least ten broad categories, one of which is laboratory services. The exact laboratory services offered in each state may vary and are based on a benchmark plan, chosen by the state.

18. When will CMS roll the medical home(s) out, and which medical-home models ultimately will qualify as MACRA APMs?

Answer: Under the Medicare Access and CHIP Reauthorization Act of 2015, CMS has new authority to develop Alternative Payment Models (APMs) for paying Medicare-participating physicians under Part B, outside of the traditional fee-for-service method. One of these APMs is defined as ³a medical home expanded under section 1115A² of the Social Security Act, which is an exception to the requirement that APMs ³bear financial risk for monetary losses that are in excess of a nominal amount.² Please tell the Committee which models are currently under consideration by CMS to be medical homes expanded under Section 1115A.

MACRA established a particular definition of alternative payment models (APMs) and established what qualifies as an “eligible APM,” for purposes of evaluating whether an eligible professional (EP) is qualifying APM participant (QP) for a year. The statute creates a high bar for eligible APMs. Many currently existing APMs – at the Innovation Center and in the private sector – are not likely to meet all these requirements, but some will. We will continuously search for opportunities to expand the range of options for participation in eligible APMs within the contours of the statute, including considering potential medical home models that qualify as eligible APMs. As we move forward with MACRA implementation, we will continue to gather and incorporate feedback from stakeholders as we promote additional physician-focused APMs and work to define the details of the eligible APM criteria contained in statute. We anticipate releasing a

proposed MACRA implementation rule, including a 60-day comment period, this spring. We look forward to continued engagement from Congress and the health care community.

Reform of the Clinical Laboratory Fee Schedule (CLFS), as required by Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), is of significant interest to me and my constituents. A primary concern is the plan by CMS to use taxpayer identification number, or TIN, to determine which laboratories will report private payer data.

19. Will CMS ensure all laboratories are able to comply with a new reporting system? How so?
20. Will CMS establish an alternative, more expansive methodology to identify laboratories that must report to the Agency, in order to ensure full market representation that includes a statistically significant number of independent, hospital, and physician laboratories?
21. If CMS used NPI number or CLIA number to identify laboratories that must report, how many laboratories would be reporting into the new system?

Additionally, the PAMA statute required CMS to issue final rulemaking on CLFS reform by June 30, 2015, providing both laboratories and the agency with sufficient time to create the necessary systems to collect, certify, report, and calculate data, with new reimbursement rates going into effect January 1, 2017. CMS has failed to meet this schedule. A proposed rule was not issued until October 1, 2015, and there still is no final rule. A January 1, 2017 effective date seems unlikely.

22. What is the status of the final rule and what are CMS' plans to provide laboratories with sufficient time and guidance to comply with reporting requirements?

Answer: On October 1, 2015, CMS published a proposed rule to implement section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requiring applicable clinical laboratories to report on how much private insurers pay for laboratory tests, which will be used as the basis for new Medicare payment rates. In the proposed rule, CMS proposed to define the term “laboratory” according to the definition used in the Clinical Laboratory Improvement Amendments (CLIA) regulations. CMS also addressed how to meet the statutory requirement that an “applicable laboratory” receive a majority of its Medicare revenues from the clinical laboratory fee schedule or the physician fee schedule. In addition, CMS proposed a low expenditure threshold to reduce the reporting burden on small laboratories, as authorized by PAMA.

CMS is currently reviewing the public comments received in response to the proposed rule, including many comments regarding the definition of an “applicable laboratory”. We will carefully consider those comments in developing a final rule implementing PAMA section 216.

Secretary Burwell, as you well know, Obamacare's CO-OP program has been a disaster. After using the American taxpayer as a piggybank, more than half of these entities have failed. I know many of my colleagues share my concerns, and I want to highlight a recent incident with a CO-OP in Ohio, InHealth. Press reports have indicated that InHealth is under enhanced oversight, which means CMS is concerned about its financial stability and is closely monitoring its operations. About 9,000 Ohioans are enrolled in InHealth, and they recently got some surprising news: at the last minute, InHealth decided to drop most OhioHealth hospitals and doctors from their provider network leaving them with few options now that open enrollment has passed. Now, I understand that this Obamacare CO-OP is struggling; that's what happens when Washington thinks it knows best and engages in crony capitalism. And I understand that they are just one of many issuers forced to narrow provider networks because of Obamacare's mandates and regulations.

But what I don't understand is how an Administration that crows about consumer and patient protections in the President's health care law can allow a CO-OP it is so closely monitoring to pull the wool over people's eyes and not announce major changes to provider networks until after the open enrollment period has passed.

23. Secretary Burwell, is monitoring decisions about providers networks part of CMS's enhanced oversight of the CO-OPs? Will there be recourse for enrollees who feel tricked?

I am disappointed that CMS has already announced they will not provide a Special Enrollment Period for these Ohioans, a decision that seems all the more perplexing when CMS is allowing one for those who broke the rules and failed to file their taxes. And, frankly, more Washington mandates are not what's needed.

Answer: We are focused on monitoring and supporting the remaining CO-OPs and making sure that consumers whose CO-OPs will not offer coverage for 2016 retain access to high-quality, affordable health insurance.

There are inherent risks in any start up; the insurance market is especially challenging. Each CO-OP is different and faces its own unique challenges. CO-OPs entered the health insurance market with a number of challenges, including: building a provider network and no previous claims experience on which to base pricing, while facing competition from larger, experienced issuers.

Provider networks are established via private contracts between health care providers and insurers, including CO-OPs, who frequently negotiate about the terms of such agreements, and frequently change from year to year. We continue to monitor network adequacy to determine whether networks meet requirements, and will work with state departments of insurance to resolve consumer complaints.

While I understand the disruption a decision like this can cause for consumers, it is important to note that plans still must maintain adequate networks that meet federal and state standards. If consumers are concerned that their plans aren't meeting these standards, they should contact their state Department of Insurance, which has primary authority for overseeing network adequacy.

Part B CMMI Demo:

- 24. Does data exist to demonstrate that cuts to drug reimbursement for physician administered treatments results in lower health care costs?**
- 25. Has CMS evaluated how this model will impact an oncology practice's ability to remain independent and keep cancer patients out of more costly care settings?**
- 26. Has CMS evaluated how the Part B demo will impact OCM participants?**
- 27. How will CMS select which value based purchasing tools are used for Stage 2? Does CMS plan to go through a rulemaking process for Stage 2 of the demo?**
- 28. Why did CMS choose to include 75% of physicians as opposed to a pilot rolled out to a smaller-scale audience?**
- 29. Once CMS accounts for sequester and the prompt pay discount, how does that affect the calculation of the add-on percentage?**

Answer: We are examining potential ways to support increased access to information, drive innovation, and strengthen incentives to improve quality care. We continue to look at a number of options in this area.

Last fall, HHS convened a forum that brought together consumers, providers, employers, manufacturers, health insurance companies, representatives from state and federal government, and other stakeholders to discuss ideas on how our country can meet the dual imperatives of encouraging drug development and innovation while protecting access and affordability. We came away with feedback to address these challenges in a holistic fashion addressing three important areas: (1) increasing access to information to support better health care decisions, (2) driving innovation that improve and save lives, (3) and strengthening incentives in the delivery system to reward quality care to patients and encourage value-based and outcomes-based decision making.

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¹³ All responses are accurate as of February 10, 2016.

[Submission for the record follows:]



Statement
Of
The National Association of Chain Drug Stores
For
United States House of Representatives
Committee on Ways and Means
On
Department of Health and
Human Services' (HHS) Fiscal Year 2017 Budget Request
February 10, 2016
2:00 P.M.
1100 Longworth House Office Building

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NACDS Statement on HHS Fiscal Year 2017 Budget
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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Brady and the members of the Committee on Ways and Means for the opportunity to submit the following statement for the record regarding pharmacy-related provisions contained within the Fiscal Year 2017 Department of Health and Human Services (HHS) Budget. NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve the quality and affordability of healthcare services.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 179,000 pharmacists. They fill over 2.9 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 22 countries. For more information, visit www.NACDS.org.

As the face of neighborhood healthcare, community pharmacies and pharmacists provide access to prescription medications and over-the-counter products, as well as cost-effective health services such as immunizations and disease screenings. Through personal interactions with patients, face-to-face consultations, and convenient access to preventive care services, local pharmacists are helping to shape the healthcare delivery system of tomorrow—in partnership with doctors, nurses and others.

Concerns with Budget Proposal

NACDS appreciates HHS's proposed goals to reduce healthcare costs and produce a more efficient healthcare system; however, we have concerns with some proposals contained in the FY2017 HHS Budget. HHS has proposed excluding brand and authorized generic drugs from the calculation of average manufacture price (AMP), thereby calculating Medicaid Federal Upper Limits (FULs) based only on generic drug prices. While the goal of this provision may be to decrease Medicaid costs, we believe it may in fact reduce access to prescription drugs and pharmacy services for Medicaid patients, resulting in increased overall healthcare expenditures.

Given that AMP has not yet been used as a basis for pharmacy reimbursement, and that AMP-based FULs remain in draft form, we believe the FY2017 budget proposals changing the calculation of FULs are premature. It is necessary for the Centers for Medicare and Medicaid Services (CMS) to meet its goal of ensuring that pharmacies are not reimbursed below their costs using the reimbursement formula created by the Affordable Care Act. Therefore, we urge Congress to reject this proposal that would conflict with CMS' objective of ensuring fair and adequate reimbursement for pharmacies so that the Medicaid population does not suffer a loss of access.

The FY2017 HHS Budget also includes a number of proposals to cut waste, fraud and abuse in the Medicare and Medicaid programs, including the ability to suspend coverage and payment for questionable Part D prescriptions, the ability to impose civil monetary penalties for providers and suppliers who fail to update enrollment records, and the authority to establish a program that would require that high-risk Medicare beneficiaries only utilize

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certain prescribers and/or pharmacies to obtain controlled substance prescriptions (i.e. a pharmacy lock-in program). NACDS applauds HHS for working to eliminate fraudulent activities from federal programs. However, NACDS urges HHS to move forward in a cautious manner so as not to disrupt beneficiary access or jeopardize beneficiary health. This can be done by ensuring that overly-burdensome requirements are not placed on providers to the point of interfering with the ability to treat and care for patients. For example, any potential program which limits a beneficiary's ability to obtain their prescription medications must ensure legitimate beneficiary access to needed medications is not impeded. Policies to reduce overutilization must be balanced with maintaining access to prescription medications by the beneficiaries who need them most.

We have specific concerns that a lock-in provision may actually be a barrier to care as supply chain issues exist around controlled substance medications that are beyond the pharmacy's control. If a pharmacy is unable to obtain the medication for a lock-in patient, then it creates a barrier that could result in harm to the patient's health. Mechanisms must be developed and executed to allow a pharmacy, in consultation with the prescriber, to fill legitimate prescriptions without needlessly delaying treatment for beneficiaries. To minimize any potential harm and address supply issues, a beneficiary should be allowed to use all locations for a pharmacy organization if that pharmacy uses a common database with an integrated patient profile. Additionally, to reduce the potential for further abuse and confusion, claim rejections should occur at the point of sale, otherwise pharmacies will have no way to determine whether a beneficiary is enrolled in a lock-in program.

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The FY2017 budget includes several provisions to increase the utilization of generic drugs. NACDS applauds the inclusion of these important provisions, which would encourage the use of generic medications by Medicare Low Income Subsidy beneficiaries, and promote generic competition for biologics. Increasing generic utilization is one of the most effective ways of controlling prescription drug costs, and the generic dispensing rate of retail pharmacies—83.5 percent—is higher than any other practice setting.

NACDS believes there are other opportunities to reduce program spending while vastly improving the health of Medicare beneficiaries; including improving access for underserved beneficiaries and the better use of medication therapy management (MTM) services.

Pharmacists as Providers

As the U.S. healthcare system continues to evolve, a prevailing issue will be the adequacy of access to affordable, quality healthcare. The national physician shortage coupled with the continued expansion of health insurance coverage in recent years will have serious implications for the nation's healthcare system. Access, quality, cost and efficiency in healthcare are all critical factors – especially to the medically underserved. Without ensuring access to requisite healthcare services for this vulnerable population, it will be very difficult for the nation to achieve the aims of healthcare reform.

The medically-underserved population includes seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Significant consideration should be given to innovative initiatives within the medically underserved population to enhance healthcare capacity and strengthen

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community partnerships to offset provider shortages and the surge in individuals with healthcare coverage.

Pharmacists play an increasingly important role in the delivery of services, including key roles in new models of care beyond the traditional fee-for-service structure. Pharmacists are engaged with other professionals and participating in models of care based on quality of services and outcomes, such as accountable care organizations (ACOs). Pharmacists now commonly provide immunizations and medication therapy management (MTM) services.

In addition to medication adherence services such as MTM, pharmacists are capable of providing many other cost-saving services (subject to state scope of practice laws). Examples include access to health tests, helping to manage chronic conditions such as diabetes and heart disease, plus expanded immunization services. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, limits the number and types of services pharmacists can provide, even though fully qualified to do so. Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (94 percent) live within five miles of a retail pharmacy. Such access is vital in reaching the medically underserved.

We urge you to increase access to much-needed services for underserved Medicare beneficiaries by supporting H.R. 592/S. 314, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which will allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services (subject to state scope of practice laws) not currently reaching them. This important legislation would lead not only

to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality.

The Benefits of Pharmacist-Provided MTM

Poor medication adherence costs the U.S. healthcare system \$290 billion annually. Pharmacist-provided services such as MTM are important tools in the effort to improve medication adherence, patient health and healthcare affordability. Studies have shown that patients who are adherent to their medications have more favorable health outcomes, such as reduced mortality, and use fewer healthcare services (especially hospital readmissions and ER visits). These studies included patients with cardiovascular disease, chronic obstructive pulmonary disease (COPD), high cholesterol and diabetes. Current MTM restrictions require that Medicare Part D beneficiaries suffer from multiple chronic conditions, be prescribed multiple medications, and meet a minimum annual cost threshold of \$3,138 in 2015 for their prescriptions before they are eligible for Part D MTM. According to the CMS MTM Fact Sheet, approximately 85% of programs opt to target beneficiaries with at least three chronic diseases in 2014. This is a contributing factor to the lower than projected eligibility levels in the MTM program.

NACDS has long been supportive of exploring new and innovative approaches to improve the Part D MTM program. One of the approaches we believe can be successful is the Enhanced MTM Model pilot allowing Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. The Enhanced MTM Pilot program

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presents an opportunity to create better alignment of program incentives and has the potential to lead to improved access to MTM services for beneficiaries and greater medication adherence. NACDS believes that the MTM Pilot program should include retail pharmacies, as a successful model test must include retail community pharmacists. Medication management services provided by community pharmacists improve patient care; improve collaboration among providers; optimize medication use for improved patient outcomes; contribute to medication error prevention; improve hospital and readmission cost avoidance; and enable patients to be more actively involved in medication self-management.

Since the pilot is scheduled to last for five years beginning in 2017, we also urge lawmakers to explore new and innovative approaches to improving the MTM program that could be implemented in the short term. NACDS believes one short term approach is more efficiently targeting beneficiaries who can most benefit from the services that will improve medication adherence and overall program effectiveness. Congress recognized the importance of MTM on a bipartisan basis, including it as a required offering in the Medicare Part D program. We urge Congress to build on this earlier action and strengthen the MTM benefit in Medicare Part D through support of legislation such as that introduced by Sen. Pat Roberts (R-KS) and Sen. Jeanne Shaheen (D-NH), S. 776, the *Medication Therapy Management Empowerment Act of 2015*, which will provide access to MTM for beneficiaries with diabetes, cardiovascular disease, COPD, and high cholesterol.

Conclusion

NACDS thanks the Committee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

