

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2017**

THURSDAY, MARCH 3, 2016

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:59 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Roy Blunt (chairman) presiding.

Present: Senators Blunt, Moran, Cochran, Alexander, Cassidy, Capito, Lankford, Murray, Durbin, Mikulski, Shaheen, Merkley, and Schatz.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF SYLVIA M. BURWELL, SECRETARY

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. Good morning. Thank you, Secretary Burwell, for appearing before the subcommittee today to discuss the Department of Health and Human Services' fiscal year 2017 budget request. We look forward to hearing your testimony.

We have many shared priorities in this budget proposal—cancer research, combating opioid abuse, increasing access to mental healthcare. I was disappointed, however, that many of these investments are not part of the discretionary budget request, something that we want to talk about today, that I at least want to talk about today. This is a precarious position I think for the department to be in.

The request leans heavily on new mandatory spending proposals that bypass the current budget caps and bypass the discretionary allocations in the committee. If the committee would follow the recommendation from the department, we would cut almost \$2 billion for programs currently funded by discretionary spending in this bill and I guess you would expect, and the administration would expect, new currently unauthorized mandatory funding to fill those holes. It is one thing if that happens, another significant thing if it does not.

My view would be that we need to figure out how to prioritize, that everything cannot be a priority, so this should be a discussion between us on the committee and with you as to where we need

to allocate the money we have to spend in your department. It seems to me the department submission just assumes that we will solve this problem by mandatory spending and new resources that I have no particular reason to believe the Congress is likely to agree with.

The subcommittee needs to look at what you have suggested, look at the cuts that would happen if we just simply would adopt your budget. For instance, with discretionary spending, we would eliminate children's hospital medical education dollars. That would theoretically come from somewhere else, but if we assume that is going to happen, there would be no graduate medical education in children's hospitals.

The administration's proposed funding increases can only be achieved by mandatory increases. My overarching concern is that whether the department would truly be prepared for the budget you submitted if those mandatory programs do not happen.

I think it is something we should all be very thoughtful about, because once we get through this process and those do not occur, that would mean a \$1 billion cut in the National Institutes of Health. It would mean, as I just suggested, no money for graduate medical education at children's hospitals.

So I do not agree with the approach, but maybe you can assure us on how that approach is going to have more success than I think it is likely to have.

But I do want to complete my opening remarks by saying I think you bring great capacity to this job. I appreciate your openness to discuss these and other issues, not only here today but you have really been extraordinary in reaching out to talk about the challenges that the department faces. And I look forward to continuing that discussion.

I am pleased now to recognize Senator Murray for her opening comments.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman.

Secretary Burwell, thank you for being here today and for all that you do every day to improve the health and well-being of our families and communities across the country.

I look forward to your testimony today and the discussion about the department's funding needs for the fiscal year 2017. While I know you are going to be highlighting the department's request in your statement, I do want to note how pleased I was to see that it proposes a significant increase for early learning and child care. That includes \$161 million to implement the safety and quality improvements that were contained in the reauthorization of the Child Care and Development Block Grant, which the Senate approved 16 months ago with overwhelming bipartisan support, 88–1, due in no small part to the leadership of Vice Chairwoman Mikulski.

And I thank you as well for that.

Those investments really support working families and help make sure our kids start kindergarten ready to learn.

I was also pleased the budget maintains support for the Affordable Care Act, which has expanded health insurance coverage to millions of people and helped a lot more families pay less for better

quality care. We need to keep working toward more coverage, not less; more affordability, not less; and better quality, not less. That is something I know that, on this side, Democrats will continue to be focused on.

Overall, there is much to like in the President's HHS budget request. It builds on the bipartisan spending bill that Congress passed late last year, a bill that was possible because Democrats and Republicans were able to come together and break through the gridlock and reach a budget agreement that allowed us to provide needed discretionary investments in NIH, CDC, worker training, child care, early learning programs, just to name a few.

That agreement showed that, once again, when we work together to find common ground, we can deliver results to the families and communities we serve. I am hopeful that we can build on last year's momentum to do the same again this year.

Many of the challenges facing us remain the same as when Secretary Burwell testified before the subcommittee last spring. There is still much more we need to do to continue work started in the Affordable Care Act to expand access to quality, affordable healthcare.

The intense competition for NIH grants means that fewer than 20 percent of applications get funded, leaving lots of promising science without support.

And the epidemic of opioid and prescription drug abuse continues to hurt families and communities nationwide.

Secretary Burwell, as you well know, our broken mental healthcare system is yet another ongoing challenge we have to tackle. I know this is a priority that many members here today as well as on the HELP Committee share, and it is a focus for the administration as well.

So I am very hopeful that the bipartisan momentum we are seeing on this can continue, and that we can work together on some solutions that expand access to quality, effective mental healthcare so many families are struggling to find.

We will be challenged to find ways to address these and other persistent needs while also taking into account the new policies laid out in the Every Student Succeeds Act that Senator Alexander and I helped write and signed into law in December.

As everyone here knows, the 2-year budget agreement rolled back the automatic cuts and allowed us to restore key investments, but it did not go as far as many of us had hoped. That means, as it often does, difficult choices will be unavoidable in 2017, as they were last year. Even so, I believe that our subcommittee can find a way to write a bipartisan bill once again. But doing so depends on this subcommittee getting an allocation that will allow us to make the needed investments in education and medical research and drug treatment and support for working families and a lot more. I know Chairman Blunt would like to work on this bill in a bipartisan manner as well, and build on the progress that we have made.

So I look forward to working with you, Secretary Burwell, and all of our colleagues who are here today, in the coming weeks and months. Thank you very much.

Senator BLUNT. Thank you, Senator Murray. We do hope to be able to work on this bill together.

Secretary Burwell, again, we are delighted you are here. We look forward to your testimony.

SUMMARY STATEMENT OF HON. SYLVIA M. BURWELL

Secretary BURWELL. Thank you. Chairman Blunt, Chairman Cochran, and Ranking Member Murray, and Ms. Mikulski as well, and all the members of the committee, I want to thank you for this opportunity to discuss the President's Department of Health and Human Services budget for this year.

As many of you all know, I believe that all of us share common interests and that we can find common ground. In the last legislative session, this Congress made timely investments in programs to improve the health and welfare of the American people, and I thank you all and this committee for that.

The budget before you today is the final budget for this administration, and my final budget. It makes critical investments to protect the health and well-being of the American people. It helps ensure that we do our job to keep people safe and healthy, accelerates the progress in scientific research and medical innovation, and expands and strengthens our healthcare system. And it helps us continue to be responsible stewards of the taxpayer 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 10 years, these reforms to Medicare would result in savings of \$419 billion.

In order for Americans to benefit from recent breakthroughs in medical science, we need to ensure that all Americans have access to quality, affordable healthcare.

The Affordable Care Act has helped make historic progress. Today, more the 90 percent of Americans have health coverage, the first time in our Nation's history that this has been true. This budget seeks to build on that progress by improving both the quality of the care that patients receive, spending our healthcare dollars more wisely, and putting engaged and empowered individuals at the center of their care.

It proposes investments to improve the access to care for underserved groups across the United States, including many living in rural communities. With \$5.1 billion in health center funding and nearly \$14 billion over the next decade proposed for our Nation's healthcare work force, even more Americans will be able to get the care they need.

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

Let me turn to an issue we have been working on here at home and abroad. As we work aggressively to combat the spread of Zika, the administration is requesting \$1.9 billion in emergency funding, including \$1.5 billion for the Department of Health and Human Services.

We appreciate Congress' consideration of this important request as we implement the essential strategies to prevent, detect, and respond to this disease.

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

Research shows that early learning programs can set a course for a child's success throughout his or her life, and that is why over the course of this administration and together with congressional support, we have more than doubled access to Early Head Start and services for infants and toddlers. Our budget proposes a total of \$9.6 billion for the Head Start program and an investment in child care services that would allow us to serve over 2.6 million children.

Today, too many of our Nation's children and adults with diagnosable mental health disorders do not receive the treatment that they need. So this budget proposes \$780 million in new mandatory and discretionary resources over the next 2 years.

While we invest in the safety and health of Americans today, we must also relentlessly push forward the frontiers of science and medicine. This budget invests in the Vice President's cancer initiative. Today, we are entering a new era in medical science, and with the proposed increase of \$107 million in the Precision Medicine Initiative, and \$45 million for the administration's BRAIN Initiative, we can continue that progress.

Finally, I just want to thank the employees of HHS. In the past year, they have helped with the Ebola outbreak in West Africa; 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 their team.

As members of this committee 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, I welcome your questions.

[The statement follows:]

PREPARED STATEMENT OF HON. SYLVIA M. BURWELL

Chairman Blunt, Ranking Member Murray, and Members of the Committee, thank you for the opportunity to discuss the President's fiscal year 2017 Budget for the Department of Health and Human Services (HHS). In fiscal year 2016, the Congress made timely investments in programs to improve the health and welfare of American citizens, such as programs to address opioids abuse and expanding access to healthcare centers and Head Start. The fiscal year 2016 appropriation also made important investments in many research frontiers like precision medicine and research to combat antibiotic resistant bacteria. We thank you for your leadership on these important issues and look forward to building on these investments in fiscal year 2017.

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 healthcare 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 Gov-

ernment, 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 opioid misuse and overdose as part of a nationwide three-pronged strategy to drive progress. And we advanced the frontier of medicine through cutting-edge research in genomics and technology. Through all these efforts, we have worked to ensure the responsible stewardship of taxpayer dollars by taking steps to further strengthen program integrity, saving money for the taxpayer and making sure our programs deliver in the best possible way for those we serve.

The President's fiscal year 2017 Budget for HHS builds on this progress through critical investments in healthcare, 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, healthcare access, 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 fiscal year 2017 Budget advances access, affordability, and quality in our Nation's healthcare system—goals that we share with Congress and this Committee. Through targeted investments, the Budget expands access to care, particularly for rural and other underserved populations, and supports primary and preventive care.

Investing in Health Centers.—For 50 years, health centers have delivered comprehensive, high-quality, cost-effective primary healthcare to patients regardless of their ability to pay. Today, more than 1,300 health centers operate over 9,000 sites and provide healthcare services to 1 in 14 people in the United States, including to approximately 454,000 patients at 217 service delivery sites in Missouri and 910,000 patients at 298 service delivery sites in Washington. 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 approximately 27 million patients across the country in fiscal year 2017.

Increasing Access to Health Care for Minority and Underserved Populations.—The Department is investing in several initiatives that will improve access to care for underserved groups across the United States, including those living in rural areas. We know that this is a priority for many of you on this Committee. The Budget includes investments of nearly \$14 billion over 10 years in our Nation's healthcare 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. In addition, the Budget will allow the Health Centers Program to serve an estimated 9.7 million rural Americans, an increase of approximately 1.5 million more rural patients than are served today.

The Department also takes steps to close health disparities for minorities and Native Americans. The fiscal year 2017 Budget provides an estimated \$13 billion, a \$382 million increase above fiscal year 2016, for programs and services to improve the health of minority communities and reduce health disparities. In addition to the investments in the Health Centers Program, where over 60 percent of patients are from racial or ethnic minorities, the Budget also extends \$14 million in funding for the Health Career Opportunities Program to increase the diversity and cultural competence of the health professions workforce.

The fiscal year 2017 Budget more than doubles available funding across the Department to help close the gap in behavioral health disparities experienced by American Indians and Alaska Natives through preventive and crisis response, an increase of \$87 million above fiscal year 2016 for a total of \$141 million. This funding would support targeted efforts within the Indian Health Service (IHS), Substance Abuse and Mental Health Services Administration (SAMHSA) and Centers for Disease Control and Prevention (CDC) to reduce rates of substance abuse, improve access to mental health services, and prevent suicide. The Budget also increases funding for the IHS by \$402 million to continue progress and reduce health disparities in Indian Country, as well as fully funding contract support costs, which

provides critical overhead funding to tribes who operate facilities under self-determination and self-governance agreements. 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.

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 3 years of full Federal support, no matter when the State expands. The Budget also funds the Children's Health Insurance Program through fiscal year 2019 to ensure comprehensive and affordable coverage for beneficiaries as well as budget stability for States.

HEALTHCARE DELIVERY SYSTEM REFORM

At HHS, we are focused on moving towards a healthcare 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 healthcare 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 percent in alternative payment models by the end of 2016, and 50 percent 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 healthcare, engaging patients more fully in decisionmaking, 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. By integrating face-to-face care with remote access care in both rural and urban areas, this proposal could improve care coordination, provide for more timely exchanges between specialists, and facilitate beneficiary access to care.

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 hospital-acquired infections and conditions 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 decisionmaking, and consistently uses high quality evidence to provide safe and high quality care for all.

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 Opioid Misuse and Overdose.—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 fiscal year 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 fiscal year 2017 and fiscal year 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 opioid 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.*—Responders to an overdose have little time to effectively reverse the effects of an opioid and save a life. To best prepare communities and first responders, the Budget includes a total of \$22 million for programs that support the use of naloxone—a lifesaving overdose reversal drug. Among other critical programs, the Budget invests \$10 million 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 2-year \$500 million investment in mental healthcare, 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 healthcare systems work for everyone. A portion of the 2-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.

Combating Antibiotics Resistant Bacteria.—The emergence of antibiotic-resistant bacteria continues to be a significant public health concern. The fiscal year 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 5 years, the United States will work with more than 30 partner countries—representing over four billion people—to help them prevent, detect, and effectively respond to infectious disease threats. I am pleased to share that work with many of these countries has already begun. We appreciate the funding provided by Congress last year for this crucial priority.

As we work aggressively to combat the spread of Zika, the Administration is requesting \$1.9 billion in emergency funding, including \$1.5 billion for HHS, to enhance our ongoing efforts both domestically and internationally. The requested resources will build on our ongoing preparedness efforts and will support essential strategies to combat this virus, such as rapidly expanding mosquito control programs; accelerating vaccine research and diagnostic development; enabling the testing and procurement of vaccines and diagnostics; educating healthcare 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 areas to better combat mosquitoes and control transmission. We appreciate the Congress's consideration of this important request.

Serving Refugees and Unaccompanied Children.—In light of a global displacement crisis, the Administration has committed to expanding the Refugee Admissions Program in fiscal year 2016 and fiscal year 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, 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, including 100,000 refugees, consistent with the Administration's commitment to admitting at least 100,000 refugees in fiscal year 2017.

In addition to serving the populations discussed above, HHS is also legally required to provide care and custody to all unaccompanied children apprehended by immigration authorities until they are released to appropriate sponsors to care for them while their immigration cases are processed. Based upon the increase in unaccompanied children apprehended at the Southwest border this fall, ACF has taken prudent steps to identify temporary capacity so that we are adequately prepared if additional shelter space is needed. To ensure that HHS can provide appropriate care for unaccompanied children in fiscal year 2017, the Budget includes the same amount of total base resources available in fiscal year 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.

With congressional support, 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 fiscal year 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 fiscal year 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 fiscal year 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.

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 fiscal year 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 fiscal year 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 percent in the last 60 years. Cancer death rates are now falling 1-2 percent per year; each 1 percent drop saves approximately \$500 billion. Breakthroughs in HIV therapies enable people in their 20's to live a full life span. The fiscal year 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 fiscal year 2017. The Budget fully funds the Health Care Fraud and Abuse Control (HCFAC) discretionary cap adjustment. In fiscal year 2015 alone the HCFAC program returned over \$2.3 billion to the Federal Government and private citizens. The Budget includes proposals that will expand and strengthen the tools available to CMS and States to combat fraud, waste, and abuse, including in State Medicaid programs. In total, proposed program integrity investments and authorities in the Budget will yield an estimated \$25.7 billion in scorable and non-scorable savings to Medicare and Medicaid over 10 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.

Senator BLUNT. Thank you, Madame Secretary, for your comments.

We will have time for a second round of questions, so with the exception of Chairman Cochran and Senator Mikulski, I am going to run a pretty tight clock here. They can, by the way, talk as long as they want to. But we will then have time for a second round. So hopefully we will all think about everybody else's time, and I will try to limit my own time in exactly the same way.

SUPPLANTING DISCRETIONARY FUNDING

What about the question I suggested in my opening statement, Secretary Burwell? What if you get the budget you asked for and the mandatory funding that you hope happen do not happen? What would you have to come back and ask us to do that would not be happening, if you got your budget and the mandatory supplements do not occur?

Secretary BURWELL. So as we put the budget together, we put it together as a budget. We put it together in terms of what we think are the right needs and the right trade-offs. I think it is important to reflect the mandates that we proposed are paid for.

When we look at the issue of discretionary funding, as we think about—

Senator BLUNT. They are paid for out of noncurrent sources of revenue, right?

Secretary BURWELL. I think we proposed the revenue choices and other choices in terms of cuts. As I said, there is \$419 billion in Medicare savings that we have, and there are a bunch of other things that we put in our budget to do the appropriate savings.

When we put forth a budget, it is about choices. And within our budget, we made the choices that we think we should make. I think it relates to the issue of the overall level of discretionary funding. That is something that I think, in the world that we live in—where we have issues like opioids, behavioral health, the research that we all want to do—that when we think that we are going to end up in a place where our discretionary spending as a percentage of GDP (Gross Domestic Product) is at some of the lowest levels we have ever seen as a Nation, is that where we want to be?

So we wanted to make sure that we are abiding by the deal but also reflecting what we believe are the right choices in terms of that spending.

Senator BLUNT. The mandatory funding is paid for out of tax increases that the Congress would have to approve. Is that right?

Secretary BURWELL. There are a combination of things throughout our budget. Some of those are revenue issues, but other things are on the other side in terms of some of the Medicare savings. In addition, there are other things in our budget alone—and some may bring this up—we have actually cut spending on a number of things in terms of programs. And it is not a popular cut we do, but we have cut funding in terms of the CDC and vaccines that we believe are now being taken care of through the Affordable Care Act, because people have that coverage, and that there is lower demand on those programs.

So we put together a combination of things to pay for those investments that we believe are necessary for the country's health.

OPIOID EPIDEMIC

Senator BLUNT. On opioids, we increased spending last year by almost 300 percent. I think we got slightly above the number that you asked for. I think we went from about \$31 million or \$32 million to \$123 million, which was a big increase. I think your proposal here is \$1 billion more over 2 years?

Secretary BURWELL. Yes. It would take us to \$1.2 billion. I think in the area of opioids, it is related to an issue that I know you have been an incredible champion on, which is behavioral health. We all know that one of the issues around behavioral health is that it is actually paid for at the State and local level.

In terms of the capacity, one of the things that is most important in a strategic approach for opioids is medication-assisted treatment. That needs to occur on the ground in the communities in States like our home State of West Virginia, and all across the Nation.

So the idea that we are going to be able to provide the capacity for treatment for the numbers of people we have is why we have proposed the increase.

The vast majority of the increase that we proposed in opioids is for medication-assisted treatment that will go to the States and local communities.

Senator BLUNT. Just to help us make that case a little better, as we discuss it, what is your view of what has happened. This is a problem that we were allocating \$31 million to 18 months ago and one that we would now be looking at something in the neighborhood of a half billion dollars a year?

Secretary BURWELL. I think it is the demand and the need. When 78 Americans are dying every day, I think we are at a point where it is a crisis in our Nation. I think you know, when I got to the Department, I asked for an evidence-based strategy to build on the work that we had been doing with very specific areas of focus that could have measurable results with regard to the reduction in the number of addictions and reduction in the number of overdoses and a reduction in the number of opioid deaths.

That strategy had three parts to it, and one of the parts is costly, but I think the more conversations we have—I know you all are having them with law enforcement officials, that they have become the healthcare and social services system. So we have to have a place for those folks to go, and we have so many of them now that the needs are great.

Senator BLUNT. Senator Murray.

Senator MURRAY. Mr. Chairman, I know that the vice chairwoman has to leave to go chair another committee, so I am happy to switch spots with her and let her go first.

Senator MIKULSKI. Thank you, Senator Murray.

There is a lot going on today. In addition to the Labor-HHS hearing with this fantastic attendance, CJS will be meeting in 30 minutes, and MilCon-V.A. is also meeting.

So I want to thank Senator Cochran for really mandating such a quick-paced schedule that we have our hearings and do our job and look forward to, again, working with both he and Senator McConnell to follow the budget agreement, get our 302(b)s and get going. So thank you very much for your leadership.

Secretary Burwell, we do want to thank you for your leadership and the way you have run the department. I think you brought stability to the work force, confidence in the Congress. Your responsiveness to us I think is very much appreciated.

As we look at President Obama's last budget, we know what your agency does, with its 73,000 people, touches every aspect of American lives. We need to be able to do what we need to do to really be able to help American lives.

I have to my right a champion of NIH, as so many of us are here, the chairman, the vice chairman of this committee. We have to recognize that the defense of the needs of our country are not only in the Defense Department, and this is why we need to look at domestic discretionary spending and maintain parity with those two.

We are going to get to my questions. Senator Murray and I conferred. She will be asking a lot of the questions that I have in mind, like the opioid issue, the early childhood issue, and so on.

ZIKA SUPPLEMENTAL

Let me get to the Zika supplemental. The chairman raised the issue of his concern about mandatory funding. I am concerned about that, too, and what could get cut. But you know, we just had a robust debate yesterday on a supplemental on opioids offered by Senator Shaheen. You have here before us the Zika supplemental. I am concerned that we just do not have enough to meet the emerging needs of our country.

And with the Zika supplemental, one, is it a big threat? And number two, why can't we use the money that has been left over from Ebola? And number three, is it that we really need to look at CDC in the same way we have to look at our preparedness for a bio-attack, a chemical weapons attack, and so on?

We have to come to grips with the Zika supplemental. I talked to Dr. Frieden, Dr. Fauci.

Dr. Fauci, we are turning to him once again. We are grateful to have him at NIH. But he is grateful to have our help.

So could you comment on the Zika supplemental? Is this the way we are going to do government, mandatory spending, supplementals? Or do we need an appropriations that America can count on and its Secretary can count on?

Secretary BURWELL. With regard to that broader question of where caps should be for discretionary funding, I could wear my old hat at OMB and we could discuss. And I certainly have opinions, but I will address directly this Zika question.

On the issue of Zika, every day I get a report, and we have more and more people. We have now in the United States more cases confirmed of sexual transmission. When we think about Zika, and thinking about it at your level, I think there are three very important things to focus on. I think right now our most important focus is on making sure that fewer pregnant women get Zika and have the consequences of babies with very serious birth defects, microcephaly.

So, one, we need to protect those pregnant women.

Number two, there are many knowns and unknowns. Right now, as I am sure Dr. Frieden and Dr. Fauci have shared with you, we do not know the answers as to how quickly this spreads, in terms of whether or not it stays in semen for an extended period of time, or how long that is. So right now, we have to give guidance telling pregnant women to be extremely careful.

We do not know what point in a woman's pregnancy that it has impact. There are many unknowns.

The money we are asking for is to make sure we can do the research and prepare the homeland. Right now, Puerto Rico has cases that are transmitted in Puerto Rico, not travel-related cases.

So with regard to the issue of Zika, the money and the needs are urgent as we prepare our Southern States especially for the summer for a mosquito that can breed in a cupful of water, that is indoors, and can bite four people in one meal.

So we are working very hard and have a plan to do that. The funding needs to come and is time-sensitive.

EBOLA

Senator MIKULSKI. Why can't you use the money that is left over from Ebola? That has been my position.

Secretary BURWELL. With regard to the issue of the Ebola money—

Senator MIKULSKI. In other words, why do we need a supplemental?

Secretary BURWELL [continuing]. I think it is important to reflect that the monies that are left are for very important things.

In Sierra Leone, after it had been declared transmission-free, 48 days later, we found another case of Ebola on a dead body, because we were still swabbing, testing the dead bodies. That is how we found it, and that is why we did not have another large outbreak in Sierra Leone after we had been told we did not have any cases.

This is a disease where we are not done.

In addition, a big portion of the money is for Global Health Security Agenda. That is money Congress gave us. You told us to put together 5-year plans to make countries meet their marks before we would put the money out.

We have worked with those countries. They have put together those plans, and we are going to put the money out on that timetable.

It is important, because right now in Nigeria, there is a Lassa outbreak. Lassa is related to Ebola. It is not the same disease, but similar.

Last year, I did not come to talk to you all about it, but we had the most cases of the Middle East Respiratory Syndrome, which is even quicker to spread—respiratory—outside of Saudi Arabia. It was in Korea. We were able to handle it because we were prepared.

That Global Health Security Agenda money and those countries' preparedness is our preparedness, because we are only as prepared as that weakest link. And we do not know where it is coming from. MERS, we have had a case in Indiana 2 years ago.

We are in a world where it is our own domestic security that we are concerned about.

Senator BLUNT. The chairman of the full committee, Chairman Cochran.

Senator COCHRAN. Mr. Chairman, thank you very much. This is an excellent hearing.

Madam Secretary, we appreciate your cooperation with us in reviewing the options for the funding levels in the bills that come under the jurisdiction of our committee. It is a big responsibility. It is a big problem, and States like mine, where we have a higher number of people who have a hard time getting access to and affording and paying for healthcare or hospitals or doctor fees or education programs.

There are a lot of places where we can do a lot of good in helping to make life more tolerable and enjoyable. That is what really moves us.

CRITICAL ACCESS HOSPITALS

We get tangled up sometimes in the procedures and forget what the big picture is. But money, for example, like critical access hospitals, I am disappointed that the administration is not requesting more funding for those facilities, where those facilities are less than 10 miles away from the nearest hospital. I hope we can look for opportunities to be more sensitive and generous, and that means stretching dollars and providing the bulk of the money where people would not have access.

So what is your response to that? Are we doing the right thing? Are we overdoing this? Are we denying emergency services in life-and-death situations?

Secretary BURWELL. So with regard to the issue of critical access hospitals, I think it falls into the larger category of rural health in America. That is something I am specifically focused on too because where I am from, in terms of being from West Virginia.

So there are a number of things in our budget that we are doing to focus specifically on how we are supporting those rural hospitals across the country. One of the things is our proposal on community health centers. Thanks to all of you for your support previously on this issue, because those community health centers are disproportionately in the communities that we are talking about. 38 percent of them are in rural America.

In addition, the proposal that we have in front of us will increase the number of those with the same dollars from last year, but we will be able to increase the numbers.

In addition, our National Health Service Corps, 40 percent of the National Health Service Corps serves rural America. We have proposed to increase the number of people that will be serving there.

In addition, our proposal and some of the proposals we were just talking about in the area of opioids are specifically targeted to rural America. We also have some telemedicine proposals that I think will particularly help rural America.

And I will say, in many States, the expansion of Medicaid has made a huge difference to hospitals. What we see is that the majority of hospital closures, and especially those rural hospital closures, are closing in States where expansion has not occurred.

There are many things that contribute. As we know, it is about providers. It is about population density. But we are already seeing those statistics. So those are a number of things.

With regard to the specifics of the critical access hospital issue, I think we believe those hospitals will still receive disproportionate Medicare payments, and our analysis says that hopefully that will be something that can help them.

Senator COCHRAN. I appreciate very much your personal attention to that challenge.

Thank you, Mr. Chairman, for providing these increases that we are submitting in our committee.

Senator BLUNT. Thank you, Chairman.

Senator Murray.

PRESCHOOL DEVELOPMENT GRANTS

Senator MURRAY. Thank you very much.

Secretary Burwell, I really was pleased to see that you have requested \$100 million increase for preschool development grants. As you know, the bipartisan Every Student Succeeds Act marked for the very first time that our Nation's primary education law authorized dedicated funding to improve access to preschool for children from low-income and disadvantaged families.

Now, the program will be funded at HHS, but it is going to be jointly administered by HHS and the Department of Education. The Department of Education has done great work in collaboration with you to help States develop and sustain strong early learning programs.

I wanted to ask you how is HHS planning to take advantage of the expertise at the Department of Education with regard to its early learning programs?

Secretary BURWELL. We plan to work on the relationship that we have had historically in this specific area in terms of how we have jointly worked on it before when it was sitting at Education, as well as how we work on a number of issues, whether that is joint letters in the space that the Secretary of Education and I do regularly in terms of when we want to communicate or do policy efforts.

In order to make it so that it is more formal in terms of making sure that we are going to follow that path and that there are set parameters, we are actually working on a memorandum of understanding, so that when the programs switches—not in this fiscal

year, but the next fiscal year, as directed by Congress—when it moves to us, there is a memorandum of understanding that will lay out specifically the ways that we ensure that we are getting appropriate input from our colleagues and run the program in a joint fashion.

Senator MURRAY. So you will be working in lockstep with them?

Secretary BURWELL. Yes. That memorandum of understanding is something we will develop together, so that we put in place processes that are formalized, because we want to build on what I think has been more informal. But we would like to go ahead and formalize it, because we think that will help us make sure we succeed.

UNACCOMPANIED CHILDREN

Senator MURRAY. Great. Thank you.

As you know, there was a surge late last year in the number of unaccompanied children crossing our southern border and referred to the custody of HHS. Your department has used the resources this subcommittee has provided to find temporary bed space for those children should this trend continue.

Yet at the same time, the Associated Press and the Senate Committee on Homeland Security and Governmental Affairs found that your department did not adequately protect these children after they were released to sponsors. Some of those children were victims of abuse, neglect, and human trafficking.

In my view, HHS should be doing more than just finding bed space for these children. Can you talk a little bit about what changes in policies you have instituted since these stories came out, that will help make sure that these vulnerable children are protected?

Secretary BURWELL. Yes. The safety of these children is our priority. As you know, that is our role in this process. We are tasked with placing the children as quickly as possible in safe settings.

I think it is important to reflect what they were looking at is a case in Ohio. That is a case where people broke the law. As soon as we had any knowledge of that, we started working with the Justice Department quickly to make sure that we worked to prosecute to the fullest extent of the law with those children. It is an awful situation that should not happen again.

There were other accusations that a whistleblower made. We looked into them. Our IG (Inspector General) has looked into them. Our IG found that there was no substantiating evidence that they had in front of them with regard to that.

Having said that, we have put in more what we consider policies that will help address some of the issues to make sure we are doing as much as we can. One, any adult in the home where a child is being placed will go through a background check. In any place where a child is placed in a nonrelative or a distant relative setting, those are places where we are going to work hard to make sure we are doing appropriate checks, some of those even in the home and making sure we do home visits. In addition, for anyone that is placed in a nonfamily member setting, there will be follow-up services.

We have put in place an 800-number for the children themselves, if they have concerns, so they can reach out.

One of the things about the funding though, and we had this conversation last year, why we would actually like flexibility in the funding is because we do not know the numbers and they fluctuate. I think you all know it was 17,000 children in the first quarter of this year. We have to make sure we have funding to get the children off the border and have the beds.

The contingent fund that we have proposed would allow us the flexibility to make sure that we know that we could provide beds, but at the same time could think about other ways we can enhance services. Right now, we are doing all of those things. I think the question of us doing more is related to funding.

Senator MURRAY. Thank you.

Thank you, Mr. Chairman.

Senator BLUNT. So the list I have, we will start with Senator Alexander, then Senator Merkley, Senator Capito, Senator Durbin, Senator Moran, Senator Shaheen, Senator Cassidy, Senator Lankford.

Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman.

Madam Secretary, first, let me thank you for the way you work with the committee and with me and our office. Some of us here in the Senate are in the results business, and a lot of us are on this committee, and we like working with a Secretary who works the same way, so thank you for that.

I have given you a letter about the so-called Medicaid bump-up. I do not want to take my time with it here, but it comes from our entire delegation. I believe there may be some unintended consequences from a well-intended effort to encourage more doctors to see Medicaid patients. So if you would look at that, I would appreciate it.

Secretary BURWELL. I will look into it.

Senator ALEXANDER. Madam Secretary, I want to talk about one subject. I want to ask for your advice and as much support as you can give to the idea.

PRECISION MEDICINE INITIATIVE

This is an exciting time for science. Many of us believe that here. There is an opportunity to help almost every American with biomedical research. The President is for a lot of things but among the few things he is really for is his Precision Medicine Initiative. I know that, and I talked with him about it a year ago. I attended his Precision Medicine events, and I pledged to him that I would do my best to help him create an architecture here in the next year that will put us on a path toward the Precision Medicine, personalized medicine, that he correctly talks about.

So the budget throws us a little curve. Senator Blunt talked about that. It is not surprising. I mean, it happens every year, really. For example, the Army Corps of Engineers, the administration know we are going to put money back in, so the administration cuts it way back.

But the idea that you would, in the discretionary fund after we worked very hard—Senator Murray, Senator Blunt, Senator Dur-

bin, several of us—to have a significant increase in discretionary funding to get on a path toward better funding for the National Institutes of Health and you come in with a lower amount of money in discretionary funding with the hope that somehow some committee might authorize mandatory funding or pass new taxes or something else, that is not very encouraging.

So since we are in the results business, let me suggest a path forward, and I will try to do this quickly, so you will have a little time to answer.

The most important legislation in the committee that Senator Murray and I chair is our biomedical innovation legislation. It is a companion to the House 21st century cures legislation. We have talked about it many times.

We are moving very well on it. We have 50 proposals that are bipartisan, and we hope by early April to approve those in the committee in a bipartisan way.

That is a train that should get to the station for the Precision Medicine Initiative, the Cancer MoonShot, electronic medical records, and anything that has to do with mandatory funding for NIH. The only way I can see to get that there is to approve these 50 proposals, most of them. That would be one vehicle. And that would be bipartisan. I think we can do that.

The second vehicle would be a bipartisan consensus on mandatory funding. I think about it a little differently than just a big block of money. I want to see this committee continue to increase our discretionary funding. I would like to see the mandatory funding not be a substitute but to be in addition, a surge of funding for such things as Cancer MoonShot, Precision Medicine, and Big Biothink.

I think we could agree on that, find a way to pay for it, and take those two bills to Senator McConnell, the 50 proposals and the bipartisan proposal on mandatory funding in mid-April. If we did that, I believe he would put it on the floor. I believe we would pass it. I believe we could merge it with a House bill. And the President would gladly sign it, because it has so many things that are important to the future of our country.

Now my question is, will you help us figure that out, particularly with your budget background? And do you have any advice?

Secretary BURWELL. So I think we are completely aligned, and I think you know, and we have had the conversation with members of this committee, about the idea and the work on the companion to 21st Century Cures here in the Senate. And we are very appreciative for the work you are doing, especially in electronic health records. We did an announcement on that as recently as Monday that I think very much aligns with the legislation that you all are considering blocking.

So that whole range of substantive issues that you are focusing on, I think we are aligned on. We want to continue to provide any technical assistance that we can and support for figuring out how you get a companion that could be conferenced. I think it is great that you are focused on the issue. I know these are complicated issues, but the idea of mandatory funding as the means by which we can move forward on these incredibly important things—you

listed them, Precision Medicine, the issue of as we think through NIH, cancer——

Senator ALEXANDER. Young Investigators, perhaps.

Secretary BURWELL. I think it will probably also touch on the BRAIN, in terms of——

Senator ALEXANDER. Yes, absolutely. The BRAIN Initiative.

Secretary BURWELL. So I think what I pledge to do is work with you and the committee on figuring out how we can.

I understand the tough questions on what mandatory discretionary caps, how we do this. I think what we want to do, and what we are excited to do, there is agreement. These are priorities for the Nation. And so how we can figure out ways to get that funding, and to get the legislation, because that is the other part of what you are speaking about on things like blocking, on things like making sure that we can do our investigations at NIH in more efficient ways, those are all things that we are excited to work on.

Senator ALEXANDER. Thank you, Mr. Chairman.

Senator BLUNT. Senator Merkley.

Senator MERKLEY. Thank you, Madam Secretary.

Thank you, Mr. Chairman.

CHILDREN'S HEALTH

I want to raise two issues related to children's health. One is a topic that I probably have had more discussions about than anything else. And it will not surprise you that I wanted to check in on the deeming rule.

The thing that concerns me so much is that, between 2013 and 2014, use of e-cigarettes by our middle schoolers and high schoolers tripled. Addiction to nicotine is a pathway to a lifetime of disease, a huge impact on quality-of-life for our children, huge cost to the healthcare system. We have the potential to do it differently.

But the rule has to emerge someday. While it is not emerging, more and more children are being targeted by the fancy flavors, the candy flavors, so on and so forth.

Is there any hope?

Secretary BURWELL. Yes. In terms of moving the rule, I think you know it had 135,000 comments, a complex rule with a number of different pieces and parts to it. The one we are focused on, e-cigarettes, certainly I think is the anchor portion of the rule.

It is something that we will move. I feel confident that this will occur. With regard to the specifics of the timing, I am not sure that I can predict that. I think you know we do rulemaking in partnership. So we will continue. I think you know, and you and I have discussed my intent to make sure that we do that.

At the same time, a number of steps have been taken in addition. For the first time, we have actually done a no-sale order on tobacco where we have providers who are not abiding by the regulations. For the first time ever, we have said that there will be providers who, because they have gone through a number of times not abiding by the law, that they can no longer sell.

In addition, I think you also know, with regard to liquid nicotine, that we have an NPRM (Notice of Proposed Rulemaking) that we are working on to continue to move forward.

So there is that rule. There are the other pieces that we are continuing to work on in this space.

Senator MERKLEY. I know you have a lot of issues you are concerned about, and this is one you do care about. I know it is out of your hands in terms of OMB, but it is still in partnership with your department. It is the potential for an important healthcare win, so please stay at it, as you have been.

Secretary BURWELL. I will.

HIV NETWORK

Senator MERKLEY. Thank you.

Second, I want to turn to the HIV network. There is a group of 18 research sites that participate in the HIV research network that was established in the year 2000. It collects data on 25,000 children, adolescents, and adults with HIV from across the United States. Together, these sites provide a unique source of information on delivery, disparities, cost-effectiveness, the quality of HIV care. It has helped to get a lot of insights about how we can address this disease more effectively. Oregon Health Sciences University is one of those 18 sites.

This particular network is slated for elimination in the 2017 budget, which I think caught many of us by surprise. So I just wanted to check in with your team. My impression is that the valuable insights of tracking this disease and the routes it is taking, so on and so forth, has contributed a lot to treatment and care management.

I am hoping you can take a look at it and see if we get your support to keep this network alive.

Secretary BURWELL. I will look into this one. This is one I am not familiar with, in terms of the change, so I will look into it.

Senator MERKLEY. Thank you.

And I will just close with a comment. I appreciated the ongoing funding for the National Institute of Nursing Research. The NINR typically allocates about 7 percent of its budget to research training to help develop more researchers who often serve as future nurse faculty, which is facing a growing shortage. They sometimes are able to address some of the pieces that get left out of pure disease, science side—end-of-life events, directives, bedside support, so on and so forth, palliative care. I appreciate that the budget does provide \$146 million to continue the institute. Thank you.

Secretary BURWELL. Thank you.

Senator BLUNT. Thank you, Senator Merkley.

Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman.

Welcome to the Secretary, my fellow West Virginian. We are very proud of you in West Virginia. I think that I said that last year, and it continues to be so. Thank you for your great representation and for your great communication with all of us.

OPIOIDS

I have a couple things quickly. President Obama came to Charleston, West Virginia, to talk about the opioid issue. You have put a lot of emphasis on it. You have mentioned this medical-as-

sisted treatment, greater emphasis in the budget on that. Some of it is targeted toward rural areas. Am I correct in that?

Secretary BURWELL. That is correct. We already, in our current funding that we have that you gave us last year, communities with high need, and many of those are rural, so we are using existing funds to do some of that targeting as well.

Senator CAPITO. The budget that was bumped up in December with I believe it was an additional \$100 million, have those dollars been spent yet? We are working a bill through the Senate right now.

Secretary BURWELL. With regard to that, those monies are going against the three priorities that we have articulated. One is medication-assisted treatment. The second is making sure that we do the appropriate work on prescribing. CDC, I think you know, is about to issue new guidelines. We want to make sure those guidelines get to the right people. The third area, and this is where money is moving right now, is naloxone and Narcan. So when you get to that situation where a person has overdosed, we can try to save their lives.

Senator CAPITO. On the prescribing issue, I have been working on an amendment to have the protocol set up for acute pain, so if you have a toothache or something, what are protocols for pain medications on that?

ALZHEIMER'S

Alzheimer's is another area of interest for me, just formerly being a family caregiver for both of my parents, it is emotionally challenging, and it is very expensive. I do not think the training is in place. What kind of arenas are you going into to try to help families and caregivers who are not really trained for this to meet this enormous challenge?

Secretary BURWELL. There is the money that is at NIH that is more focused on the science, which I think gets to a little bit of the caregiver issues in terms of, if we are better able to do prevention and care for the individuals.

But the piece in terms of the caregivers themselves is more at the Administration for Community Living. Last year, at the White House Conference on Aging, I think it is every 5 years, maybe every 10. But last year's conference, we spent a lot of time, and we actually did regional meetings across the country. This was one of the issues that we focused on, both in terms of getting input for what would be the agenda when we came to Washington, D.C., but also trying to make sure that we are putting out as much information as we have as easily as we can.

But it is a place where I will say I think we can do more and better.

Senator CAPITO. Yes, I would say, definitely. As the population ages, it hits every family. It is very difficult.

I think the BRAIN Initiative is terrific. I know West Virginia University is participating in part of that, and I am very pleased about that.

HOSPICE

The other issue I wanted to talk to you about was hospice. I am not sure, I think we have written to you. We understand the need to audit Medicare providers, but some of our hospices have a backlog of appeals at the Office of Medicaid Hearings and Appeals, for hundreds of thousands of dollars. The local hospice in my area, you are holding like over \$1 million worth of payments while they go through the appeals.

That is difficult on a nonprofit organization that I think really has great services.

Is this a function of not enough administrative law judges? What is the backlog here?

Secretary BURWELL. So the backlog that we have in Medicare appeals is related to a number of issues. It is related to administrative law judges. We asked for the funding. We put together a three-part strategy to reduce the backlog.

Number one is administrative actions that we can take to create a process that works more quickly. We have taken those steps.

Number two, we have legislation. And on the Senate side, the Finance Committee actually has passed portions of that legislation. We need statutory changes. It would be helpful to get that.

And the third is money so we can actually increase our numbers of administrative law judges.

Senator CAPITO. Have you asked for that in this budget?

Secretary BURWELL. We have. We have.

Senator CAPITO. Lastly, you have mentioned two or three times about a \$419 billion savings in Medicare. When I was looking through your statement, I noticed that you referred to alternative payment models. What is an alternative payment model, simply?

Secretary BURWELL. An alternative payment model is sometimes called an accountable care organization. These alternative payment models are places where we pay for value, not for volume.

So what that means is, instead of paying for the number of services, you pay for an episode of care or the result for the individual. We do that in working with providers and insurers and others across the country.

The Center for Medicare and Medicaid Innovation is where we do these demonstrations and experiments. We are already seeing results. We have seen over \$400 million in savings in terms of these accountable care organizations.

So they focus on, you get the benefit if you get well people, and you treat them for their wellness and the results, versus service by service.

Senator CAPITO. Well, we will have to have an extended discussion on that. It is very complicated.

Thank you very much.

Secretary BURWELL. Thank you.

Senator BLUNT. Senator Durbin.

Senator DURBIN. Thanks a lot, Mr. Chairman.

Madam Secretary, thanks for being here. In this room at this table sit some people who have done some amazing things in this year's spending when it comes to medical research. And I give spe-

cial credit, of course, to the chairman and to Senator Murray on this committee, Senator Alexander on the HELP Committee.

Virtually 5 percent real growth at the National Institutes of Health. It is a shot in the arm and an encouragement to medical researchers that we are serious about our commitment to biomedical research.

CDC, similar increases. I think CDC is our Nation's first line of defense when it comes to national health security. We should start describing it as such, because day in, day out, year in, year out, that is their mission.

I was disappointed with your budget. I will accept Senator Alexander's analysis that sometimes you cut in areas where you know Congress is going to step in and fill the void. I hope that is the case here.

But what the chairman said at the outset, counting on mandatory spending to make up the difference is a risk I hope we never take. We should do our part on the discretionary side, and hope, as Senator Alexander described it, that we can supplement that with some commitments on the mandatory side.

I just think we make a serious mistake—and Dr. Collins has told me as much; I am sure he has told you—if we do not have constancy in our commitment to biomedical research. There is just a real question by researchers as to whether they ought to take the risk and continue in the field, if there is uncertainty about funding in the future.

So I am looking forward to working with you and Senator Murray who bridges both committees, HELP and the Appropriations Subcommittee, and Senator Blunt, to achieve that goal.

PREScription DRUGS

I would like to ask you, if I might, on the issue of opioids and heroin, 80 percent of heroin users start with opioid prescription drugs. That is a number that has been repeated many times. I would like to ask you about two things.

What is the responsibility of pharma when it comes to this current challenge? They are generating, I am told, 14 billion pills a year, opioid pills, enough to provide a 1-month prescription to every adult American. Clearly, they are flooding the market with product.

That has to be part of our calculation about why we find ourselves in the position we are in.

Secondly, what are we doing in this world of pain management? You and I have talked about this on the phone. Understanding physicians have a responsibility when it comes to pain management, understanding it is a subjective statement as to whether I feel good or do not feel good, I think there is still a question that should be raised as to whether there is proper management by the physician when it comes to pain.

Handing someone 40 or 50 pills, as we have heard in testimony in other committees, is overkill in many instances, and putting more pills out into the potential illegal market.

So in those two areas, pharma's responsibility and the responsibility of physicians, what would you suggest?

Secretary BURWELL. So in regard to pharma, I think two of the most important things that pharma can do right now is develop true abuse-deterrent products for existing opioids. The other thing is that they need to develop products for pain that are not addictive, in terms of the research and the work that they need to do in these spaces, at the same time making sure that in all of their work that they are making clear the dangers of addiction.

That brings us really to the bridge to the second issue, which is the prescribing, and how the prescribing goes.

Ms. Capito mentioned bills and approaches to limiting that. I think we believe right now one of the most important things we can do is put out new prescribing guidelines and then make sure people are trained in them.

I am sure you all have the same conversations I have with physicians. When you talk to a physician and you say, how much time did you spend in training on pain, and usually the answer is a very small number of hours, if at all. So making sure that we make the advances in terms of that.

At the same time at NIH, we need to continue our research both on the opioid and the treatment of pain side and what work we can do there.

So prescribing, though, is an essential key, as you reflected. That large number pills, they are going out time and time again. We want to make sure that we are doing everything we can to do that.

The NGA (National Governors Association) just put out a number of proposals that we think align with our three-part strategy, and we are going to continue working with them as well.

Senator DURBIN. Some States are monitoring this, and others are not. Shouldn't we have a national standard, if we are dealing with a national crisis here? Why would we have reporting in some States, so we can monitor abuses, and in other States not have it?

Secretary BURWELL. So prescription drug monitoring programs exist in all States but one in the union. They are, as you are reflecting, at varying levels of quality. And the other thing that is a problem with them is their ability to talk to each other.

I did speak with the Governors at the recent NGA about getting regional compacts, so we can get some alignment. I have 2 years running have brought together representatives from each of the Governors, all 50 States, so that we start sharing best practices, so we can start to raise the level of these prescription drug monitoring programs, because that is the other thing if you talk to physicians. They say it is hard to use—different technologies, number of clicks, those kinds of things.

So working to get best practices and working to get them to communicate across State lines, and I think in the Northeast, we will get a regional compact.

Senator DURBIN. Thank you.

Senator BLUNT. Thank you, Senator Durbin.

Senator Moran.

Secretary MORAN. Mr. Chairman, thank you very much.

Secretary, thank you for joining us. Thank you for your phone call inquiring about anything we were interested in visiting with you about.

I am always interested in a number of issues that face rural hospitals, community pharmacists. I would again express my gratitude for the times that CMS, in particular, but your department, has worked with us to try to solve individual issues that create what appears to be insurmountable problems for a community attempting to deliver healthcare to patients in the region. I just would thank you for the past cooperation and ask if you would continue that and encourage the folks who work with you to understand the distinction and the difficulties that many small town, rural providers face.

Let me focus for a moment on NIH. I apologize that I was in the Commerce Committee, but perhaps you have addressed this.

But the mandatory issues that your budget raises are troublesome to me, particularly in light of what occurred last year. Congress is stepping up and increasing the support under the leadership of this subcommittee and our full committee. I would encourage you to work with us on budget solutions that are likely to occur once—you continue to propose, in some instances, user fees.

I chair the subcommittee on the FDA budget. User fees there, mandatory spending here, are unlikely to be solutions to the budget challenges that you believe your department faces.

WELDON AMENDMENT

Then I want to ask you a specific question related to the State of California. This involves the issue of healthcare provider coverage for abortion. Religious entities, as you would know, have moral objections. They are protected by something called the Weldon Amendment.

You were asked a year ago about this issue and indicated that an ongoing investigation was occurring. The allegation is, as you know, that California requires its providers to provide abortion services. That presumably violates the Weldon Amendment that prohibits that requirement.

Your answer a year ago was that the investigation was occurring, and it would be completed expeditiously. It is now a year later, and my question is, is it the opinion of the department that the order of California is a violation of the Weldon Amendment?

Secretary BURWELL. With regard to this issue, I think you know when it was raised with me, raised both externally but raised by Members of Congress, we opened the investigation with the concerns that have been expressed. The investigation is still open, so my ability at this point to comment specifically on the question you asked, we need to wait for the completion and the finalized investigation for me to comment on the specifics of what the outcome of that investigation is.

So we are not there yet. When we are, we will make sure we communicate.

Senator MORAN. That investigation has been ongoing for how long?

Secretary BURWELL. The investigation has been ongoing for well over a year.

Senator MORAN. Do you have any opinion as to when that will be concluded?

Secretary BURWELL. My hope is that it will be soon. I wish I could give you a timetable, but I do not want to do that because it is an open investigation.

Senator MORAN. I will let my question stand for my concern, criticism. I am worried that this is an issue, as you know, that has differences of opinion about the outcome. But in my view, the law is clear and California is violating the law. It is the administration's responsibility to enforce the law. And I worry that there may be a plan afoot in which this just continues to the end of your term and the end of the administration, as compared to fulfilling your responsibilities.

Secretary BURWELL. I hear your concerns, Senator.

Senator MORAN. Thank you, Secretary.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Moran.

Senator Schatz.

Senator SCHATZ. Thank you, Mr. Chairman.

Secretary Burwell, thank you for being here.

TELEHEALTH

The last we spoke, we were talking about telehealth, and we were talking about the sort of two tracks to move on. Since then, we have had some pretty good legislative collaboration. Senators Wicker, Cochran, Cardin, Thune, Warner, and myself, as well as a bipartisan group on the House side, introduced the CONNECT for Health Act, which attempts to amend 1834(m) in such a way that does not cost any money to the Treasury but also improves outcomes and reduces cost.

My question for you is, we also talked about what you thought you could do within the existing statutory authorities to expand the use of telehealth. I wonder if you have an update for me?

Secretary BURWELL. We have expanded the number of categories, that we will pay for in that space, so I think that is one of the advances that we have made. We are also using telehealth in situations right now with the tribes. Right now, tribal suicide in the Great Plains is a very serious issue. Our ability to get providers there for those children—it is child suicide. So we are also working there in new ways to do that.

In addition to the administrative actions, though, there are two important statutory actions that are part of this budget that I think are important to highlight because we would like to get these authorities. One is, in this budget, you will see money for HRSA, and this gets to the rural issues that we are focused on. HRSA, some of our federally qualified clinics, can actually be the sites to do the telemedicine, so we can get that access in rural America. There is money for that in this budget.

The second area is in Medicare Advantage and helping us make some changes statutorily so we can use Medicare Advantage funding to pay for telehealth, because one of the prohibitions to the growth of telehealth is the ability for it to be paid for, so the question of whether providers will provide it or not.

So we are doing things administratively. There is legislative movement. Thank you for your leadership. And we do have two

very specific things in the budget that we think will make a difference.

Senator SCHATZ. We will continue to support you on that. Some of those provisions are included in our legislation, so whichever vehicle ends up succeeding, I think we are on the same page.

Are there additional administrative actions that are on deck, or do you think you have pushed your authorities to their limits?

Secretary BURWELL. I think we have pushed our authorities, although we continue to look and examine where we can continue to add, as we have in terms of adding conditions. But I think we need a little help in terms of the payment issues.

MEDICARE ADVANTAGE

The other place that we are working on, in terms of administratively, I should mention, is as we are working with accountable care organizations, coming back to Ms. Capito's question, a number of the accountable care organizations are using telemedicine as means by which they can serve their patients better. So there are ACOs that are doing it.

Senator SCHATZ. Yes. Can you talk about the Medicare Advantage proposed change? I think it is an important way to make sure we can—for Hawaii, it is 40 percent, 50 percent of the market. It makes a big difference, and it potentially addresses some of the CBO concerns. So can you flesh that out for us?

Secretary BURWELL. Just the idea that if we can get to the space, as you said. Medicare Advantage continues to grow, and the coverage of Medicare Advantage across the country, not just in Hawaii, there is deep penetration. So once we can change that payer model, in terms of having Medicare Advantage, we think we can lead as a government as a payer, and then others will follow in terms of if we can set a standard and have that access to do that.

Senator SCHATZ. Thank you.

Last week, CMS announced a partnership with Hawaii to help navigate how to best leverage Medicaid in the effort to reduce homelessness. We are encouraged by this partnership, and we are thankful for working with the State of Hawaii.

We have a terrible problem with homelessness. It is unique among the States, because of our geographic isolation and because of our cost of living, in particular the cost of housing.

As you know, a lot of these individuals are more likely to have complex medical needs. Can you describe how HHS is supporting efforts to permanently house medically fragile individuals?

Secretary BURWELL. Yes. So in addition to the work we are doing directly on homelessness with Hawaii, the broader issue that I think gets to issues that each of you probably face in your State, in terms of the medically frail and other issues, is right now as part of the Center for Medicare and Medicaid Innovation—and this is just such an important place where you all give us authorities and money—right now, we are actually doing a demonstration to understand when people are coming into the healthcare system, if you can establish whether there are certain other needs that you can connect them to the services, that then you can reduce healthcare costs.

What we know is so many people, the emergency room visits have to do with other complications in people's lives. So what we have seen in some work in the private sector is, when you actually ask the question about if the person is homeless, do they need connections, sometimes to behavioral health services or other services, that we can actually reduce the cost, because they become more adherent to the drugs. Sometimes they are not taking the drug because they do not have food. If you can get them connected to the right place to get the food, they can take the drugs.

So there are a number of things that we think, as part of what you all gave us in those monies, we will have to measure and show that there are results financially and that you do not reduce quality of care and hopefully you increase it.

So those are the places we are working on it.

Senator SCHATZ. Thank you very much.

Senator BLUNT. Thank you, Senator Schatz.

Senator Cassidy.

Senator CASSIDY. Hey, Secretary Burwell, how are you?

Secretary BURWELL. Hello.

Senator CASSIDY. It seemed to be a special pleasure when you said it would be the last budget that you will present.

You know, we only have 5 minutes so if at any point I interrupt, it is not to be rude. It is just to expedite.

A week ago, before Energy and Commerce, you were asked, regarding the fact that the administration appears to be giving \$2 billion to the reinsurance program under the ACA (Affordable Care Act), which CRS says contradicts a plain reading of the law, knowing that you know that, knowing that you know of which I speak, just for context, I think it is Section 1341. It is the bottom of page 92, but it is 91 through 93, where this is.

On the Energy and Commerce Committee, they pointed out a CRS memo that said that you were given this \$2 billion "appears to conflict with the statute." You said that you had not had time to read the CRS report, but they gave it to you. That was a week ago.

So any thoughts now, after having had a chance to review as regards to why the administration appears to be conflicting with the statute?

Secretary BURWELL. Senator, we believe that we have the authorities. As I mentioned in that hearing, we actually published for comment and notice the approach that we were going to take to use those authorities, and did not have any of the concerns raised as part of that public process.

Senator CASSIDY. Just to point that out, I can tell you I have seen comments in which it is buried within a huge Federal Register, so sometimes it is not seen until actually implemented.

But it says, "notwithstanding any other provision." I think maybe that is what CRS focused upon. Let me see if I can find it exactly here.

But nonetheless, it is very explicit. Money remaining unexpended should be used to make—notwithstanding the preceding sentence, any contribution shall be deposited into the general fund of the Treasury.

So the fact that \$2 billion, which explicitly was said to be put into the general fund—do you have a legal memorandum, which would justify your position as opposed to that assumed by CRS?

Secretary BURWELL. With regard to the decision that we made, I know that any of our rulemakings and any of this would have gone through our Office of General Counsel. With regard to the question of a memo, I do not know if it was done in that form.

I would say that we believe we have the authorities. And as one looks at this question, it is an issue that I think we are all concerned about, which is downward pressure on health care costs.

Senator CASSIDY. Now, if I may interrupt, again, we have limited time. And that is what you mention on the Energy and Commerce Committee.

There is a certain letter of the law and spirit of the law. I think you are arguing now that that we, by the spirit of the law, would want to decrease, et cetera. But the letter of the law said that, notwithstanding any other provision, the money shall be put back into the Treasury.

If your attorneys have had the chance to review that CRS memo, could you share that with us, because if we are a Nation of laws, whatever we think about the ACA, if we are a Nation of laws, it cannot just be expediency. It has to be what Congress passed. I voted against it, but Congress passed it.

There is a sense right now that it is expediency. It is not the letter of the law, not even a kind of plain reading of the law, CRS would put it.

If I may pause and move to something else, and I do not mean to be rude, but there is just such limited time.

Next, I understand there is going to be a demonstration project which would decrease—you mentioned earlier value-based reimbursement for drugs. And currently, as we know, there is the average sales price plus 6 percent. I think the fear in the administration is that might be incentivizing the use of more expensive medicines.

I am told there is a demonstration project that will be rolled out in which that will be modified, if you will. You know far more about this than I, so if you tell me I am wrong, I will accept that.

What I do not know is, will it just be a decreased percentage? Will it be ASP-plus 2 or ASP-plus 4? Or will there be a different model in which value-based purchasing is going to somehow be used to judge what should be the reimbursement or the percent reimbursement on a drug being used.

Secretary BURWELL. With regard to the specific of rolling out a proposal, I want to be very careful. This is obviously market-moving information, so I won't speak to the specific.

But with regard to the general point, I think there is general bipartisan, actually, support for the fact that when you pay someone based on X plus 6 percent, that you actually are going to encourage the person in terms of their own economic well-being to do that. So I can speak to the broader issue.

With regard to the specifics, we will have more to say soon.

Senator CASSIDY. Okay. Got you.

My gosh, rarely do I exhaust my questions before the end of my time, but we were so efficient, thank you.

I yield back.

Senator BLUNT. Thank you, Senator Cassidy.

And there will be time for a second round here.

Senator Lankford.

Senator LANKFORD. I ask unanimous consent for his 39 seconds left over.

Senator BLUNT. Denied.

Senator LANKFORD. Secretary Burwell, good to get a chance to visit with you again. Thanks for the way you always come through and answer our questions. I have many questions as well.

HOSPITAL REIMBURSEMENT

Hospital Consumer Assessment of Healthcare Providers and Systems survey, one of our favorite surveys when you are checking out of the hospital to be able to kind of score your own hospital, which is part of the ranking. You have mentioned multiple times about the opioid issue. I have a concern, hospitals have a concern, that they are being graded and reimbursed based on how they treat pain in the hospital, and that if someone leaves a hospital, which, frankly, by definition, when you leave a hospital, you are going to experience pain—you don't go there because of the spa treatments—that if you leave the hospital with pain or feel like the pain is not being taken care of while at the hospital, which incentivizes the hospital to overprescribe, that they get a bad score and they are not reimbursed as high.

The simple question is, have you looked at that language lately? Have you evaluated the possibility that CMS is incentivizing hospitals to overprescribe pain medicine, so they get a higher reimbursement because their scores do not go down?

Secretary BURWELL. Yes, we have looked into it. Mr. Alexander raised this issue with me, and we have actually done a look at it.

I think what is important to reflect is we are in the middle of the look at it. An initial look in terms of the analytics, the money is not enough. It is a very, very small percentage. Having said that, I believe, and have gone back to the team, that even if it is not about the economics, it may be about prescriber's belief. And it may be that they behave in ways that are not economically driven and, therefore, we need to go at this again.

So yes, we have looked at it.

Senator LANKFORD. I would agree on that, and I would tell you that hospitals do not tell me that the money is not enough. Right now, they are counting every single penny. To them, that is a significant issue, and there seems to be an incentive to be able to push doctors—I am not saying that hospitals are forcing them, but it is one of the questions they are going back to make sure everyone—is everyone treating pain, because we are going to ask them when they leave? That creates a very perverse incentive.

RECOVERY AUDIT CONTRACTORS

Now let me talk about your favorite subject, RAC (Recovery Audit Contractors) audits. I cannot imagine anything we would want talk about more fun than RAC audits.

I questioned one of our hospitals of many just about how RAC audits are going and what is happening with that. They sent me

49 denials that they have. Thirty-nine of the 49 have so far been overturned. All of these are related to a signature that was not there, or a date or time was not there.

The question goes back to you, "Was it medically necessary?" Yes, they were shown to be medically necessary.

But the RAC audit proposal and what we are trying to approach with RAC audits, my understanding was this is going after fraud and medical necessity. It seems to be a tremendous amount of money. Just this one group is at \$650,000 that was about signatures and date and time.

Secretary BURWELL. So we have changed our policy since our last conversation that I hope in ways that will take care that.

So an audit, if one of these is overturned, as you just indicated those were, people will not be paid. The other thing is, if it is over 30 days, they will not be paid.

So much of the feedback that we have received from folks like you and your constituents, we have taken into account and now have different policies in place.

Senator LANKFORD. Is there a possibility to have a financial incentive on the auditors themselves, that if they are pulling files that are then overturned, that there is a financial penalty on them?

Secretary BURWELL. I think the economics for them in terms of spending time on something you will not receive anything for is an economic incentive. Is it enough—

Senator LANKFORD. Even if there is a small penalty in there just to incentivize them to pay attention to it does help, because if they scoop up a bunch and only 20 percent get pulled, the incentive is to pull up a larger amount, because then if only 20 percent are going to actually go all the way through, get a larger amount with 20 percent.

There is a whole series of issues that are here. Dealing with the contingency fee structure versus flat fee. Reducing the lookback period so not as long. I think it is 5 years now, if I remember that correctly. Lowering that a year, 6 months, whatever it may be, so there is not this perpetual sense of a long lookback on it. Trying to deal with good actors. When a provider has consistently shown they have been good at it, not pulling as large of a group. Trying to coordinate between the RAC audits and ZPICs (Zone Program Integrity Contractors) to make sure they are not getting both at the same time that are coming at them.

A lot of issues that are out there that I would love to be able to just send you some of these things. I know you are working on them.

The issue about the reimbursement, they are not paid for it. I understand that. That was taken care of a long time ago.

But there is still more to go. We are still creating a hostile environment.

Secretary BURWELL. So we welcome your suggestions and thoughts, and I think one of the things we all want to do, though, is make sure that we are eliminating fraud in the Medicare system.

Senator LANKFORD. I would totally agree. That was the intent at the beginning. Not giving the date, time, and a signature in the right spot on the right sheet is not taking care of fraud. That was medically necessary, but we are now holding large files for it.

WELDON AMENDMENT

One last thing I want to get a chance to get to is going back to something that Senator Moran had mentioned before on California and the Weldon Amendment issues. Have you gone to the Office of General Counsel to ask a legal opinion about California and the Weldon Amendment? Has that been done?

Secretary BURWELL. The Office of General Counsel will be involved. The Office of Civil Rights does the investigation.

Senator LANKFORD. Correct. Has that formal request already been made of them to give a legal opinion to you on it?

Secretary BURWELL. With regard to the question, the General Counsel's Office is a part of any of the conversations with OCR. I am not sure when you say "formal request."

Senator LANKFORD. Just to be able to make sure—this is a legal question that is out there that seems pretty cut and dry.

Yes, it is clear California is violating the law. I cannot seem to find any wiggle room. And 18 months later, we are still getting, "We are still investigating." We want to find out how thorough is this investigation after 18 months and a clear violation of law.

Secretary BURWELL. The General Counsel is deeply involved.

Senator LANKFORD. So can we get a copy of some of those reports that are coming in, so we can track what is happening?

Secretary BURWELL. We are in the middle of an investigation, and when the investigation closes, we will communicate—

Senator LANKFORD. Which you would expect by when?

Secretary BURWELL. As I said to Senator Moran, at this point, I do not have a timetable, but I do expect us to come to closure.

Senator LANKFORD. Eighteen months is a long time to look at something.

Secretary BURWELL. I appreciate that.

Senator LANKFORD. So it is still unknown. It could be another 18 months.

Secretary BURWELL. I do not think it will be another 18 months, because I will not be here.

Senator LANKFORD. So it ends at the point?

Secretary BURWELL. I do not want to commit to a time table, but I think your question is, is this an issue that will become resolved, I think it is your question.

Senator LANKFORD. Yes.

Secretary BURWELL. And I look forward to doing that.

Senator LANKFORD. In your time.

Thank you. I yield back.

Senator BLUNT. We will start our second round with Senator Murray.

NALOXONE

Senator MURRAY. Thank you again, Madam Secretary.

We have talked a lot about opioids. You spoke about the need to increase medication-assisted treatment to solve the opioid crisis, the importance of naloxone.

Could you talk a little bit about how your budget increases access to that lifesaving drug?

Secretary BURWELL. With regard to naloxone or what some refer to as Narcan, we are using some of the monies that we have available right now. But a portion of the money, of the \$1.1 billion that we have asked for, would be for those.

What we would want to do is get that money to communities so that first responders can get those treatments and get that out. Some of the money would need to be used for training, so we make sure people know how to use it. But we want to get the money out.

In addition, we are complementing those efforts. The FDA just approved recently the most recent nasal naloxone or Narcan, which will mean that others can be able to give it out in terms of people who are trained in terms of injections. So we are working on that side of it as well.

Senator MURRAY. That is part of your budget?

Secretary BURWELL. It is. The FDA, has already approved it and is moving forward. But we want to make sure that the monies will go toward whatever types of access people want, whether it is injection or nasal.

ANTIBIOTIC RESISTANCE

Senator MURRAY. Okay.

As I said in my opening statement, I am concerned about many pressing needs facing the subcommittee, but one area I did not talk about that really worries me is combating antibiotic resistance.

As you know, we face the prospect of living in a world where antibiotics are no longer effective. Your request includes an additional \$40 million at CDC for the second year of an initiative to address antibiotic resistance, which brings the total to I believe to \$200 million. I applaud that increase. It is significantly less than you requested last year, which was \$264 million, and you are not requesting an increase at NIH or BARDA for addressing antibiotic resistance.

So I wanted to ask you, where do we stand in our fight against antibiotic resistance? And are NIH and BARDA developing promising new drugs in the pipeline? Is there more to come?

Secretary BURWELL. Yes. In terms of where the money is focused, NIH is focused on making sure that we are developing the antibiotics that are not resistant. At the same time, diagnostics are also a very important part of this, in terms of our ability for people to go and be tested and, no, you do not need an antibiotic. Many people demand it because they think that is what they need, and our diagnostics are not fast and quick enough. So that is part of the research.

BARDA is deeply involved as the drugs and things are coming through, and the research gets to the place where we can work with the private sector to move those along. That is the part that BARDA is playing.

I think with regard to our effort, it is both research and there is the other part of the effort, which has to do with animals and the question of prescribing in animals. Through FDA rulemaking, we are working to get to a place where people only prescribe actually for conditions in animals where there is something wrong with them versus using these kinds of antibiotics for growth and other issues.

Also making sure that when they are going to be used in animals, that they are going to be used with a veterinarian, in terms of prescribing and making sure that it is being used in an appropriate form.

Senator MURRAY. So it is not blanket.

Secretary BURWELL. That is right. So working on all of those fronts.

The other place that I think that is very important—I am glad you raised the issue. I just had the Global Health Security Initiative group of countries that President Bush started after 9/11. This is a group that met in October 2011 to address—and it is our partners like Japan, Mexico, the G-7. They are many of the partners.

This is an issue that we talked about specifically. There is a lot of energy on antibiotic resistance, and I think we may even hear conversations about it at this year's United Nations General Assembly.

Senator MURRAY. Because it is an international discussion.

Secretary BURWELL. Yes. So we have our plan. We have a strategy as the United States, but we are also working around the world and in partnership with others. The British have a leadership role. The Germans have a leadership role here, too.

Senator MURRAY. Good. I really appreciate that. In talking to doctors at the Children's Hospital in Seattle and hearing that kids are born today resistant, and there is nothing they can do when they are 4 or 5 days old. This is an increasing problem.

WOMEN'S HEALTH

Finally, I wanted to ask you, for a lot of women, the Affordable Care Act expanded coverage of all FDA-approved contraceptives has reduced their out-of-pocket costs and given them access to more effective methods. In fact, we know that women have saved nearly \$500 million because of this provision.

But unfortunately, we are still hearing from women experiencing difficulty in getting guaranteed no-cost coverage from their plans. I understand some insurance carriers are not adhering to the requirements. I wanted to ask you if you knew which carriers are requiring cost-sharing, are declining coverage, or are otherwise limiting coverage for contraceptives?

Secretary BURWELL. Since we last spoke, we put out additional guidance to the insurers to make sure they know. If there are cases that you are hearing from your constituents, if you can let us know, because then it becomes an enforcement matter.

Senator MURRAY. Okay. That is really important, and we will do that. I hope you will follow up on that.

Secretary BURWELL. Yes.

Senator MURRAY. Great.

Senator BLUNT. Thank you, Senator Murray.

Just as an aside, this is not really a question, but on the mandatory funding issue, which I have great confidence that Senator Alexander and Senator Murray and their committee are going to look at in a way that does not slow us down with discretionary funding, I will say the history of mandatory funding would discourage you on that front.

Congress added mandatory funding for community health centers. There has been no increase in that discretionary account since that happened.

We had mandatory funding for the National Health Service Corporation. There has been no discretionary funding at all for that, since it went mandatory. I noticed in your budget this year you are asking for discretionary funding again for the National Health Service Corps.

It probably does not have to be that way, but I will tell you it has been that way. Whenever there is a mandatory component that steps in, the history has been that the whole focus is on maintaining the mandatory component, not on what used to be the discretionary funding. And I would hope that would not happen again.

PAIN MANAGEMENT

Senator Murray had a question about antibiotics that led me to another thought on pain I meant to make. Is there any advance being made in trying to find less addictive pain alternatives? What can we do to encourage that?

Secretary BURWELL. It can happen in a number of different ways.

One is the pharmacy question and making sure that pharmaceutical companies are developing drugs that actually are not addictive that can be treatments for pain.

Another place where we can make probably some advances is actually in how anesthesia is done, because if anesthesia is done in a way that a person does not have acute pain in the first 24 to 48 hours after surgery—and it can depend on anesthesia that was used to put you under.

I recently had a conversation with medical providers about that issue. The Governors, actually, are the ones who brought up that issue.

But I think the other place where we are as a government working on it is actually the Veterans Administration. The V.A., as I am sure you know, has a lot of patients with a lot of pain. And one of the things that Secretary McDonald is focusing on are alternative approaches to pain, whether it is approaches like acupuncture or other issues that people can use as alternative approaches to pills for pain.

So working across that whole suite of how we can treat pain at the same time we reduce the prescribing, I think we need to do both of those steps at once.

RAC AUDITS

Senator BLUNT. I hope we can find solutions there and in other places.

On the RAC audit topic, I appreciate what you have had to say about that. I think clerical errors are not what we should be headed for here. We obviously should discourage needless clerical errors, but that should not become a reason to hold somebody's money for multiple months at a time.

Last year, we provided a \$20 million increase. It was a little less than you asked for, but this year you have asked for \$90 million more. What do you think \$90 million gets you beyond where we are today?

Secretary BURWELL. I think it gets us a major reduction in the numbers. As I said, we want to work across a three-part strategy. Our success is going to be dependent on the funding of the administrative law judges, as well as some of the statutory changes. If you get both of those together, I think we can reduce this backlog much more quickly. So the interaction of how much the money will help, but at a minimum, we know we are increasing the productivity of our administrative law judges by having the administrative changes we are doing. We are increasing what is going to come in and what we can process. Some of that has to do with settlements and moving things through more quickly.

We have asked for the money that we think can put us on a path to get that backlog down. I think you know, right now, it is hundreds of thousands.

Senator BLUNT. And what are you gaining by now looking at clerical errors different than fraud, in terms of the backlog.

Secretary BURWELL. I will have to go and check on the specific issue of things like signature and how they go through the system. I apologize, I do not know the answer.

Senator BLUNT. Whatever you do there I think will be very well-received by all of the people who are impacted, including the committee, because we are constantly hearing from the healthcare providers that we represent that they are winning case after case after case, but the money is held for a long time. By the time they get it, other problems have been created because of the fact they did not have the reimbursement that they were qualified for.

It sounds like to me, hopefully, we are headed in a much better direction there.

I have a couple other questions, but Senator Cochran.

Senator COCHRAN. Mr. Chairman, there is some concern about whether or not the Appropriations Committee's prerogatives are being supported not by the administration in its totality. But a review suggests that they are requesting funding through legislation under the jurisdiction of the legislative committees instead of through the Appropriations Committee.

Is this accurate or is my staff confused?

Secretary BURWELL. Are they referring to the mandatory requests?

Senator COCHRAN. Yes.

Secretary BURWELL. I think this is a question, and we have seen it. Mr. Blunt just gave the examples of where these issues have crossed over. I think your point, Mr. Blunt, was not successfully for the long term, I think.

But we have seen it occur on either side. I think this comes to the question of where we want to be as a Nation with regard to our levels of discretionary spending. And I think the important issue that we try to meet in terms of the standard that we know people care about is making sure things are paid for, in terms of as we put the stuff on mandatory, we did not just add to the deficit. We put in mechanisms overall that we believe are paying for it.

The question of how we get there with the partial buyback of sequester in already what were probably, some might say, tighter levels before the sequester and how we do it, I think it can be done in any number of ways. I think we are trying to do it in a way that

is paid for, but also sticks with the sequester and the caps that are given.

How it works and whether or not the caps can go up, we could move to a different place and pay for that again, as we have starting with Ryan-Murray a number years ago, I think we are open to the conversation. We try to provide monies so that it can be covered. I think that is one of the most important things, whether it is on the mandatory or discretionary side, how it impacts the deficit.

Senator COCHRAN. Thank you.

Senator BLUNT. Senator Alexander.

Senator ALEXANDER. Thanks, Mr. Chairman.

I want to go back just for a moment to the question of discretionary and mandatory funding again, particularly while these three Senators are here and I am here and you are here.

NATIONAL INSTITUTES OF HEALTH

I agree with Senator Blunt. There is a real risk in depending on mandatory funding for the increase we want to see in a bipartisan way for the National Institutes of Health. Some will want to see more and some will think we can afford less, but there is an unusual consensus right now that we want to take advantage of this period of time, this exciting period of time in science that has the opportunity to help so many people. And for my part, I am not interested in seeing mandatory funding replace discretionary funding. I would like to see us have a goal.

We did this in the Energy and Water bill to deepen our harbors. We saw that as a national imperative and Congress said this is the funding goal that we want over the next several years, and we have met it for the last 2, and we are making pretty good progress on deepening our harbors before the Panama Canal widens.

Now this is a different and I would think more urgent issue. So I would like to not think about mandatory funding as a replacement for what we should be doing with discretionary funding. I think we should build on the 5 percent increase of this past year's discretionary funding and continue to move upward and forward, if we possibly can.

That is hard to do, but that is our job to set priorities. So I think about mandatory funding, and I am being a little repetitive here, as in addition to that. When I think about it that way, I want to make it hard for people to think of mandatory funding as a substitute.

So one way, and several of us have talked about this, is to have this innovation fund to take several areas where Dr. Collins, you, the President have said these are urgent areas, and they have a timeline and they have a beginning and an end.

So for example, we might add to the Precision Medicine launch X billion dollars for X years. When that was over, it would be gone. You could not say that is going to replace discretionary funding.

The same with 650 more young investigators for a period of time. Congress could replace that, but wouldn't have to. The Big BioThink Award, Dr. Collins has talked about that, giving each of the institutes an amount of money for the biggest idea in their field to see what that turns up.

The Cancer Moonshot, we have yet to hear exactly what that is, but we look forward to that.

Or let's take the BRAIN Initiative, Senator Cassidy even suggested this the other day, and I thought it was interesting. He said perhaps one way to think about it is as a surge of funding. The mandatory funding would be a surge on top of the discretionary funding.

So we would have the discretionary going up every year. That would be our goal. But we can move there more rapidly if we had a mandatory surge going on for the first 4 or 5 years, and then they come together and we would be closer. I thought that was pretty interesting.

So that is the way I am thinking about it, and I just wanted to say those things while we are all here.

Secretary BURWELL. Building on that thought and that approach, as you think about medication-assisted treatment and getting that initial capacity, the idea that what you need to do because behavioral health and many of these issues are taken care of at the State and local, and what we do is actually jumpstart the State and local communities' ability to get to a place where they have the capacity and then they take it on.

So to build on your idea, I think there are approaches that we can think through that might work in terms of your approach to thinking of it as additive, but not replacing.

Senator ALEXANDER. If I may interrupt, if you did it that way, let's say we had a 5-year surge to help launch Precision Medicine, we would not have to spend the same amount every year. In fact, that may be a waste of money. We might spend some this year, some next year, the most the third year, less the fourth year, and back down the fifth year. That might be the most effective use of money.

That can be done with mandatory. That can be done with mandatory funding.

So then I just want to reiterate the obvious. There is a lot in the legislation that Senator Murray and I are working on in support of Precision Medicine in addition to the money. The electronic healthcare records that you have given a lot of attention to, giving NIH researchers the authority to share their data, more flexibility so you can have more arrangements like the Google Vanderbilt arrangement that you announced the other day, strengthen privacy protections.

That plus the electronic medical records are absolutely essential to the Precision Medicine Initiative, as well as the money.

I just want to reiterate, none of that is likely to happen unless it is part of this bill we are doing.

So we have to get a result. We have to come to some consensus. And I hope we do it by about mid-April.

Senator BLUNT. Well, Secretary Burwell, on the research component and, in fact, on many of the things we are talking about, I think there is a commonality of goals here, shared goals, that hopefully we can figure out how to take advantage of. Our increase in NIH research was actually 6.6 percent. That is 5 percent plus inflation.

That is a goal that Senator Durbin said that if we just had that as our goal from now on, that would do a lot for families that would do a lot for taxpayers.

A statistic that gets anybody's attention when I use it is our projection that, on Alzheimer's alone, we are spending a quarter of \$1 trillion annually right now. We will be spending \$1.1 trillion of today's dollars by 2050, which is more than twice the defense budget. Most people, including me, when you say \$1.1 trillion, that does not trigger a whole lot in my mind that is more scary than some lower number than that. When you say twice the defense budget, obviously, whatever we learn from what will be relatively small investment in research is important.

But if you are going to have a pattern, the second year of a pattern is really important. So we did \$2 billion, added \$2 billion to the \$30 billion last year. This would be a terrible year to wind up cutting that by \$800 million. This would be a great year to add another 5 percent plus inflation, in addition to whatever else we can do for short-term ways to move us forward there.

MENTAL HEALTH

My last question is going to be on just mental health. I do appreciate your stepping forward and looking at Excellence in Mental Health.

Again, I will do just exactly what Senator Alexander did, while I have Senator Alexander and Senator Murray here, I would say when we were able to pass the demonstration projects on Excellence in Mental Health, which has been very well-received by the mental health community, the goal that Senator Stabenow and I had when we introduced that legislation was that the initial problem to be solved is having somewhere to go.

Having providers is really important. Various different ways to handle privacy issues that might relate to your support group is important. But if you do not have anywhere to go, none of those things really matter.

I know you are looking at a way we can move from 8 to 14 States. We are talking to CBO about some numbers that might let us move further than that, because I think, and this is the question for you, I think what is generally believed to be the case, and what initial studies have indicated, is that really is it not only the right thing to do, but it really does not cost anything in total healthcare dollars to treat behavioral health like all other health because it is so much easier to deal with every other problem that someone has that has a behavioral health problem. And I will let you comment on that.

Secretary BURWELL. Yes, I think it gets to the part of the conversation that we had with the Senator from Hawaii in terms of the importance of how these issues interact with our overall healthcare cost whether it is behavioral health issues or also the issues of homelessness, other kinds of things that inhibit people from getting to the health they do.

I think you know we had put the money in to build on the project that you and Senator Stabenow and Ms. Matsui on the House side have been very engaged in. I think you know we have worked with you to implement it faster than the statutory deadline in terms of

getting everything out, because we want to shift very quickly to what you said. Where there is equity in terms of behavioral health issues and places for people to go to do it, we think we can do that in ways, as I think you indicated, that can move us to a place where we have delivery system reform, too, the way you have done it in terms of quality measures, access for people, and getting to a base where you get better quality at a more affordable price.

Senator BLUNT. I think the way we have required the law enforcement community and emergency rooms to become the go-to place for behavioral health is outrageous.

Secretary BURWELL. It is.

Senator BLUNT. Just outrageous.

Also, on the opioid problem, and Senator Shaheen, we are coming right to her, and this is an issue that she has been very engaged in, in telehealth, I have an amendment that I believe will be accepted on that bill that would allow telehealth to also be part of the mix of things coming together for dealing with opioids.

Senator Shaheen.

Senator SHAHEEN. Thank you, Mr. Chairman.

Thank you very much, Secretary Burwell, for being here today.

Just to pick up on the comments about behavioral health, as you both know, and the committee knows I am sure, that is a critical piece of addressing the substance abuse problem that we have in the country. We are not talking about just treating overdoses and heroin and opioid abuse, but often there is a mental health issue that accompanies that. So we have to start looking at this as an integrated system that treats the whole person.

DRUG ABUSE EPIDEMIC

I very much appreciate what you have put in and the administration has put in to address the heroin and opioid—I call it a pandemic, because that is what it really is. We are losing 47,000 people a year. In New Hampshire, we are losing more than a person a day due to drug overdoses.

The chairman talked about the emergency supplemental funding that we tried to pass yesterday as we were trying to get the Comprehensive Addiction and Recovery Act through. I was disappointed that that did not pass, because as I have traveled around, what I hear, whether it is the treatment providers or whether it is families who have lost someone or are trying to get someone into treatment or law enforcement professionals, the issue is the same. And that is that they are looking for funding because they do not have the resources they need.

Just to give one example, I do not know if you have talked about this, but we have chronically underfunded the accounts within Health and Human Services that allow us to provide treatment and prevention. In fiscal year 2017, it would take \$483 million just to bring SAMHSA prevention and treatment block grants back to the levels in 2006.

With that as a little background, can you talk about how your budget will address the drug abuse epidemic and how you are coordinating with other agencies within the Federal Government to address this huge problem that so much of the country is facing?

Secretary BURWELL. Thank you for your leadership, especially in the area of the funding issue, which I think you know we think is critical and have discussed, because it is what you just said, Mr. Blunt, in terms of, if people cannot get access to the care, and if that is not available, and that is the issue. As I said, I have talked to the sheriffs who say, "I do not want to be a healthcare provider, and I do not want to be a social worker, but I see this person again and again and again. I have young men who are trained to do the law enforcement, but not trained to help a person get off of their addiction. We apply the Narcan, but then I am going to see them again."

So having that access and that is what the vast bulk of that money goes toward, in terms of the medication-assisted treatment. We need to build the capacity.

It is related to our behavioral health issues, that we do not have the capacity that we need across the country. That is why I am happy and open to thinking about, is it a one-time shot to get the capacity?

But as you reflected, the budgets of SAMHSA and other parts of our organization that deal with these issues have not grown with inflation over the past years.

That is why I think it is a critical moment for the increases that we need to see. I think more than anything, it is about the problem and the magnitude of the problem, because I do not know that one should argue that you should just grow. I do not believe that, having come from OMB. So I don't believe it is just about growth year over year. It is about need. So that is where I would focus the issue of the money.

With regard to our coordination with others, we obviously coordinate very closely with the Office of the National Drug Coordinator, Mr. Botticelli at the White House, and also with our partners. As I mentioned, V.A. is working on the pain issue, so I have met with Secretary McDonald, so that they can make progress in that space. I spent time with the Attorney General.

The PDM piece that we discussed earlier, the Prescription Drug Monitoring programs that I think it was Senator Durbin raised. Much of that work is actually done out of Justice. The other thing is drug takebacks are done out of Justice.

The other issues around heroin, we have talked about them in conjunction with the opioids and the transition that people make, but there is also the heroin coming into our country. That is more a Justice Department issue.

So working coordination, those are the main pieces. But also, as you know, Secretary Vilsack has become engaged on the rural part of this and is helping us in that space as well as a voice, a convener, and getting to one of the other attenuated issues, which is economics. USDA's sole focus is on rural economic development, so they are a part of that solution as well.

Senator SHAHEEN. Thank you.

Mr. Chairman, my time is up. Can I ask one more question?

Senator BLUNT. Go ahead.

ZIKA VIRUS

Senator SHAHEEN. Okay. Thank you.

I know that you are also focused on the Zika virus, and what we need to do to get in front of that. As you pointed out, it is very scary to think of what the potential impact of that could be. We just had a woman in New Hampshire who was diagnosed as having the Zika virus. Fortunately, she was not pregnant, but she had gotten it through sexual transmission with her partner who had been in the Caribbean.

Can you speak to the role of family planning, and the accounts that are included in the budget and the role that they play in the life of women and families as we look at something like a potential Zika outbreak?

Secretary BURWELL. I think one of the things we are very focused on is making sure that everyone has the information that they need to make the choices and decisions that they need to make, and that they have access to the tools that they need and want with regard to family planning and contraception.

Our budget, the supplement, proposes no changes to our approaches in terms of making sure that there is access. We talked a little bit about that access issue in terms of the Affordable Care Act and the idea that you can do this without copayments in terms of not being charged. So we are very focused on making sure that people have the right information to make the right choices for them, especially in the area of contraception and protection.

I think you know we have recommended that there be no unprotected sex for pregnant women who have partners who have traveled to the region. That is the guidance that we have offered from CDC during the entire time of the pregnancy. So as we learn more, we will continue to put out updated guidance, as soon as we get the research back.

I am hopeful that in the next bit, we will see more research in terms of women and their pregnancies and understanding if there is a more acute impact in that first trimester, like we have seen with measles and rubella. Does it follow that pattern or not? We do not know yet.

But as we get more information, people can make the choices across-the-board with regard to prevention, as well as uses of contraception during pregnancy.

Senator SHAHEEN. Thank you.

Thank you, Mr. Chairman.

Senator BLUNT. Senator Murray.

Senator MURRAY. Madam Secretary, thank you. I just want to clarify one thing, and then conclude. So your recommendation from CDC is that even if a man travels in October and his wife is pregnant, for 9 months, unprotected sex, coming back from traveling to a foreign country?

Secretary BURWELL. We recommend that they are careful because right now we cannot determine how long Zika lives in semen. We know that Zika lives in blood. Our research to date has shown Zika lives in a person's blood system, in terms of that, we think it is about a week after you have had finished to the disease.

But remember, for 80 percent of the people, you do not know if you have had it or not, because you are not symptomatic.

With regard to semen, we do not know yet.

Senator MURRAY. So it could be much longer.

Secretary BURWELL. We do not know.

Senator MURRAY. All right.

With that, thank you very much. I do have additional questions I will submit for the record.

But thank you very much, Mr. Chairman.

ADDITIONAL COMMITTEE QUESTIONS

Senator BLUNT. Well, the record will be open for additional questions.

One question I will ask for the record, but I want to be sure it was heard today is, I have heard lots of concerns about round three of the competitive bidding for durable medical equipment, with some concern that we are rushing through those changes too quickly and that they will have a negative impact on seniors living in rural Missouri. I will have two or three questions on that topic, and several others on other topics. The record will stay open for 1 week for additional questions.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

RISK CORRIDOR PROGRAM

Question. The Risk Corridor program was designed to be budget neutral over 3 years. In the first year of the program, insurers paid \$362 million into the Risk Corridor program while submitting \$2.87 billion in payment claims. Had the Labor/HHS bill not continued a general provision requiring the program to operate in a budget neutral manner, the Federal Government would have lost \$2.5 billion. Yet, the budget request includes, for a second year, a request to eliminate this provision. Why does the Department propose to eliminate this provision when HHS has issued guidance stating the program should be implemented in a budget neutral manner?

Answer. As in prior years, the Administration remains opposed to including policy riders in appropriations bills because they are an unwarranted limitation on Administrative flexibility.

It is important to note that we have made payments for the first program year of the 3-year program. Additional risk corridors payments for program year 2014 will be paid out of program year 2015 risk corridors collections, and if necessary, program year 2016 collections. We will not know the total loss or gain for the program until the fall of 2017, when the data from all 3 years of the program can be analyzed and verified. As we have said previously, in the event of a shortfall at the conclusion of the 3-year risk corridors program, the agency will work with Congress to provide necessary funds for outstanding payment.

Question. If the Risk Corridor account faces a shortage in its final year, do you intend to use discretionary dollars to make payments to insurers? Is that why you want the prohibition on using discretionary funding contained in the Labor/HHS bill removed?

Answer. It is not possible to know whether or not other sources of funding will be necessary. Additional risk corridors payments for the 2014 program year will be paid out of program year 2015 risk corridors collections, and if necessary, program year 2016 collections. As we have said previously, in the event of a shortfall at the conclusion of the 3-year risk corridors program, the agency will work with Congress to provide necessary funds for outstanding payment. We will not know the total loss or gain for the program until the fall of 2017, when the data from all 3 years of the program can be analyzed and verified.

Question. Will the Risk Corridor program be budget neutral over 3 years?

Answer. Risk corridor payments and charges are based on many factors, including how issuers price their premiums compared to the costs they incur, as well as any reinsurance and risk adjustment payments or charges. Risk corridor collections from subsequent years can be used to make payments for prior year shortfalls. We will not know the total loss or gain for the program until the fall of 2017, when the data from all 3 years of the program can be analyzed and verified.

PROJECT BIOSHIELD

Question. Madam Secretary, in fiscal year 2016, the Subcommittee provided \$510 million for Project Bioshield, \$136 million below the President's request. For fiscal year 2017, you requested \$350 million, \$160 million below fiscal year 2016. Why was there such a dramatic funding reduction to this key national preparedness program?

What priorities changed?

Specifically, what happened to the 12 medical countermeasures that were waiting to be purchased for Project Bioshield?

How will this reduction in funding impact our national preparedness? Will the Department be able to purchase enough medical countermeasures to protect the public?

Answer. Thank you for your ongoing leadership on this critical national security issue. Project BioShield is a shared national defense priority. The fiscal year 2017 President's Budget will enable us to make meaningful progress on vital medical countermeasure procurements. Unlike a grant or research program that supports a steady and recurring level of effort, the Project BioShield budget is made up of a different set of discrete procurements in any given year when medical countermeasures are mature enough in development to meet FDA requirements for accessibility under Emergency Use Authorization.

In addition to the fiscal year 2017 Budget request of \$350 million, the Department has obligated nearly \$50 million already for the purchase of anthrax antibodies out of the \$510 million from the fiscal year 2016 appropriation and has plans to obligate the remaining balance on new medical countermeasures (new anthrax vaccine, lyophilized smallpox vaccine, and radiation-related point-of-care biodosimetry devices) in the coming months. In fiscal year 2017 the new resources will enable the Department to procure small quantities of a few additional chemical, biological, radiological and nuclear medical countermeasures sufficiently mature for procurement, including:

- New Ebola vaccines and immunotherapeutics for the prevention and treatment of Ebola infections.
- New high throughput biodosimetry devices to measure internal radiation exposure following a detonation.
- New antibiotics for the treatment of bacterial biothreats and high priority antimicrobial resistant bacteria.
- New diagnostics for the detection of anthrax in exposed persons.
- Replenishment of anti-neutropenia cytokines for the treatment of radiation-induced blood illnesses.

In fiscal year 2014–2015, BARDA purchased five new medical countermeasures under Project BioShield and anticipates purchasing three new medical countermeasures in fiscal year 2016. Through its advanced research and development program, BARDA has built a robust portfolio of candidate products.

Additional candidates have the potential to transition to procurement under Project BioShield in the future.

BARDA and the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) are committed to maintaining our national preparedness and making sure that medical countermeasures are available when needed. Maintaining stockpiles of medical countermeasures typically entails large procurement costs and is associated with substantial carrying costs. In an era of constrained resources, BARDA and its PHEMCE partners are mindful of the need to meet established requirements, sustain preparedness, and be good stewards of the taxpayers' investments. To this end, the PHEMCE is currently working to refresh the material threat assessments that form the foundation for our requirements, many of which have not been reassessed in years. BARDA, for its part, emphasizes innovative approaches to total lifecycle cost-containment and strives to decrease the long-term costs of stockpiling medical countermeasures.

- One method is repurposing of commercial products and taking advantage of their commercial market, under vendor managed inventory (VMI). This method is currently being leveraged for cytokines to address neutropenia resulting from exposure to ionizing radiation.
- Another method that BARDA is employing is stockpiling of bulk intermediates. Bulk products do not have expiry associated with them like final drug products and can be maintained for longer periods of time. Stockpiling of bulk intermediates also allows BARDA to cut manufacturing times if additional product is necessary for a larger event.

RECOVERY AUDIT CONTRACTORS/MEDICARE APPEALS PROCESS

Question. Madam Secretary, your budget provides significant support for several levels of the Medicare Appeals Process but what are you doing to address the root of the problem: the Recovery Audit Contractors (RACs) who serve as the gatekeepers to the process? What is the status of the RAC contracts that include the new requirements to address these problems?

Answer. Recovery Auditors are important partners as we work to identify and correct Medicare improper payments. In 2014, in response to stakeholder and industry feedback, CMS took several steps to improve the Recovery Audit Program to increase transparency and reduce provider burden. For example:

- Hospitals should not be the only provider type subject to review by Recovery Auditors. Recently announced additional documentation request (ADR) limits will require diversification of ADRs across all facility claims in proportion to the provider's types of bills and will be based on provider risk, being adjusted up or down based on a provider's denial rate.
- CMS established a requirement that Recovery Auditors must complete complex reviews within 30 days, and failure to do so will result in the loss of the Recovery Auditor's contingency fee, even if an error is found.
- CMS has required Recovery Auditors to wait 30 days before sending a claim to the MAC for adjustment. This 30-day period allows the provider to submit a discussion period request before the MAC makes any payment adjustment.
- Recovery Auditors will not receive a contingency fee until after the second level of appeal is exhausted. This delay in payment helps assure providers that the decision made by the Recovery Auditor was correct based on Medicare's statutes, coverage determinations, regulations, and manuals.

In addition, CMS is implementing a risk-based approach that will allow Recovery Auditors to focus their reviews on providers who demonstrate a high denial rate or have not changed their billing patterns despite additional education, while focusing less on providers following Medicare's rules. These and other program improvements to reduce provider burden, enhance oversight and review accuracy, and increase program transparency can be found here: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Recovery-Audit-Program-Enhancements11-6-15-Update-.pdf>.

As of November 16, 2015, all current Recovery Auditors signed contract modifications that implemented enhancements to the Recovery Audit program. The current Recovery Auditors will continue recovery auditing activities at least through July 31, 2016 while CMS continues the procurement process for new Recovery Audit Program contracts, which will implement the remaining program enhancements.

Although the growth of Recovery Auditor appeals has contributed to the Medicare Appeals backlog, the other types of workload are also contributing to growth in appeals, and subsequently the backlog, in significant ways. The increase in the backlog has resulted from growth in each of the three workloads that HHS measures—Recovery Auditor, traditional workload (Medicare Part A and B; Durable Medical Equipment), and dual eligible workload, also known as the Medicaid State Agency workload. Further, with administrative actions undertaken by the Department to address the backlog, the current appeals in the backlog that were generated by Recovery Audit activities represent only a small fraction of the backlog.

My budget request for OMHA, the Department Appeals Board, and CMS is an important component of the comprehensive strategy the Department has developed to significantly reduce the backlog of Medicare appeals. Taken together, the additional funding, administrative initiatives and legislative proposals will help make sure beneficiaries and providers have timely resolution of appeals.

WORLD HEALTH ORGANIZATION GUIDELINES FOR MILK CONSUMPTION

Question. In January, the World Health Organization (WHO) issued draft guidance on milk consumption by young children. The guidance proposes the establishment of significant new restrictions and prohibitions on the promotion and marketing of milk products for young children. It is my understanding that this proposal received little public input and that when several Member States requested more time to review the proposal, they were given four weeks. What is the Department doing to ensure that such examination takes place and that U.S. concerns about this proposal are properly taken into account by the WHO?

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, and presented it to the WHO Executive Board for potential endorsement. This draft guidance aims to support countries in protecting and pro-

moting optimal nutrition for children during the first 3 years of life, a critical window for health and nutrition outcomes.

The WHO developed the draft guidance using a Scientific and Technical Advisory Group process. Convened in 2013, the Scientific and Technical Advisory Group produced several reports, including a draft of the guidance that they presented to WHO in 2015. Following online and in-person public consultations, the WHO presented a revised draft guidance to Member States at the WHO Executive Board meeting in January 2016. Following the meeting, the WHO opened an additional consultation period in 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. The draft does not seek to prohibit the marketing of all milk products consumed by young children, to limit product availability, 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 3 years of age.

In February 2016, HHS led a process to solicit input from relevant Federal agencies and prepare a technical comment submission to the WHO. HHS also met with multiple stakeholders, both individually and with other agencies, on the matter. HHS transmitted comments and discussed them with the WHO Nutrition Department, conveying that revisions are needed to present Member States with clear, evidence-based recommendations. The HHS Office of Global Affairs continues to monitor the development of the draft guidance and will continue dialogue with U.S. agencies and stakeholders in developing a U.S. position on the issue for the World Health Assembly this May.

Question. It is my understanding the Department provided technical comments to the WHO on the guidance. Please provide a copy of the comments to the Subcommittee.

Answer. Please see attachment "U.S. comments on WHO Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children."

WELDON AMENDMENT

Question. The Weldon Amendment has been Federal law for over a decade. It prohibits any State government receiving funds we appropriate to discriminate against a health insurance plan that does not cover abortion. Can you tell me how it is possible that California's refusal to license such a plan is not discrimination in violation of the Weldon Amendment?

Answer. The Department takes our responsibilities under the Weldon Amendment seriously, and HHS supports clear provider conscience clause protections. As you know, the Office for Civil Rights currently has open investigations related to complaints of Weldon Amendment violations. We cannot comment on the status of this particular investigation because it is still an open case.

Question. The Weldon Amendment violations have been pending since September 2014. Why is the investigation taking more than a year when, fundamentally, this is a legal question? The Weldon Amendment is what it is and California has issued its order.

Answer. I take our responsibilities under the Weldon Amendment seriously. We cannot comment on the status of this particular investigation because it is still an open case.

Question. Have you asked the Office of the General Counsel to provide an opinion?

Answer. As expected given the legal issues involved, the Office of General Counsel is involved in the issue.

STRATEGIC NATIONAL STOCKPILE PURCHASES

Question. Since 2005, the CDC has stockpiled enough antivirals to treat at least 25 percent of the U.S. population. This amount came from recommendations outlined in the National Strategy for Pandemic Preparedness. The budget requests \$77 million for new asset purchases, which is on top of the \$345.5 million requested for expiring asset replacement. Can you provide details on CDC's planned replacement purchases, for both new and expiring assets?

Answer. CDC collaborates with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to prioritize and adjust the Strategic National Stockpile (SNS) formulary annually based on current clinical practice, threats, market availability and available funding. CDC also uses PHEMCE recommendations to prepare the SNS Annual Review Report that informs HHS budget formulation for influenza antiviral drugs and the other medical countermeasures held in the SNS.

The current PHEMCE recommendations for stockpiling goals represent a shift in antiviral drug stockpiling from a shared Federal and State responsibility to a solely Federal responsibility. Prior to 2014, the goal was for the Federal Government to stockpile 50 million 5-day treatment courses of influenza antiviral drugs with the remaining 31 million courses met through State stockpiling. PHEMCE recognized that States were unlikely to continue contributing to stockpiling goals due to:

- Limited funding;
- Decreases in staffing;
- Reduced risk perceived by States due to the presence of a Federal stockpile; and
- Low ranking of influenza antiviral stockpiling as a preparedness priority.

With the change to sole Federal responsibility, CDC is working towards meeting the 80 million course stockpiling goal by increasing Federal inventories.

The following table displays the stockpiling goals for influenza antiviral drugs, as well as the SNS on-hand and on-order inventory through February 2016.

Medical countermeasure treatment* in the SNS (courses in millions)	SNS Stockpiling goal ¹	SNS on-hand inventory	Difference between goal and on-hand	On-order inventory
Oseltamivir (Tamiflu®) 75 mg capsules	38.1	38.0	— 0.1	0
Oseltamivir (Tamiflu®) 45 mg capsules	4.83	3.2	— 1.63	0
Oseltamivir (Tamiflu®) 30 mg capsules	16.8	11.8	— 5.0	0
Oseltamivir (Tamiflu®) Oral Suspension** 6 mg/ml, 60ml bottle	1.61	0.99*	— 0.62	0
Zanamivir (Relenza®) 5 mg blisters	19.2	16.4	— 2.8	3.4
Total	80.54	70.39	— 10.15	3.4

* One treatment course = twice daily administration for five days

** Does not include 500K of old suspension formulation that is expired and is in quarantine and awaiting disposal.

¹ The U.S. National Antiviral Strategy was updated in Jan 2014 and based on this revision, the target SNS goals for influenza antiviral stockpiling increased from 50M treatment courses to 80M treatment courses.

This table shows current influenza antiviral products expiring between fiscal year 2016 and 2022 as well as the projected replacement costs for each fiscal year.

Medical countermeasure treatment	Product in inventory expiring 2016–2022 (treatment courses)	Projected replacement costs (millions of dollars)						
		2016	2017	2018	2019	2020	2021	2022
Oseltamivir (Tamiflu) 75 mg capsules ...	38.0M	.00	.00	.10	20.14	33.98	251.83	184.03
Oseltamivir (Tamiflu) 45 mg capsules ...	3.2M	.00	.00	.65	1.33	.77	1.26	1.31
Oseltamivir (Tamiflu) 30 mg capsules ...	11.8M	.00	.00	1.27	1.76	3.29	1.67	4.27
Oseltamivir (Tamiflu) Oral Suspension 12 mg/ml, 25ml bottle	0.99M	.00	7.73	.00	.48	.00	.56	1.55
Zanamivir (Relenza) 5 mg blisters	16.4M	90.64	72.95	31.81	.00	.00	37.19	122.37
Total		90.64	80.68	33.83	23.71	38.04	292.51	313.53

STRATEGIC NATIONAL STOCKPILE REPLENISHMENT

Question. The initial efforts to prepare for and fund the National Strategy for Pandemic Influenza cost billions. How does the CDC envision paying for the cost of replenishing the antiviral stockpile? What is the cost estimate to replenish?

Answer. Projections for expiring product are incorporated into the Public Health Emergency Medical Countermeasures Emergency (PHEMCE) Multiyear Budget to inform enterprise decisionmaking and allow for effective prioritization of medical countermeasure procurement in the Strategic National Stockpile (SNS) and across the participating PHEMCE agencies. These recommendations help inform the President's Budget request for the SNS, while recognizing that the request must balance a number of competing priorities. This will allow CDC to maintain SNS Readiness to support response to pandemic influenza and other threats to health security.

This table shows current influenza antiviral products expiring between fiscal year 2016 and 2022 as well as the projected replacement costs for each fiscal year.

Medical countermeasure treatment	Product in inventory expiring 2016–2022 (treatment courses)	Projected replacement costs (millions of dollars)						
		2016	2017	2018	2019	2020	2021	2022
Oseltamivir (Tamiflu) 75 mg capsules ...	38.0M	.00	.00	.10	20.14	33.98	251.83	184.03
Oseltamivir (Tamiflu) 45 mg capsules ...	3.2M	.00	.00	.65	1.33	.77	1.26	1.31
Oseltamivir (Tamiflu) 30 mg capsules ...	11.8M	.00	.00	1.27	1.76	3.29	1.67	4.27
Oseltamivir (Tamiflu) Oral Suspension 12 mg/ml, 25ml bottle	0.99M	.00	7.73	.00	.48	.00	.56	1.55
Zanamivir (Relenza) 5 mg blisters	16.4M	90.64	72.95	31.81	.00	.00	37.19	122.37
Total		90.64	80.68	33.83	23.71	38.04	292.51	313.53

PHEMCE MULTI-YEAR BUDGET

Question. The PHEMCE Multi-Year Budget released last March proved very helpful in developing the fiscal year 2016 appropriations allocation for the Project Bio-Shield Special Reserve Fund. Can you provide any details regarding when this year's Multi-Year Budget will be released? And will this year's Budget include much-needed information on pandemic influenza, which was not included last year?

Answer. HHS develops the Multi-year Budget in response to the Reauthorization Act of 2013 (PAHPRA), which amended the Public Health Service Act to require the Assistant Secretary for Preparedness and Response to lead the development of a coordinated 5-year budget plan and annually update the plan. This report covers the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) estimates for spending in fiscal year 2015–fiscal year 2019 based on professional judgment on these programs. The report describes the importance of programs that address specified threats identified through the Material Threat Determination process used to set strategic requirements for medical products. Projected estimates are based on specific assumptions to maintain current preparedness efforts and projections are made without consideration of other competing priorities that are reflected in the formulation of the President's Budget. This year's multi-year budget on PHEMCE will include additional information on pandemic influenza. HHS is in the final phase of finalizing the report for transmission to Congress.

ZIKA VIRUS RESPONSE (GENETICALLY MODIFIED MOSQUITOES)

Question. The Zika Supplemental requests funding for vector control activities. Is the Department exploring opportunities related to genetically modified mosquitoes to suppress the population of wild mosquitoes carrying Zika? Has the Department examined the possibility of deploying this technology in the United States, U.S. territories, or other countries?

Answer. Yes, the Department is exploring opportunities related to using a genetically engineered (GE) line of the mosquito *Aedes aegypti* to help suppress the population of wild type mosquitoes known to transmit potentially debilitating human viral diseases, including Zika virus, dengue, yellow fever and chikungunya. As you know, there has been much interest in this proposal and we are working to ensure that we meet applicable National Environmental Policy Act (NEPA) requirements to ensure that the interested and affected public is informed.

There has been public discussion about this new method to potentially help control mosquito populations through the use of a GE line of the mosquito *Aedes aegypti* (OX513A) developed by Oxitec, Ltd. The release of male Oxitec GE mosquitoes is intended to cause suppression of the mosquito population in a release area over time because the offspring resulting from the mating of male GE mosquitoes with wild type females do not develop to adulthood. Oxitec is seeking to conduct a field trial to determine whether the release of its GE mosquito will suppress the local *Aedes aegypti* mosquito population in the release area at Key Haven, Florida.

The NEPA requires Federal agencies to assess the environmental impacts of certain actions. Pursuant to Food and Drug Administration (FDA) regulations, spon-

sors opening an Investigational New Animal Drug (INAD) file must submit either a draft environmental assessment (EA) or a claim of categorical exclusion from the EA requirement. The FDA also released a preliminary finding of no significant impact (FONSI) that agrees with the draft EA's conclusion that the field trial of such GE mosquitoes will not result in significant impacts on the environment.

After the close of the required 30-day public comment period, FDA will review and consider relevant comments. The FDA will then either issue a final EA and FONSI, or prepare an environmental impact statement (EIS). The field trial cannot begin until the environmental assessment is complete. Once FDA has issued either a final EA and FONSI or an EIS, the company and its local partner (the Florida Keys Mosquito Control District) will decide when to begin the field trial.

COMMUNITY BEHAVIORAL HEALTH CLINIC DEMONSTRATION

Question. Madam Secretary, the budget's mental health initiative requests funding for six additional States to join the Community Behavioral Health Clinic Demonstration which is based on my Excellence in Mental Health Act. I believe that if you treat mental health like all other health, and if those suffering from a mental illness have access to care we would see overall healthcare costs go down. Can you speak to any healthcare savings we might see if we expanded access to care? How much cost savings would result in healthcare expenditures in the future by supporting all 24 States that currently have the planning grants?

Answer. Thank you for your leadership on this legislation and your continued engagement in the demonstration project. We are excited about the Community Behavioral Health Clinic Demonstration and confident that it will promote high quality, community-based services for mental and substance use disorders. We are hopeful that the demonstration will show both the benefits of increased access to behavioral health services and coordination of behavioral health services with primary care services, and the potential savings that could result from earlier treatment of a variety of conditions. However, at this stage in the demonstration, it is not possible to reliably predict the extent of any savings.

DURABLE MEDICAL EQUIPMENT

Question. Rural providers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are facing payment reductions between 30 and 50 percent from the Center for Medicare and Medicaid Services (CMS) under Round 3 of Competitive Bidding. These reductions are currently being phased in over a six month timeframe. In the past, CMS has provided multiyear transition. Why is CMS applying such an expedited phase-in for these suppliers who provide important medical equipment and services that allow patients to remain in their home?

Answer. Section 1834(a)(1)(F)(ii) of the Social Security Act, as added by section 6410(b) of the Affordable Care Act of 2010, requires that CMS adjusts the DMEPOS fee schedule rates for competitive bid items using information from the DMEPOS competitive bidding program beginning January 1, 2016. We are phasing in these adjustments to the payment amounts to allow time for suppliers to adjust to the new payment rates and would allow time to monitor the impact of the change in payment rates on access to items and services. We believe a phase in of 6 months provides suppliers with an adequate amount of time to make adjustments to their businesses in light of the reduced payment amounts. In addition, CMS will be closely monitoring access and health outcomes using real time claims data and analysis during this period. If there are any issues identified through our monitoring, we will take appropriate actions depending on the situation.

Question. As part of the final rule establishing the modified fee schedule, CMS indicated that they will monitor the impact of the rate reductions using real-time data. What specific data does CMS plan to use?

Is there a delay in data and if so, how will CMS address that delay given the abbreviated phase-in timeframe?

What specific criteria will CMS use to assess whether these reductions have interfered with patient access?

Answer. 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.

Question. If suppliers are unable to continue caring for patients due to these reductions, will there be options for rural patients to continue to receive access to supplies and services in their home?

Answer. CMS established a special rule for adjusting fee schedule amounts used in making payment for the item or service in areas within the contiguous United States that are defined as “rural” areas. For the purpose of implementing this rule, a rural area is defined as a geographic area represented by a postal zip code if at least 50 percent of the total area included in the zip code is outside any Metropolitan Statistical Area. In addition, a rural area includes a geographic area represented by a postal zip code that is a low population density area excluded from a competitive bidding area. For these areas, in no case will a fee schedule amount for any DMEPOS item furnished in the area be reduced below the national ceiling amount, which is 110 percent of the average of the regionally adjusted rates.

CMS will be closely monitoring access and health outcomes using real time claims data and analysis during this period. If there are any issues identified through our monitoring, we will take appropriate actions depending on the situation.

FISCAL YEAR 2017 MEDICARE ADVANTAGE RATE NOTICE

Question. On February 19, 2016, as a part of the fiscal year 2017 Medicare Advantage Rate Notice, the Center for Medicare and Medicaid Services (CMS) proposed a reduction to Medicare Advantage Employer Group Waiver Plans (EGWPs), also known as Medicare Advantage Retiree Coverage. 3.3 million seniors, including nearly 37,000 Missourians, receive their Medicare Advantage coverage through these plans. While producing an analysis of the impact of many provisions proposed in the Advance Notice, CMS did not provide an impact analysis on these proposed reductions. On March 7, 2016, CMS released an impact analysis confirming a negative 2.5 percent cut to Medicare Advantage Retiree Coverage. The information was released after the comment period was closed, which ensures that the public is unable to comment on the new information. A Milliman report and an Oliver Wyman Report both provided similar estimates to CMS’s impact analysis. Did CMS consider the impact the reductions to Medicare Advantage Retiree Coverage would have on the 3.3 million seniors who depend on this form of coverage when developing the Advance Notice?

Answer. Employer Group Waiver Plans (EGWPs) serve specific employer groups, and are either offered through negotiated arrangements between Medicare Advantage plans and employer groups or by the employer directly. Because of the nature of these unique agreements, EGWPs do not compete against other plans through the bidding process, and therefore have little incentive to submit lower bids. CMS has previously waived bidding requirements for Part D for EGWPs and set payment amounts for Part D plans based on the competitive bids submitted for non-EGWP Part D plans. In the 2017 Draft Call Letter, CMS proposed a similar waiver and payment policy for EGWP Part C plans for 2017. This proposal would provide Medicare Advantage EGWP plans with a fair benchmark, reflective of comparable local Medicare Advantage trends and prices. CMS believes that waiving the requirement to submit 2017 Part C bids will facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare eligible retirees by avoiding the cost and administrative burden of submitting complex bids. CMS will consider comments we receive on this and other proposals in the draft Call Letter.

Question. Why did CMS fail to include this cut in the agency’s calculation of the overall Medicare Advantage Advance Notice impact analysis initially?

Answer. In the Advance Notice of Methodological Changes for Calendar Year 2017 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies, which was released on February 19th, CMS proposed to change the methodology for Part C payments to Employer Group Waiver Plans (EGWPs) without providing an estimated impact. Impacts are not always provided for all proposed changes in the advance notice. In response to subsequent inquiries regarding the impact of the proposal, we provided an estimate of the expected impact of the proposed change for Part C payments to EGWPs.

UNACCOMPANIED CHILDREN

Question. In the summer of 2014 there was a sudden and significant increase in children coming to the United States from Central America. There was then a sudden decrease at the end of 2014 through most of 2015, another significant increase at the end of 2015, and now a decrease through the beginning of 2016. What is causing these significant swings? Has the situation in Central America changed over this time? Has Mexico's enforcement strategy changed over this time?

Answer. HHS receives regular briefings from the intelligence agencies on conditions in Central America. We know that many of the unaccompanied children crossing the U.S. border are fleeing poverty and violence, or seeking to rejoin their parents or close relatives. However, interagency partners' analysis on the situation on the ground does not indicate that conditions in these countries have changed in ways that can easily explain the volatile fluctuations in the number of children coming to the United States. The Office of Refugee Resettlement (ORR) is involved in ongoing operational communication with partners to monitor and analyze trends and works with several components of the Department of Homeland Security on a daily basis on the referral and transport of unaccompanied children from the border to ORR shelters.

Question. These significant swings in the number of children coming to the United States from month-to-month makes it difficult for HHS to budget for the unaccompanied children program, but it also makes it difficult for this Committee to judge budget requests. How is the Department coordinating between different Departments to get a better grip of the trends driving the fluctuations in children coming into this country?

Answer. The Office of Refugee Resettlement (ORR) continuously monitors and analyzes the trends of referrals of unaccompanied children to HHS custody. In addition, ORR engages with interagency partners on a regular basis to better understand migration trends and the sociopolitical dynamics currently existing within the home countries. ORR coordinates with interagency partners through the Unified Coordination Group (UCG) created in 2014 in response to a Presidential directive to ensure unity of effort across the executive branch in response to the sharp increase of unaccompanied children arriving at the southwest border at that time. Since then, the UCG has continued to meet regularly to continue coordinating to plan for and respond to shifts in numbers of unaccompanied children. ORR also works with several components of the Department of Homeland Security on a daily basis on the referral and transport of unaccompanied children from the border to ORR shelters. ORR also coordinates with staff at the Department of Justice (DOJ), the General Services Administration (GSA), the Department of Defense (DOD) and the State Department on various aspects of the unaccompanied children program that intersect with their operations and responsibilities. UCG members routinely compare trends with historic annual and seasonal patterns. Given how much the number of unaccompanied children has fluctuated in the last couple of years, it is difficult to accurately predict the number of children that would be referred to ORR.

Given the range of external factors that may affect the number of children coming into HHS care, it would be prudent for Congress to provide access to additional funding that would allow ORR to accommodate higher than expected caseloads. For instance, referrals to the unaccompanied children program in fiscal year 2014 were the highest on record for the program, requiring the deployment of temporary shelter facilities as well as the expansion of standard shelter capacity. However, referrals to the program in fiscal year 2015, though still the second highest year on record, were substantially lower than the prior year, and allowed ORR to reduce the costs associated with shelter budgets during the low season referrals. Referrals in the first quarter of fiscal year 2016 were significantly higher than during the same period in previous years. While they decreased significantly in the second quarter of the current fiscal year, they still exceed second quarter referral levels for every prior year except for fiscal year 2014. Since mid-March, we have begun to see the numbers rise again.

These fluctuations in just this fiscal year alone underscore the unpredictable nature of referral numbers, and creates serious operational challenges for ORR as they budget for beds across the fiscal year. The President's fiscal year 2017 budget request creates a contingency fund that would trigger additional funds, not to exceed \$400,000,000, if referrals were higher than could be supported with base program funds and any carry over funds for the program from the prior year. The Administration estimates that the cost of the contingency fund in fiscal year 2017 would be \$95,000,000 based on the probability that additional funds would be outlayed.

The lack of contingency funds in fiscal year 2016 has hindered HHS's ability to plan for a full range of scenarios including having the number of unaccompanied

children coming into its care increase significantly during the latter part of the fiscal year. While base budgetary resources are sufficient to accommodate a significant increase over current referrals, if the number of referrals spiked suddenly to levels above those seen in fiscal year 2014, resources could prove inadequate. If such a spike were to occur late in the year, when it would be difficult for Congress to respond, HHS could be left with insufficient resources to house these children. This is why a contingency fund mechanism is so critical to ensuring that if an unexpected increase in referrals occurs, the Federal Government is equipped to provide appropriate care to children. We welcome the opportunity to explore these issues further with the Committee and discuss mechanisms that would ensure that HHS has the resources necessary should an unexpected increase, particularly one that occurs late in the year, arise.

FUNDING FOR EARLY CHILDHOOD CARE AND EDUCATION

Question. The fiscal year 2017 budget request includes significant increases in funding for Head Start, the Child Care and Development Block Grant (CCDBG), and Preschool Development Grants. Particularly now that Preschool Development Grants are funded within HHS, what is the Department doing to ensure these programs are well coordinated at the Federal, State, and local level and that we aren't duplicating efforts?

Answer. The Department of Health and Human Services (HHS) and Department of Education will continue to jointly administer the Preschool Development Grants program in 2017 and beyond HHS has worked closely with our colleagues at the Department of Education to ensure that our programs are coordinated, serve our Nation's children as best as possible, and create a continuum of high-quality early learning services beginning at birth and continuing through age five.

The Departments have had success in the joint administration of Race to the Top-Early Learning Challenge and Preschool Development Grants in previous years and engage in numerous other activities to ensure coordination at all levels. For example, the Departments co-chair an Interagency Policy Board on Early Learning, that coordinates policy, programs, research, and technical assistance across agencies and issues joint policy statements on key issues, including the inclusion of young children with disabilities in classrooms and programs with typically developing peers and preventing and eliminating the expulsion of young children from early childhood programs. Other examples of collaboration include the joint development of Birth to Five: Watch Me Thrive, which provides a toolkit to increase rates of developmental screening and follow-up and dissemination of materials highlighting how to utilize Medicaid to support creating school environments with physical and mental health supports.

We appreciate the importance of close coordination in the joint administration of the Preschool Development Grants Program, and will continue to keep your staff updated as we proceed with planning and implementation.

Question. The Department has proposed regulations that would increase the length of the Head Start school day and year, to increase the duration of services provided, which is consistent with research on what characteristics of early childhood education are most important. Similarly, the CCDBG Act of 2014 includes important reforms that require States to take steps to improve the quality of child care programs. In light of these important and costly proposed reforms, why has the budget proposed a \$100 million increase for Preschool Development Grants, and not focused all available resources on changes underway in Head Start and CCDBG?

Further, why has the budget proposed \$40 million of the increase for CCDBG for a new competitive grant program instead of focusing those resources on State efforts to comply with the new requirements in the CCDBG Act?

Answer. We appreciate your work on the passage of the Child Care and Development Block Grant Act of 2014 and your continuing support for implementing the law's new provisions. The fiscal year 2017 Budget includes an increase of about \$200 million for the Child Care and Development Block Grant (CCDBG), and the majority of this increase is focused on helping States and communities to implement the new requirements of the law. Of the total increase, \$40 million will be used for competitive grants to States, territories, tribes, local governments, and public entities to develop, implement, and evaluate approaches and innovative models of providing the types of care that working families need most. These grants are part of CCDBG, rather than a separate program. The focus will be on two areas: (1) care during non-traditional hours, and (2) care in rural areas. This funding is fully in line with the reauthorized CCDBG Act, which included a provision that requires States to develop and implement strategies to increase the supply and improve the quality of child care services for certain populations, including children in under-

served areas (which may include rural areas) and children who receive care during nontraditional hours. The goal of these pilot grants is to help States and communities to meet this new provision, as well as other provisions in the law.

Despite large numbers of families with non-traditional work hours, the National Survey of Early Care and Education found that only 8 percent of center-based early care and education programs offered services during non-standard hours. Home-based providers are more likely to provide non-standard hour care, yet such care was only available from 34 percent of home-based providers who appear in official State and national lists of early care and education services. Families living in rural communities also face unique challenges when accessing high-quality child care due to the lack of affordable child care, lack of public transportation, and the longer distances families must travel between work, home, and child care settings.

These pilots will provide dedicated resources that will support States and communities to identify and implement innovative solutions to serving these populations and populations specified by Congress as critical to address. The lessons learned from these pilots can then inform nationwide efforts to meet the goal of the CCDBG reauthorization legislation directing States to increase supply for underserved populations.

The Budget also requests a total of \$9.6 billion for Head Start, an increase of about \$434 million from 2016. This increase includes \$142 million for a full cost-of-living adjustment for all grantees, including Early Head Start-Child Care Partnership grantees. This funding would ensure that Head Start and Early Head Start grantees can maintain the number of children served and the quality of their program. The increase also includes an additional \$292 million over 2016 to enable more Head Start programs to offer full school day and year services, which, as you mentioned, is based in high-quality early childhood education research.

The increase in Preschool Development Grants is necessary to expand upon the efforts already underway in the 18 States that make up the first cohort of grantees. This additional funding would enable HHS and ED to fund new grants under the reauthorized Elementary and Secondary Education Act (ESEA) program in addition to supporting the final year of continuation grants for the first cohort. The new grants will improve the overall quality of preschool programs while improving coordination across early learning systems and increasing parent choice and knowledge about these programs. Ultimately, if all children are to have access to high quality pre-K programs, State efforts must be supported. This investment will also support and enhance many of the activities required under the reauthorized Child Care and Development Block Grant.

The fiscal year 2017 Budget request reflects the Administration's overall strategy to expand access to high quality early learning programs by improving the quality of existing programs and expanding the availability of high quality pre-K opportunities. This means investing in Head Start and child care while helping States to build high quality pre-K opportunities for 4 year olds.

Question. What does the Department estimate is the total cost to States in fiscal year 2017 to implement changes in the CCDBG Act?

Answer. In December 2015, HHS proposed revisions to the program regulations to reflect the changes contained in the Child Care and Development Block Grant Act of 2014. The Notice of Proposed Rulemaking's regulatory impact analysis estimated the average annual cost of full implementation at \$1.1 billion. Of this total, only \$5 million in costs stem from areas where HHS interpreted the statute and proposed clarifications through regulation, including applying background checks to regulated and registered child care providers and non-caregivers. As you know, the child care program is supported by a combination of Federal and State dollars, with, on average, 60 percent of the funds coming from the Federal funding streams. The Department is committed to supporting States through technical assistance and additional resources as they implement the law's requirements.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

HRSA TELEHEALTH RESOURCE CENTERS PROGRAM

Question. What changes is HHS, specifically HRSA, considering to the HRSA Telehealth Resource Centers program, which supports regional Centers across the United States? If changes are being considered to this program and/or current Centers, what steps are being taken by HHS and HRSA to ensure the continuation of existing Centers and the integral role they have in helping expand access to underserved populations? Are there plans to maintain support for the current Telehealth

Resource Centers and ensure any updates to the program build on important Federal investments already made to these important Centers across the U.S.?

Answer. The fiscal year 2017 President's Budget includes \$17 million for Telehealth Grants. The Telehealth program expands the use of telecommunications technologies within rural areas that can link rural health providers and patients with specialists to increase access to, and the quality of, healthcare provided to rural populations. These grants support the Improving Rural Health Care Initiative by strengthening rural healthcare infrastructure. Of the \$17 million total, \$4.6 million will be used to maintain support of regional Telehealth Resource Centers, which provide technical assistance to communities striving to establish or enhance and expand telehealth services. HRSA does not plan to make major changes to the Telehealth Resource Centers program in fiscal year 2017, as it will continue to support the regional Centers.

QUESTIONS SUBMITTED BY SENATOR THAD COCHRAN

PREVENTATIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Question. I am concerned about the proposed elimination of the Preventative Health and Health Services Block Grant (PHHSBG). In Mississippi, we use these funds to fluoridate water and to fund health educators, among other things. What other resources at HHS would provide these important activities such as fluoridation and health educators if the PHHSBG is eliminated?

Answer. As you stated, the fiscal year 2017 Budget request eliminates the Preventive Health and Health Services Block Grant (PHHSBG). We believe these activities may be more effectively and efficiently implemented through State and local chronic disease funding, which provides resources to States to coordinate activities across categorical funding streams. For example, the Centers for Disease Control and Prevention's (CDC) has requested \$18 million for oral health programs to support fluoridation and other oral health activities, continuing the \$2.25 million increase appropriated in fiscal year 2015. When the PHHSBG was first authorized in 1981, there were minimal resources within CDC's budget allocated for categorical programs such as heart disease, diabetes, oral health, immunizations, and obesity, and many States did not receive funding from CDC to support prevention of chronic disease. However, since 1981, categorical programs at CDC have grown and can better address these public health threats. Given the limited funding environment and our commitment to investing in the highest-priority, evidence-based programs, elimination of this program allows us to increase funding for key areas where CDC can have the greatest impact, including combating antibiotic-resistant bacteria and expanding the fight against opioid misuse, abuse, and overdose.

MOBILIZATION FOR HEALTH: NATIONAL PREVENTION PARTNERSHIP AWARDS PROGRAM

Question. What types of programs were funded under the Mobilization for Health: National Prevention Partnership Awards Program administered by the Office of Assistant Secretary for Health? It is my understanding that this particular program was last competed in fiscal year 2014. What are the Department's plans for this program going forward?

Answer. The Office of the Assistant Secretary for Health (OASH) made 13 grant awards in fiscal year 2014 through the Mobilization for Health: National Prevention Partnership Awards (NPPA) Program. This funding opportunity created a network of partnerships and resources to promote health and wellness, educate and train, and establish communication programs to all community populations, regardless of social and economic barriers, race, and ethnicity. These awards are for a 3 year project period.

NPPA projects addressed an array of OASH priorities, including: preventing teen pregnancy among Latino families by engaging community health workers/promotores; improving access to preventive healthcare services among limited English speaking families by strengthening links among school, home and medical settings; and improving clinical preventive services among the elderly by increasing the capacity of existing networks of community-based health, service, and business organizations.

OASH will continue to monitor and assess these projects to determine future funding opportunities. We will keep your staff updated.

DME REIMBURSEMENT

I am concerned about the short timeframe that the Centers for Medicare and Medicaid Services (CMS) has laid out for expanding competitive bidding for durable

medical equipment to rural areas. As you know, my State of Mississippi is largely rural and, as a result, Mississippians face many challenges in accessing healthcare. Why does HHS believe that these competitive bidding rates, which will cut DME reimbursement by 30 to 50 percent by July 1 of this year, will not further impede access to quality healthcare for Americans living in rural areas? What are CMS's plans, including the timeline, to collect pertinent data to determine effects on access?

Answer. 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.

NON-INVASIVE POSITIVE PRESSURE VENTILATION

Question. It is my understanding that the National Coverage Determination (NCD) currently in place covers Non Invasive Positive Pressure Ventilation (NIV) for patients with neuromuscular diseases, restrictive thoracic diseases, and/or chronic respiratory failure consequent to chronic obstructive pulmonary disease (COPD). CMS is currently requiring that a patient be on NIV machine 24/7 in order to for the NIV to be covered under Medicare. What is the medical justification for this requirement? Is there medical benefit to NIV for less than 24/7? Is CMS in violation of the NCD for patients with the specified conditions?

Answer. A Medicare National Coverage Determination (NCD) is developed by CMS to describe the circumstances for Medicare coverage nationwide for an item or service. An NCD is binding on all Medicare contractors in making determinations on Medicare claims and on adjudicators during the Medicare claims appeal process. Under the NCD, ventilators are covered for treatment of neuromuscular diseases, thoracic restrictive diseases, or chronic respiratory failure consequent to chronic obstructive pulmonary disease, including both positive and negative pressure types. In making coverage determinations, the Medicare contractors may consider criteria that would account for the reasonable and necessary use of a ventilator in order to avoid risk to the patient's health in a claim by claim adjudication.

CRITICAL ACCESS HOSPITALS

Question. It is my understanding that, during the process of recertification, several CAHs in Mississippi have been asked to produce the original letters they received when they originally obtained the CAH status. This could be a substantial administrative burden on these small rural hospitals, requiring many of them to comb through decades of files. What is the justification for this requirement? Did CMS consider the burden on CAHs when instituting this requirement? Will CMS offer other alternatives to the original recertification letter?

Answer. Response: Thank you for your ongoing leadership on this critical issue. I understand firsthand the challenges of healthcare in rural America. Critical access hospitals provide valuable services to Americans in rural areas, and we are committed to reducing administrative burdens while meeting requirements outlined in statute.

Thank you for your ongoing leadership on this critical issue. I understand the challenges of healthcare providers in rural America. Critical access hospitals provide valuable services to Americans in rural areas, and we are committed to reducing administrative burdens while meeting requirements outlined in statute.

Section 1820(c)(2)(B) of the Social Security Act (the Act) requires a Critical Access Hospital (CAH), other than a necessary provider CAH, to be located in a rural area, more than a 35-mile drive (or 15 miles in areas with only secondary roads or mountainous terrain) from a hospital or another CAH. CMS regulations repeat this statutory requirement.

The Office of Inspector General (OIG) report entitled, “Most Critical Access Hospitals Would Not Meet the Location Requirements if Required to Re-enroll in Medicare,” recommended that CMS periodically reassess CAHs’ compliance with all location-related requirements. CMS concurred with the recommendation. Also consistent with OIG recommendations, CMS determined to provide a 1 year transition period for any CAH that would have its CAH status revoked due to such a reassessment.

The OIG subsequently called on CMS to maintain evidence that it is routinely re-evaluating the compliance of currently Medicare-certified CAHs with these status and location requirements. In order to facilitate this, CMS has developed the CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification for use by the CMS Regional Office staff, which includes the requirement to retain the original letter.

CMS Regional Offices use this checklist to determine if the CAH is located outside the Metropolitan Statistical Area (MSA) by consulting the OPM’s latest MSA list. If the CAH had been certified as a Necessary Provider, it is exempt from the distance requirements.

Question. Providers in my State have contacted me with their concerns about how slow the Medicaid credentialing process is with Managed Care Organizations (MCOs). Why can’t MCOs accept a provider’s State Medicaid credentialing? Has CMS examined the whether MCOs take too long in credentialing providers?

Answer. Credentialing is the process the managed care organizations (MCOs) use to ensure that providers are qualified and meet the MCO’s quality standards for healthcare providers. CMS regulations require States to establish a uniform credentialing and re-credentialing policy that each MCO must follow. Nothing prohibits a State and the MCOs from using a common credentialing process. CMS has not examined the length of time that it takes MCOs to credential providers; MCOs’ credentialing process is an activity that falls within a State’s normal contract oversight.

LONG-TERM CARE HOSPITALS

Question. The Senate report for the fiscal year 2016 appropriations bill included the following language on page 149:

Severe Wounds.—The Committee directs the Secretary, in consultation with relevant stakeholders, to conduct a study on the treatment needs of individuals entitled to benefits under part A, or enrolled under part B, of Medicare, requiring specialized wound care, and the cost, for such individuals and the Medicare program, of treating severe wounds in rural and urban areas. The study shall include an assessment of: (A) access of such individuals to appropriate levels of care for such cases; (B) the potential impact that section 1886(m)(6)(A)(i) of the Social Security Act (42 U.S.C. 1395ww(m)(6)(A)(i)) will have on the access, quality, and cost of care for such individuals; and (C) how to appropriately pay for such care under the Medicare program. The Secretary shall submit the report within 1 year after enactment of this act to the Committees on Appropriations of the House of Representatives and the Senate with recommendations for such legislation and administrative actions as the Secretary determines appropriate.

Madame Secretary, has HHS begun to prepare this report? If so, what steps have been taken and what future steps have been identified?

Answer. HHS is reviewing the language, and will work to provide the report as directed. We will share the report with you as soon as it is completed.

PHYSICIAN SHORTAGES AND GRADUATE MEDICAL EDUCATION IN RURAL AREAS

Question. Mississippi faces physician shortages across the State, particularly in our small towns and rural communities. Research has shown that doctors most often practice in close proximity to where they complete their residency training, yet across the Nation, our physician residency slots are concentrated in metropolitan areas. What is HHS doing to increase the number of resident physicians training in small towns and rural communities? What role can Community Health Centers (CHCs) play in addressing this challenge? What is HHS doing to build the capacity for residency training within CHCs in our most rural underserved areas?

Answer. HHS is committed to improving access to quality healthcare for rural Americans, and to expanding and strengthening the health workforce. The Budget provides a total of \$1.3 billion for Health Resources and Services Administration (HRSA) workforce programs, including \$715 million in mandatory funding to provide access to high-quality healthcare professionals, particularly those living in areas across the country with shortages of providers. This funding includes investments in graduate medical education, the National Health Service Corps, and workforce diversity efforts. By addressing the shortage of primary care professionals that

exists in certain parts of the country, HRSA health workforce programs play a critical role in making sure all Americans have access to high-quality healthcare.

As you suggest, rural training track residency programs are a proven model for addressing rural physician workforce shortages. Rural training track residency programs provide graduate medical education to prepare resident physicians broadly for rural family medicine. As part of our efforts to strengthen the health workforce and connect skilled professionals to communities in need, HRSA operates two residency training programs that train and place healthcare providers in underserved areas across the Nation, including rural communities: the Teaching Health Center Graduate Medical Education Program and the Primary Care and Enhancement Program.

Teaching Health Center Graduate Medical Education Program

The Teaching Health Center Graduate Medical Education Program provides funding for residency training in primary care medicine and dentistry in community-based, patient care settings. In addition to increasing the number of primary care residents training in these community-based patient care settings, the Teaching Health Center Graduate Medical Education Program seeks to improve healthcare quality and increase overall access to care, especially in rural and underserved communities.

Since the program's inception, nearly all residents received training in a medically underserved community, and just over 1 out of every 5 received training in a rural area.

Of the 98 residents who completed the program in Academic Year 2014–2015, approximately 34 percent intended to practice in a medically underserved area. This is an important programmatic accomplishment toward increasing the numbers of those practicing in rural areas, since physicians trained in rural areas tend to practice in rural areas.

In fiscal year 2014, the East Central Mississippi Health Network, Inc. (EC-HealthNet), in Decatur, Mississippi, became a Teaching Health Center Graduate Medical Education awardee. The purpose of the EC-HealthNet Residency Consortium is to train physicians in rural areas to increase the likelihood that they will 1) choose to practice in a rural area and 2) have the clinical philosophy and skills to care for rural residents. In fiscal year 2015, EC-HealthNet Residency Teaching Health Center received \$880,099 in Teaching Health Center Graduate Medical Education funding to train 12 resident FTEs.

The fiscal year 2017 President's Budget includes \$60 million in already enacted mandatory funding in fiscal year 2017 and a request of \$527 million for fiscal year 2018 through fiscal year 2020 to support 876 residents, the currently approved number of residents in Teaching Health Center Graduate Medical Education programs. The funding request through fiscal year 2020 is critical for the sustainability of primary care residency programs which require up to 3 to 4 years per resident to complete training.

Primary Care Training and Enhancement Program

The Primary Care Training and Enhancement Program focuses on training for transforming healthcare systems, and supports the clinical training experience of trainees in rural and underserved areas, as well as encourages interprofessional primary care education. In fiscal year 2015, 49 percent of our Primary Care Training and Enhancement grantees were located in rural counties.

The fiscal year 2017 Budget requests \$38.9 million for the Primary Care Training and Enhancement Program to improve the quality of primary care providers, increase the capacity of physician assistant education programs, promote interprofessional practice, enhance medical education through curriculum innovations and improve the distribution and diversity of the healthcare workforce.

The Primary Care Training and Enhancement Program includes a funding preference for applicants that demonstrate a high rate for placing graduates/program completers in medically underserved communities or a significant increase in the rate of placing graduates/program completers in medically underserved community settings over the preceding 2 years. Applicants receiving the preference are placed in a more competitive position compared to other eligible applicants.

CHRONIC PAIN

Question. People across the country suffer from chronic pain, and there are some with pain so severe that opioid medication pills are no longer effective for them or put them at risk for addiction or diversion. For these patients, treatment with opioid medications via an implanted infusion pump is often a good alternative for pain management. These implanted infusion pumps slowly administer pain medication

solutions into a patient's intrathecal space to control pain and reduce the need for opioid pain pills. CMS implemented Change Request (CR) 7397 in 2013, despite feedback from patients, physicians, and pharmacies across the country. This CR eliminated pharmacies' ability to bill Medicare Part B for pain medication solutions used to refill a patient's implanted infusion pump while in a doctor's office. The change in policy contained in CR 7397 prohibits pharmacies from billing Medicare for these solutions and requires that physicians "buy and bill" these solutions in order for Medicare to cover them for beneficiaries.

Are you aware that many State boards of pharmacy, including Mississippi's, do not allow the practice of pharmacies selling compounded solutions to physicians or other third parties for resale to patients?

In your opinion, would the use of intrathecal pain pumps reduce the quantities of oral pain medication prescribed?

Patients across the country have lost and are losing access to this treatment option since pharmacies can no longer bill Medicare directly and cannot legally sell the compounded medications to physicians. Would you be willing to publish a new Change Request implementing this change?

Answer. HHS is committed to ensuring that the many Medicare beneficiaries across the country that suffer from chronic pain have access to the medications and treatments they need. In the Calendar Year 2013 Medicare Physician Fee Schedule final rule, CMS clarified longstanding policy that drugs used by a physician to refill an implanted item of DME were considered to be "incident to" a physician's services and not in the DME benefit category. Therefore, for the drug to be paid under Part B, the physician must buy and bill for the drug, and a non-physician supplier that has shipped the drug to the physician's office may not bill CMS separately. It was our understanding at the time the rule was written, that the majority of pharmacies in the country were in compliance with the physicians' "buy and bill" approach. We have not received reports that the situation has changed, nor have we received reports of significant access problems. CMS will continue to monitor this situation.

As additional background, in order to be covered by Medicare Part A or Part B, an item or service must fall within one or more benefit categories within such Parts, and must not be otherwise excluded from coverage. Drugs and biologicals paid under Medicare Part B fall into three basic categories:

- Drugs furnished "incident to" a physician's services. These are typically injectable drugs that are bought by the physician, administered in the physician's office, and then billed by the physician to the Medicare Administrative Contractor (MAC). By definition, "incident to a physician's professional service" requires the item or service to be billed by the physician.
- Drugs administered through a covered item of durable medical equipment (DME). These drugs are supplies necessary for the effective use of DME and are typically furnished to the beneficiary by suppliers that are pharmacies (or general DME suppliers that utilize licensed pharmacists) for administration in a setting other than the physician's office. Most DME drugs are billed to the DME MAC.
- Other drugs specified by the statute, including a variety of drugs, such as certain oral immunosuppressives and vaccines.
- Depending on the circumstances, drugs used to refill an implanted intrathecal pump can be paid under either "incident to" a physician's services under Part B, under the DME benefit category, or under Medicare Part D. We note that payment to pharmacies (or suppliers) for drugs used to refill an implanted pump can be made under the DME benefit category where the drug is directly dispensed to a patient and the implanted pump is refilled without a physician's service. However, it is our understanding that implanted pumps are rarely refilled without utilizing the service of a physician.

ANTIBIOTIC RESISTANCE

Question. Language was included in the fiscal year 2016 Senate report that highlights the significant effect of animal/human interactions on antibiotic resistant bacteria. I believe our strategies to combat antibiotic resistance must include both animals and humans. What are your immediate plans to develop such an effort to stimulate the synergy among academic medical centers and colleges of veterinary medicine to advance the science related to antibiotic resistance?

Answer. I share your concern regarding the development of antimicrobial-resistant bacteria and agree this is a critically important public health issue. Over the past several years, HHS has taken important steps toward fundamental change in how medically important antibiotics can be legally used in feed or water for food producing animals.

FDA is engaging in efforts to foster the advancement of education and research focused on antimicrobial resistance. As an example, FDA served in an advisory role to a task force that the Association of American Veterinary Medical Colleges (AAVMC) and the Association of Public and Land-grant Universities (APLU) formed to identify education and research needs. FDA's Center for Veterinary Medicine is also continuing to collaborate with AAVMC/APLU in the context of a working group convened to develop core competencies related to antimicrobial resistance for students at various levels. FDA believes that detecting and controlling antibiotic-resistance requires the adoption of a "One-Health" approach to disease surveillance that recognizes that resistance can arise in humans, animals, and the environment. Collaborations with academic organizations are of critical importance for advancing good antibiotic stewardship principles that impact both human and animal health.

COMMUNITY PHARMACIES

Question. It is my understanding that Medicare Part D prescription drug plan sponsors may contract auditing of pharmacies to large pharmacy companies like CVS Caremark. I am concerned that these contracts may present a conflict of interest as a pharmacy chain's parent company audits prescriptions filled by its competitors. Does CMS approve these contracts, or are they purely at the discretion of the Medicare Part D prescription drug plan sponsor? What CMS policies are in place to ensure that there is no conflict of interest in these auditing contracts?

Answer. The Part D regulations obligate Part D plan sponsors to adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct a sponsor's non-compliance with Part D program requirements as well as prevent and detect fraud, waste, and abuse. A sponsor's compliance program must include a plan for the performance of internal and external audits. In Chapter 9 of the Medicare Prescription Drug Benefit Manual ("Compliance Program Guidelines"), CMS provides guidance to sponsors on the effective administration of their compliance plans, including the conduct of audits. In particular, CMS instructs sponsors that they must ensure that their auditors are independent and do not engage in self-policing. Also, CMS instructs sponsors to develop a strategy for auditing their first tier entities to make certain that such entities are monitoring their downstream entities properly.

Many Part D sponsors contract with large pharmacy benefit managers (PBMs) to perform, among other things, claims processing and network contracting functions, on their behalf. In some instances, these PBMs are the corporate relatives of large pharmacy chains. In these arrangements, the PBMs are first tier entities to the Part D sponsor, while the sponsor's network pharmacies are downstream entities to the PBMs. Plan sponsors may also include in their PBM contracts provisions requiring the PBM to audit the operations of the pharmacies participating in the sponsor's Part D plans. CMS does not review or approve these contracts.

Sponsors using their PBM to conduct their pharmacy audits are responsible for ensuring that the PBM will conduct their audits in an independent manner. Since sponsors remain accountable to CMS for their compliance with all Part D requirements, it is in their interest to ensure pharmacy audits provide the full picture of their contracted pharmacy operations. Also, the Part D program's capitated payment structure places the financial burden on the sponsors to scrutinize closely the claims paid at all its contracted pharmacies, without exceptions. Further, to comply with Part D program requirements described above, sponsors need to conduct their own "audit of the auditor" to confirm that the first tier auditing entity (e.g. the PBM) is providing a fair account of the performance of downstream network pharmacies. Finally, CMS, as part of its administration of the Part D program, conducts audits of selected sponsors' Part D operations each year, including a review of the audit strategies sponsors have implemented to meet the compliance program requirement.

EARLY CHILDHOOD EDUCATION

Question. The fiscal year 2017 budget request, in line with the authorization included in the Every Student Succeeds Act (ESSA), proposes to transition funding for the Preschool Development Grants program from the Department of Education to the Department of Health and Human Services. Can you provide more detail as to how this transition will occur? How will the Department of Health and Human Services work with the Department of Education to support high-quality preschool programs?

Answer. The Department of Health and Human Services (HHS) and Department of Education will continue to jointly administer the Preschool Development Grants program in 2017 and beyond. HHS has worked closely with our colleagues at the Department of Education to ensure that our programs are coordinated, serve our

Nation's children as best as possible, and create a continuum of high-quality early learning services beginning at birth and continuing through age five.

The Departments have had success in the joint administration of Race to the Top-Early Learning Challenge and Preschool Development Grants in previous years and engage in numerous other activities to ensure coordination at all levels. For example, the Departments co-chair an Interagency Policy Board on Early Learning, that coordinates policy, programs, research, and technical assistance across agencies and issues joint policy statements on key issues, including the inclusion of young children with disabilities in classrooms and programs with typically developing peers and preventing and eliminating the expulsion of young children from early childhood programs. Other examples of collaboration include the joint development of Birth to Five: Watch Me Thrive, which provides a toolkit to increase rates of developmental screening and follow-up and dissemination of materials highlighting how to utilize Medicaid to support creating school environments with physical and mental health supports.

We appreciate the importance of close coordination in the joint administration of the Preschool Development Grants Program, and will continue to keep your staff updated as we proceed with planning and implementation.

Question. The fiscal year 2017 budget requests \$350,000,000 for Preschool Development Block Grants, including \$100,000,000 for new awards. It is my understanding that these grants are intended to build State and local capacity to implement preschool for underserved 4-year olds. What steps does the Department plan to take to ensure that funding awarded through Preschool Development Block Grants is awarded to States where Federal support for early childhood education can meet the needs of rural, minority, and low-income students?

Answer. The creation of the Preschool Development Grants program in 2014, consistent with the President's Preschool for All mandatory proposal, provides funding to States to build and expand high-quality preschool for children from low- and moderate-income families in a mixed delivery system of providers. This mixed delivery includes schools, licensed child care centers, Head Start, or other community-based organizations prepare low-income and disadvantaged children to enter kindergarten.

The fiscal year 2017 request would allow HHS to work with the Department of Education to issue 18 continuation grants for the fourth and final year of the existing initiative, which enables existing Preschool Development Grant grantees to continue building and expanding preschool in their States. Working in over 200 high need communities, the current grantees have demonstrated tremendous success in building the fundamental components of a high quality preschool system and expanding high quality preschool models. For example, Arizona is providing early childhood mental health consultation and intervention as part of the comprehensive supports to Preschool Development Grant-funded programs, which are located in high-need communities. The increase in 2017 will allow for new grants under the ESSA to improve the overall quality of preschool programs while improving coordination across early learning systems and increasing parent choice and knowledge about these programs.

The PDG expansion is one of several efforts the Budget supports to expand access to high quality early learning to children in underserved communities. The fiscal year 2017 Budget also includes an increase of approximately \$200 million for the Child Care and Development Block Grant (CCDBG), including \$160 million to support implementation of the changes required by the recent bipartisan reauthorization and \$40 million to test innovative strategies to address the child care needs of working families, such as care during non-traditional hours and in rural areas. Increases are also requested in Head Start and Home Visiting.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

INTERDEPARTMENTAL REVIEW OF EARLY LEARNING PROGRAMS

Question. On November 19, 2014, the President signed the Child Care and Development Block Grant Act into law. This law required the Secretary of Health and Human Services to conduct, within 1 year of enactment, an interdepartmental review of all early learning and care programs to identify overlapping programs and make recommendations to Congress for elimination and consolidation. We are nearly 3 months past the mandated deadline of this report. When does the Department plan to issue this report?

Answer. The Departments are currently in the process of finalizing the joint report and are working to get the completed report to Congress. The Departments will provide the joint report to Congress as soon as the process is complete.

CHILD CARE AND DEVELOPMENT BLOCK GRANT VOUCHERS

Question. The Child Care and Development Block Grant (CCDBG) Act stipulates that nothing shall “favor or promote the use of grants and contracts for the receipt of child care services under this subchapter over the use of child care certificates.” Report language reinforces Congressional intent that the primary goal of CCDBG is to promote parental choice through the use of vouchers. Any requirements through regulations to mandate States to use grants and contracts, in any capacity, interferes with a State’s ability to maintain the use of vouchers. As your department continues to develop proposed regulations for the Child Care and Development block grant, how do you intend to maintain the use of vouchers, as well as State discretionary authority to decide how and when to use grants and contracts to deliver services?

Answer. We agree that parental choice is important to the Child Care and Development Block Grant (CCDBG) program and the families it serves. Under the December 2015 Notice of Proposed Rulemaking, States must continue to offer every family receiving a subsidy the option to use a certificate/voucher. The proposal did not require the option of a grant- or contract-funded slot for every family, rather each State would determine the extent to which it will use grants and contracts. We believe that parents are in the best position to choose the care that best fits their families’ needs. Child care certificates (or vouchers) are important because they give parents the opportunity to select from a range of child care options.

Some communities lack an adequate supply of child care providers, particularly of high-quality providers, and particularly for certain types of care, such as infant and toddler care. A lack of supply limits parent choice because there are simply no quality providers from which to choose. For example, the National Survey of Early Care and Education found that while 89 percent of centers served 4-year old children, only 36 percent of centers served babies less than a year old. Without an adequate supply of providers, a certificate or voucher is ineffective because a family cannot use it. The 2014 bipartisan reauthorization of the CCDBG Act recognized this problem by including important supply-building provisions. Where States have used grants and contracts in a targeted manner, they have helped stabilize the supply and quality of care for specified populations of children.

In our December 2015 Notice of Proposed Rulemaking, we proposed that every State make some use of grants and contracts, with the extent of use determined by the State, in order to address supply gaps for high-quality care in communities. We are currently reviewing public comments received in response to this proposal will give the comments careful consideration as we develop the final rule.

PRESCHOOL DEVELOPMENT GRANTS PROGRAM

Question. As part of the Every Student Succeeds Act, Congress authorized a new Preschool Development Grants program to be jointly administered by the Department of Health and Human Services and the Department of Education. How do you intend to preserve the Congressional intent outlined in the program purposes, which call for collaboration and coordination among existing programs and new partnerships in order to maximize parental choice in a mixed delivery system of early childhood education programs? How will you promote the continuation of coordination efforts past the initial planning year through the lifetime of the grant and beyond?

Answer. Consistent with the statute, the purpose of the Preschool Development Grants program is to coordinate early childhood education programs in a mixed delivery system of providers including schools, licensed child care centers, Head Start, or other community-based organizations that will prepare low-income and disadvantaged children to enter kindergarten and to improve the participation of children in high-quality programs in this system. These goals are consistent with our efforts to align all early learning programs and ensure a continuum of services for children birth to school entry. We are working collaboratively with the Department of Education to ensure that the purposes as defined in the statute are clearly articulated and promote coordination beyond the initial planning year through the lifetime of the grant and beyond. Although we are early in the process, we are working to identify how these goals and principles will be articulated. Additionally, we are working to ensure that we remove any barriers for States to implement and provide services through a mixed-delivery system and through better alignment of policies and regulations that cross the departments and funding sources.

FDA GENERIC DRUGS

Question. On November 13, 2013 the FDA released a proposed rule that would require generic drug manufacturers to make unilateral changes to the labels for ge-

generic drugs, even if the manufacturer of the corresponding brand name drug has not implemented the same labeling change. If finalized, this rule would impose new regulatory burdens and potentially expose generic drugmakers to significant new State law tort liability.

The President's fiscal year 2017 budget request includes several proposals that, according to the Administration, would "address the rising cost of pharmaceuticals." At the same time, the proposed generic labeling rule imposes significant new burdens that could be passed on to consumers in the form of higher drug prices. By some estimates, the rule could increase spending on generic drugs by as much as \$4 billion, \$1.5 billion of which would be borne by taxpayers through government healthcare spending. In contrast, the cost estimate in the proposed rule States that it is expected to generate little cost.

Given the potential impact on consumers and taxpayers, it is critical that we have an accurate cost estimate. Please describe the process by which the Department of Health and Human Services analyzes the economic impact of new requirements, including a description of which factors are and are not considered as part of that analysis. Please also explain why the cost estimate included in the proposed generic labeling rule is billions of dollars less than other cost estimates, and describe whether and how the Department is considering revisions to its prior estimate.

Answer. The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), healthcare associations, drug and pharmacy associations, brand and generic drug companies, law firms, State governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment (see Docket No. FDA-2013-N-0500). These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association (GPhA) on September 8, 2014, to listen to their comments and views regarding the proposed rule. In addition, FDA held a public meeting on March 27, 2015, at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve communication of important, newly acquired drug safety information to healthcare professionals and the public. In the February 18, 2015, notice announcing the public meeting, FDA reopened the docket for the proposed rule until April 27, 2015, to allow the submissions of written comments concerning proposals advanced during the public meeting. FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting.

Any final rule that is adopted will reflect FDA's consideration of public comments, including the varying perspectives related to the potential economic impact, and would be accompanied by an analysis of the economic impact of the regulatory change described in the final rule. This regulatory impact analysis would be based on the framework described in Executive Orders 12866 and 13563, and use the best available techniques to quantify anticipated present and future benefits and costs. The regulatory impact analysis would help ensure that any regulation is adopted only upon a reasoned determination that its benefits justify its costs, and is tailored to impose the least burden on society, consistent with obtaining regulatory objectives.

FDA BUDGET AUTHORITY FOR MEDICAL PRODUCTS

Question. I am disappointed that the President's budget request for the Food and Drug Administration does not acknowledge the exciting time in science by requesting a meaningful increase in budget authority for medical products. An additional \$25 million was requested this year after the \$104 million in additional funds was provided to the agency last year for food safety activities, while an increase of only \$3.196 million was requested for medical product safety and availability. FDA involvement in patient focused drug development, next generation sequencing, and biomarkers is integral to Precision Medicine and the Cancer Moonshot Initiatives. Can you explain?

Answer. The President's Budget requests \$2.8 billion for Medical Product Safety, an increase of \$116 million when accounting for all resources above fiscal year 2016 enacted levels, and includes \$75 million in new mandatory funding for the Vice President's Cancer Moonshot. Patient focused drug development, next generation se-

quencing, and biomarkers continue to be important priorities to FDA. The request considered various priorities when deciding on the requested increase for medical product safety and availability.

QUESTIONS SUBMITTED BY SENATOR MARK KIRK

SMART CARD TECHNOLOGY

Question. In several meetings, you and I have discussed the potential for smart card technology to reduce administrative procedures, eliminate fraudulent spending, and protect identity in healthcare spending, specifically in Medicare. You conveyed your support for broadly addressing this very issue across all agencies from your previous post at OMB. Recent GAO reports support the use of smart cards for identity protection and recovering improper payments.

Please name which programs within HHS that would benefit from this technology and how they would benefit.

Answer. MACRA directed HHS to review the cost effectiveness and technological viability of use electronic Medicare beneficiary and provider cards (such as cards that use smart card technology, including an embedded and secure integrated circuit chip), as presented in the Government Accountability Office report required by the conference report accompanying the Consolidated Appropriations Act, 2014 (Public Law 113—76). This work is currently underway. Given that analysis is still underway for Medicare, we have not at this time determined how this technology would be viable or benefit other HHS programs.

Question. If a pilot program could be conducted to demonstrate the effectiveness of the smart card technology, what would the structure of the pilot look like?

Answer. MACRA directed HHS to review the cost effectiveness and technological viability of using electronic Medicare beneficiary and provider cards (such as cards that use smart card technology, including an embedded and secure integrated circuit chip), as presented in the Government Accountability Office report required by the conference report accompanying the Consolidated Appropriations Act, 2014 (Public Law 113—76). This work is currently underway.

In 2011 and 2012, CMS conducted a pilot program in which physicians and suppliers were issued electronically readable cards that they swiped when referring or fulfilling medical supply orders. When swiping the cards, they entered the last four digits of the beneficiary's Medicare number into credit card readers. CMS used information from the card transactions, including the date and beneficiary Medicare numbers, to match the transactions to submitted claims. The pilot only studied the ability to match card transactions with submitted claims, and did not involve any changes to claims processing systems or the adjudication process.²

As a result of the pilot program, CMS found that many providers could not participate in the program because they did not have access to the necessary technology. Further, CMS was unable to assess any program integrity effect from use of the cards due to low provider participation in the pilot.

Question. Specifically within the Centers for Medicare and Medicaid Services (CMS), could smart card technology reduce improper payments in outpatient billing in Medicare Parts A, B, C, or D?

Answer. The GAO recently found that the use of smart cards could have affected about 22 percent (165 cases) of cases GAO reviewed in which the entire or part of the case could have been affected because they included schemes that involved the lack of verification of the beneficiary or provider at the point of care. However, in the majority of cases (78 percent), smart card use likely would not have affected the cases because either beneficiaries or providers were complicit in the schemes, or for other reasons. For example, the use of cards would not have affected cases in which the provider misrepresented the service (as in billing for services not medically necessary), or when the beneficiary and provider were not directly involved in the scheme (as in illegal marketing of prescription drugs).

In these instances, the schemes would not have been affected by the smart cards because although the beneficiary and provider were present at the point of care, the provider misrepresented the services rendered after the smart cards would have registered their identities. These schemes included the following:

- billing for services that were not provided along with services that were provided legitimately,
- billing for services that were not medically necessary,

²From March 2015 GAO report Potential Uses of Electronically Readable Cards for Beneficiaries and Providers.

- upcoding,
- unbundling of services,
- billing for services that were not prescribed or not referred by a physician, and
- billing for services as if they were provided by a physician to receive a higher payment rate when they were actually provided by another provider in which the payment rate would have been lower.

In these schemes, smart cards would not be able to detect that the provider misrepresented the actual services provided even if the cards verified the beneficiary's and provider's presence. Similarly, schemes that involved a provider misrepresenting eligibility to provide services would not have been affected by smart cards, including schemes in which bills were submitted for services provided by an excluded provider or by an unlicensed, uncertified, or ineligible provider. Many of these schemes involved healthcare entities that billed for services provided by employees or contractors that were not licensed or were excluded from providing care.³

Medicare Advantage organizations and Prescription Drug Plan sponsors issue cards directly to their enrollees.

Question. Similarly, could smart card technology reduce duplicative procedures and duplicative or fraudulent spending in Medicare Parts A and B combined?

Answer. The GAO recently found that using electronically readable cards to authenticate beneficiary and provider presence at the point of care could potentially limit certain types of Medicare fraud. However, the GAO could not determine the extent to which authenticating beneficiaries and providers at the point of care could limit fraud because there is no reliable estimate of the extent or total dollar value associated with specific types of Medicare fraud schemes.

According to the GAO, use of the cards would not prevent providers from mischaracterizing services, billing for medically unnecessary services, or adding a service that was not provided to a claim for otherwise legitimate services because such fraud does not involve issues related to authentication. Instead, these types of fraud typically involve providers that wrongly bill Medicare for the care provided, or misrepresent the level or nature of the care provided. The use of electronically readable beneficiary and provider cards would also have little effect on preventing fraud that involves collusion between providers and beneficiaries because complicit beneficiaries, including those who receive kickbacks, would likely allow their cards to be misused.⁴

Question. What about its effectiveness in Medicare Advantage?

Answer. As noted above, Medicare Advantage organizations issue cards directly to their enrollees. The GAO has noted that Medicare beneficiaries who enroll in Part C or Part D plans receive separate cards from those plans, in addition to their traditional Medicare card.

Question. Which parts of Medicare could CMS conduct a pilot in that includes insurers already utilizing smart card technology, thereby reducing burden on CMS?

Answer. CMS regularly works in partnership with insurers and is frequently interested in exploring ways to work with the private sector to reduce waste, fraud and abuse. For example, the Healthcare Fraud Prevention Partnership (HFPP) is a voluntary public-private partnership between the Federal Government, State officials, law enforcement, private health insurance plans and associations, and healthcare anti-fraud associations.

QUESTIONS SUBMITTED BY SENATOR SHELLEY MOORE CAPITO

FDA LABELING FOR ANDA RULE

Question. In 2013 the FDA released a proposed rule on labeling changes for ANDA holders. This proposed rule, titled Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, Docket No. FDA-2013-N-0500, has not yet been finalized. Have you made a determination whether you are going to move forward with this rule?

Answer. The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

³From Jan 2016 GAO report Information on Most Common Schemes and the Likely Effect of Smart Cards.

⁴From Jan 2016 GAO report Information on Most Common Schemes and the Likely Effect of Smart Cards.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), healthcare associations, drug and pharmacy associations, brand and generic drug companies, law firms, State governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment (see Docket No. FDA-2013-N-0500). These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association (GPhA) on September 8, 2014, to listen to their comments and views regarding the proposed rule. In addition, FDA held a public meeting on March 27, 2015, at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve communication of important, newly acquired drug safety information to healthcare professionals and the public. In the February 18, 2015, notice announcing the public meeting, FDA reopened the docket for the proposed rule until April 27, 2015, to allow the submissions of written comments concerning proposals advanced during the public meeting. FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting.

The Unified Agenda, available at <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201510&RIN=0910-AG94> currently lists an anticipated publication date of July 2016 for the final rule. The dates for rules in the Unified Agenda are projected dates that may be adjusted to reflect ongoing work on specific rules.

Question. Is there evidence that the current reporting requirements are not being complied with by generic drug manufacturers or that they are inadequate?

Answer. The proposed rule focuses on the obligation to update labeling to reflect newly acquired information, not on the legal duties to report adverse drug events to FDA or more generally to meet post-market surveillance requirements associated with adverse event reporting obligations. The proposed rule neither cites nor is based on evidence that generic drug manufacturers are not submitting to FDA required reports of spontaneous adverse event reports that they receive.

Question. Has the FDA estimated the impact the rule could have on prescription drug costs and access? If so, what is the impact?

Answer. The proposed rule is intended to improve the communication of important drug safety information to healthcare professionals and patients. FDA has received a great deal of public input from stakeholders during the comment period on the proposed rule regarding the best way to accomplish this important public health objective.

FDA is carefully considering comments submitted to the public docket established for the proposed rule from a diverse group of stakeholders including: consumers and consumer groups, academia (including economists), healthcare associations, drug and pharmacy associations, brand and generic drug companies, law firms, State governments, and Congress, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multi-source environment. These comments include a summary of FDA's meeting with the Generic Pharmaceutical Association (GPhA) in September 2014, to listen to their comments and views regarding the proposed rule. In addition, FDA held a public meeting in March 2015, at which any stakeholder had the opportunity to present or comment on the proposed rule, or on any alternative proposals intended to improve communication of important, newly acquired drug safety information to healthcare professionals and the public. In the February 18, 2015 notice announcing the public meeting, FDA reopened the docket for the proposed rule until April 27, 2015, to allow the submissions of written comments concerning proposals advanced during the public meeting. FDA will determine next steps based on our analysis of comments on the proposed rule and additional information submitted as part of the public meeting.

Any final rule that is adopted will reflect FDA's consideration of public comments and would be accompanied by an analysis of the economic impact of the regulatory change described in the final rule. This regulatory impact analysis would be based on the framework described in Executive Orders 12866 and 13563, and use the best available techniques to quantify anticipated present and future benefits and costs. The regulatory impact analysis would help ensure that any regulation is adopted only upon a reasoned determination that its benefits justify its costs, and is tailored to impose the least burden on society, consistent with obtaining regulatory objectives.

QUESTIONS SUBMITTED BY SENATOR JACK REED

LIHEAP PROGRAM

Question. Access to affordable home energy is a matter of health and safety for many low-income households, children, and seniors. Unfortunately, the average LIHEAP grant has declined over the last few years and now covers just a fraction of average home energy costs, leaving many low-income families and seniors with fewer resources available to meet other basic needs. There remains a significant gap between the need and the funding.

What are the reasons why LIHEAP doesn't rate more highly among HHS priorities? How will HHS continue its commitment to providing our most vulnerable populations with vital home energy assistance?

Answer. The budget proposes to fund LIHEAP through a combination of discretionary funds (\$3 billion) and a proposed mandatory funding trigger providing additional resources in response to energy price spikes, increases in eligibility, and extreme cold at the beginning of winter (\$769 million based on a probabilistic score). Total resources of \$3.8 billion are requested, an increase of \$379 million over fiscal year 2016.

Question. Congress provided \$3.39 billion for LIHEAP; however, only \$3.02 billion has been released to date. This means approximately \$372 million has not yet been released for its intended purpose, to provide home energy assistance to the most vulnerable households in the country.

What is the Department's plan for these funds? When can we expect to see the \$372 million released to States under the LIHEAP formula?

Answer. HHS expects to make another release of LIHEAP funding in the near future. We will keep your staff updated as that occurs.

CDC HEALTHY HOMES LEAD POISONING PREVENTION PROGRAM

Question. As you know, I have been advocating for the full restoration of CDC's healthy homes/lead poisoning prevention program for many years. Almost 5 years ago, this program was nearly eliminated and since then I have been working with my colleagues to restore the funding. Given the situation in Flint, Michigan, I was disappointed that the President's budget request only flat funded the CDC program, given the considerable need. It seems to me that this is one program we would want to increase this year.

How will we be able to effectively prevent situations like Flint if some States still don't have lead poisoning prevention programs?

Answer. The recent events in Flint have highlighted the continued risk that lead poisoning presents to communities and children. CDC currently funds 29 States, Washington D.C., and five other cities through a lead poisoning prevention cooperative agreement. The cooperative agreement focuses on reducing children's blood lead levels through surveillance and primary prevention. These awards support grantees to:

- Implement and/or improve lead surveillance systems and data collection; and
- Increase the use of surveillance data to guide population-based prevention strategies (e.g., housing rehabilitation, enforcement of housing and health codes, and early childhood and other educational activities).

These surveillance data can help grantees and other partners target testing and resources to the highest-risk children as well as identify and address emerging sources of exposure.

However, most unfunded States are unable to collect lead surveillance data and/or report it to CDC. Without such data, States and cities are unable to target resources towards those with the greatest need or identify and address areas of concern. We would like to work with Congress to help ensure that States have the support needed to prevent lead poisoning.

Regarding the Flint water crisis specifically, the Federal response in place is supporting State and local leaders identify the size and scope of the problem, and to make and execute a plan for mitigation of the short- and long-term health effects of lead exposure. Specific activities include:

- HHS has deployed a total of 24 Commissioned Corps officers in support of eight distinct mission elements of the Public Health Assistance and Support Team, including mental health support, psychological first aid training focusing on schools and faith entities, and behavioral health support for community-based health and human services providers.
- On March 3, the Centers for Medicare & Medicaid Services (CMS) approved the State of Michigan's 1115 demonstration to extend Medicaid coverage and services to Flint, Michigan residents impacted by the lead exposure. Approximately

15,000 additional children and pregnant women will be eligible for Medicaid coverage and 30,000 current Medicaid beneficiaries in the area will be eligible for expanded services under this new waiver agreement. Additionally, we are working with the State to design and expeditiously process an alternative option through a targeted and time-limited health services initiative under title XXI of the Social Security Act for abatement activities that would complement other State and local efforts to remove lead hazards from the homes of Medicaid and CHIP eligible children and pregnant women.

- HHS awarded \$500,000 in emergency supplemental funding to Hamilton Community Health Network, Inc. and Genesee Health System, Health Resources and Services Administration (HRSA)-funded health centers, to hire additional personnel and provide more lead testing, treatment, outreach, and education to meet the increased need for health services in the Flint community.
- ASPR is using existing resources to help State health officials identify vulnerable populations in Flint who may need further targeted outreach and assistance.
- The Administration for Children and Families (ACF) and HRSA continue working with their grantees in the area to disseminate public health education through Head Start, Community Health Centers, and other programs to help families understand the risks of lead in the water. ACF and HRSA are working to leverage Medicaid to ensure that children and pregnant women have access to services to assist in treating exposure to lead.
- The Disaster Distress Helpline, sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA), is available to provide crisis counseling and support to people—including children and families in Flint—who are experiencing emotional distress related to natural or human-caused disasters.
- The Centers for Disease Control and Prevention (CDC)'s Agency for Toxic Substances and Disease Registry (ATSDR) is providing technical assistance to the State on lead exposure, water sampling protocols, and home inspections. ATSDR is working with the State to determine the number of children exposed to lead in Flint to ensure that children who should be screened are getting screened. After a formal request from the State to investigate rashes and other skin concerns affecting Flint residents, a team of experts from CDC and ATSDR began an Assessment of Chemical Exposure investigation on February 22.
- The Food and Drug Administration (FDA)'s Detroit District Office assessed potential impacts on FDA-regulated industries in the Flint area, including human food and animal feed production. No impacts were found, and FDA continues to assess and monitor the situation.
- The National Institutes of Health (NIH)/National Institute of Environmental Health Sciences (NIEHS) has an expedited process for reviewing research proposals and funding grants to address environmental emergencies, such as the lead-contaminated water crisis in Flint. The NIEHS is soliciting these research proposals now. Additionally, the new NIH Disaster Research Response initiative is working to improve research tools, protocols, and training necessary to conduct time-critical health research in response to disasters, which can be found at <http://dr2.nlm.nih.gov/>.

ACCESS TO NALOXONE

Question. While the Senate recently passed legislation to help prevent drug overdoses and expand access to treatment, more needs to be done, particularly to ensure new funding is made available immediately for these efforts. I have introduced legislation to provide communities access to naloxone—the overdose reversal drug—to prevent deaths and help move people into treatment options.

What is HHS doing to expand access to naloxone and to help prevent overdose deaths?

Answer. In March 2015, I announced the Department's plan for combatting opioid misuse, abuse, and overdose deaths, which includes a set of targeted strategies focused on stemming the rise in opioid-related mortality and morbidity. One of the three priority areas of my plan is promoting the use of naloxone.

I am grateful for the \$12 million the Congress provided in fiscal year 2016 for the Substance Abuse and Mental Health Services Administration for grants to States to purchase naloxone, equip first responders in high-risk communities, and provide education and other materials to assemble and disseminate overdose kits. This funding and training support aims to allow States to target resources where it is most needed in their communities. The fiscal year 2017 President's Budget includes \$12 million, the same level as fiscal year 2016, to continue support for this critical activity.

I also thank you for the \$1.8 million the Congress provided in fiscal year 2015 to support rural communities in reducing morbidity and mortality related to opioid overdoses through the Health Resources and Services Administration's Rural Opioid Overdose Reversal Grant Program. These awards were announced on September 17, 2015 to purchase naloxone, and training for its use by licensed healthcare professionals and emergency responders in rural areas. The fiscal year 2017 President's Budget requests an additional \$10 million to support these activities, increasing the number of rural communities that will be served, and placing a stronger emphasis on prevention, education, referral and treatment.

Further, HHS also continues to make progress in several other areas that will promote the use of naloxone. This past July, the Food and Drug Administration, in collaboration with other HHS agency partners, held a scientific workshop to initiate a public discussion about issues surrounding the uptake of naloxone in a variety of medical and non-medical settings to reduce the incidence of opioid overdose fatalities. FDA continues to make naloxone a priority, having approved, on an expedited timeframe, both an auto-injector and an intranasal formulation. Both of these products are designed for use by lay bystanders, as well as first responders. FDA continues to explore alternative methods for making naloxone more available.

HHS has also held two national meetings since 2014 where States were able to collaborate with one another to develop and share best practices for interventions to address the opioid epidemic, including those related to naloxone dissemination and utilization.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

ZIKA SUPPLEMENTAL

Question. Unfortunately, New Hampshire had the State's first confirmed case of Zika this week. An adult female contracted the virus after sexual contact with a male who was symptomatic and had traveled to a country where Zika virus transmission is occurring. Thankfully, the patient has fully recovered and is not pregnant.

I know that the Administration is seeking a \$1.9 billion Zika supplemental to combat the spread of Zika.

What funding sources does HHS currently have to work immediately on the Zika issue while we deliberate the supplemental funding?

Answer. HHS is supporting Zika efforts through reprioritization of existing funding resources, including reprogramming fiscal year 2016 funding for CDC's Public Health Emergency Preparedness program, transfer from CDC's fiscal year 2016 funding for the Strategic National Stockpile, and repurposing of prior-year balances from the Prevention and Public Health Fund. This funding will enable HHS to respond to urgent needs in the short-term; however this funding approach will not be sustainable and emergency funding, as requested, will be necessary for an effective response. To minimize the impact of the reallocations noted above, the Administration's emergency supplemental appropriations request includes a provision which would allow funds to reimburse HHS accounts for activities supporting Zika disease response that occurred prior to enactment. This authority is critical to maintain our preparedness and response capabilities.

Question. What funds are available to help States address Zika, particularly to help with State public health laboratory testing capabilities and protocols?

Answer. CDC is working with health departments across the country to ensure coordination and to expand capacity for detecting and responding to Zika virus. Surveillance is essential to monitor and quickly identify areas with mosquito-borne (local) Zika transmission. This includes multi-faceted surveillance for arboviruses, including Zika, through ArboNET, an integrated network which funds staff in 49 States, Puerto Rico, and six large municipalities to conduct human case investigations, collect and test mosquitos, and perform laboratory analysis on arboviruses including Zika. Zika virus is now a nationally notifiable disease, meaning States report the virus to CDC, which will aid Zika surveillance efforts. CDC is also working with several States and Puerto Rico to determine a baseline prevalence of microcephaly so that any increase, should it occur, can be quickly and accurately identified.

Additional funding, as requested in the Administration's emergency supplemental appropriations request, will be essential to supporting CDC's expansion of efforts to provide financial and technical resources to States and territories to strengthen their capacity to prepare for and respond to emerging insect-borne threats such as Zika virus. These resources will be used to help health departments expand their

capability to manage cases of local Zika virus transmission in their areas and to implement community education and prevention programs to reduce human-mosquito contact and subsequently, the risk of Zika transmission. Resources will also be used to implement mosquito control strategies, including mosquito surveillance. Current mosquito surveillance capacity is uneven across the country, which makes our knowledge about the locations of the two mosquito vectors that transmit Zika virus potentially incomplete. To effectively track the spread of the outbreak, it is critical that States and territories receive specimens and test for Zika virus to diagnose and report travel-related and locally acquired cases of Zika. Under the supplemental request CDC will expand its efforts to assist public health labs nationwide with the tools necessary to test for Zika and to provide guidance on how to interpret test results.

CDC is also currently distributing testing kits so that more health departments have the proficiency to perform testing, but will need to increase the existing capacity to meet the projected demand for Zika testing. Given that, last year, it is estimated that over 500,000 travelers to areas of current Zika transmission were pregnant women and 36,000 pregnant women are currently living in Puerto Rico, the expansion of testing capacity in public health labs nationwide, included in the request, is urgently needed in order to ensure that every pregnant woman needing testing for Zika virus has access.

Question. How are you coordinating with other agencies working on Zika, and with other countries who are experiencing an outbreak?

Answer. CDC is working in collaboration with other components of the Department of Health and Human Services (HHS), including the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA), the National Institutes of Health, and the Food and Drug Administration. In addition, HHS is working with partners across the U.S. Government to communicate with travelers and healthcare providers; update travel alerts and clinical guidance; and develop improved mosquito-control methods.

Through the Office of Global Affairs and CDC, HHS is also coordinating its response with the Pan American Health Organization (PAHO), the regional body of the World Health Organization (WHO), with other parts of WHO, and is collaborating with many international partners to learn more about this outbreak. ASPR and OGA also lead our efforts with the Global Health Security Initiative, a partnership with Canada, France, Germany, Italy, Japan, Mexico, the United Kingdom, the United States and the European Commission. CDC is also working with the Brazilian Ministry of Health on investigation and research partnerships. Research teams from CDC are also in other countries, including Colombia, to explore collaborations that will shed light on the risk of microcephaly in relation to Zika virus infection during pregnancy.

In addition, CDC is offering support to all countries so that they can test samples from microcephaly cases for serologic evidence of Zika virus infection, and CDC is helping countries throughout the Americas establish in-country diagnostic capacity. To that end, we are currently, in conjunction with the PAHO, providing training to laboratorians in South and Central America on diagnostic tests, including two recent workshops in Brazil and Nicaragua.

CDC's Central American office has also facilitated the verification of Zika cases in several countries throughout Latin America, including Colombia, Venezuela, and Nicaragua. At the request of the Department of State's Bureau of Medical Services, staff from CDC's Global Disease Detection Center in Guatemala has been involved in communication efforts to ensure that new information regarding Zika virus and its possible link to birth defects is communicated to U.S. Mission Health Unit staff throughout the Americas.

Question. Could you specifically speak to family planning accounts included in the budget and the important role they play in the life of women and families, particularly as we face a potential Zika outbreak?

Answer. The Title X family planning program is developing information resources for providers to use when educating clients and providing client-centered counseling. This includes hosting a webinar for providers and ensuring that providers have access to the full range of FDA-approved contraceptives, particularly long acting reversible contraceptives which can be offered to clients. Additionally, all CDC guidance is made available to grantees via a program listserv which is disseminated weekly or as needed for urgent information updates.

The fiscal year 2017 request for family planning is \$300 million and will expand family planning services to low income individuals by improving access to family planning centers and preventive services. The request is expected to support family

planning services for approximately 4.3 million persons, with approximately 90 percent having family incomes at or below 200 percent of the Federal poverty level.

Given our goal of preventing the risk of Zika virus to pregnant women, and women of childbearing age, we continue to support expanding access to preventive services such as contraception, and will closely monitor whether demand exceeds current funding in the context of our Zika response.

FISCAL YEAR 2017 OPIOID INITIATIVE

Question. As you know, I believe that the opioid abuse and heroin epidemic is a public health emergency. I appreciate the efforts that the administration has made, but I do not think it is enough. In New Hampshire, we are losing a person a day, and nationwide each day 120 people die from an overdose. More needs to be done.

Everyone I meet with in New Hampshire tells me more resources are needed for law enforcement, prevention, intervention, recovery and treatment. We have chronically underfunded these accounts—and in fact \$483 million dollars would need to be appropriated in fiscal year 2017 to bring the SAMHSA prevention and treatment block grant back to fiscal year 2006 levels. I am disappointed that an emergency supplemental funding amendment to provide immediate funds to the States to address the crisis failed yesterday.

Your budget addresses the drug abuse epidemic by providing \$1.1 billion in discretionary and mandatory funding.

How will these funds will get to the healthcare providers and treatment and prevention professionals at the front lines?

What in your proposal will assist those in recovery?

How will you better coordinate your agencies resources at the State level and front lines of the crisis?

Answer. Thank you for your continued support and leadership on this issue. The President's \$1 billion opioids investment will expand the availability of opioid use disorder services by expanding access to treatment, reducing the cost of treatment, and engaging patients in treatment. Specifically, this new investment includes \$920 million for new cooperative agreements to expand access to treatment services across the Nation. These funds will target areas of highest need and allow States to implement evidence-based strategies that help individual seek treatment, successfully complete treatment, and sustain recovery. These funds will meet local treatment needs like medication-assisted treatment. States may also use these funds to further promote access to treatment services by expanding the availability of substance use disorder treatment providers and increasing use of health information technology. Eligible activities could also include care transition and care coordination services for those in recovery.

The fiscal year 2017 President's Budget also includes \$50 million for the National Health Service Corps to support additional behavioral health providers, including those with medication-assisted treatment training, in communities with healthcare provider shortages, and \$30 million for cohort monitoring and evaluation, to understand what works best and disseminate that knowledge.

Coordination among Federal agencies and with our State and local partners has been a centerpiece of my strategy for combatting opioid misuse, abuse, and overdose, and is reflected in the investments proposed in the fiscal year 2017 President's Budget. This coordination begins within the Department. Senior staff led by the Office of the Assistant Secretary for Planning and Evaluation work assiduously to ensure that efforts at all stages from new research to developing new treatments to making grant awards and releasing prescribing guidelines are coordinated and leverage the expertise of the whole Department.

In addition, we are coordinating this work with Federal agency partners through the Interagency Workgroup on Prescription Drug Abuse Prevention/Opioid Overdose Prevention, led by the White House's Office of National Drug Control Policy. One example of the Federal coordination taking place at this level is the \$10 million fiscal year 2017 President's Budget proposal to partner with the Department of Justice to implement a new Buprenorphine-Prescribing Authority demonstration to expand the types of providers who can prescribe Medication-Assisted Treatment.

Coordination also continues between HHS and the States. For example, since 2014, HHS has held two 50-State meetings on the topic of opioids and has worked to engage our State and regional partners, including the National Governors Association, the Association of State and Territorial Health Officials, and the National Association of State Alcohol and Drug Abuse Directors in a variety of ways to advance efforts to prevent opioid use disorder and overdose death and to identify how best we can leverage our collective resources to bring us closer to ending this epidemic.

HOSPITAL CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYSTEMS SURVEY

Question. I recently joined Senator Collins in a letter to you with concerns about quality metrics, pain management and the move to value based purchasing.

As you know, as CMS implements the Hospital Value-Based Purchasing Program, part of the payments will be based on performance of quality measures, based on patient feedback gleaned from the Hospital Consumer Assessment of Health Care Providers and Systems, or HCAHPS survey.

I am concerned that the survey questions on pain management may not be adequate and may serve as an incentive for healthcare providers to over prescribe.

What is CMS doing to address the inadequate survey questions and quality metrics related to opioid prescription and what more needs to be done to enhance provider education on pain management?

Answer. HHS and the Centers for Medicare & Medicaid Services (CMS) share your concern about the misuse of prescription pain medications, especially opioids, and how survey questions, including those used on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, may affect pain management practices and opioid prescribing. Last fall, the Administration announced that it will undertake a review of how pain management is evaluated by patient experience surveys used by hospitals and other healthcare providers, including a review of how the questions these surveys use to assess pain management may relate to pain management practices and opioid prescribing. We typically test our survey questions on beneficiaries but we are also committed to consulting with physicians and hospital administrators as we explore possible changes to the survey. We look forward to updating you and other interested Senators when this work is completed. CMS has also launched several educational activities, including a national webinar in January, which will clarify the proper use of the HCAHPS Survey and its role in hospital payment, as well as call attention to revised instructions for proper opioid prescription practices.

EARLY INTERVENTION FOR MISUSE AND ABUSE OF PRESCRIPTION OPIOIDS

Question. The misuse and abuse of prescription opioids and of illicit drugs has become a true public health crisis, with overdose deaths quadrupling since 1999. One area that often gets lost in this debate is primary prevention. This is a critical part of our efforts to address opioid abuse—stopping it before it starts. Research supported by the National Institute on Drug Abuse, Substance Abuse and Mental Health Services Administration and the Centers for Disease Control has found that early intervention, during pre-school or elementary school before problems emerge, can reduce risky behaviors during the teen years. These interventions will not only help reduce substance misuse, they will also improve academic performance and reduce bullying, depression, violence, suicide, unsafe sexual behavior and other problems.

There is 40 years of research behind a prevention first approach and there are models underway right now that are working, but most prevention strategies are not in widespread use. My questions are:

The Institute of Medicine has called for 10 percent of public funds spent on young people to be directed toward effective prevention interventions that promote healthy behaviors. Can you tell us what percentage of the President's opioids initiative would be directed toward prevention? Or what percentage from the overall HHS budget?

Can you tell us how you plan to incorporate primary prevention into HHS' work addressing the opioid epidemic? How can we help communities to implement these interventions?

There are multiple grant programs addressing prevention at the Department of Education, HHS and Justice. How is HHS coordinating with those departments to leverage resources?

Answer. Again, thank you for your continued support and leadership on this issue. We know that preventing substance use during youth is a key factor in preventing future substance use, especially problematic substance use in adulthood. As noted, several NIDA-funded studies have found that universal, evidence-based prevention programs targeting youth such as the Iowa Strengthening Families Program can reduce future nonmedical use of prescription opioids in high school and early adulthood.

In general, youth are doing the better than other age groups with respect to opioids. Rates of nonmedical use of prescription opioids among people 12–17 years old have been declining since 2002. In 2002, 7.6 percent of individuals 12–17 years old reported nonmedical use of prescription opioids in the past year compared to 4.7

percent in 2014. Similarly, opioid-related mortality rates have also remained stable among 12–17 years since 2002.

It is critical that we focus our resources on where we can have the greatest impact. As you know, my plan for combatting opioid misuse, abuse, and overdose is a coordinated, multi-faceted initiative that relies on education, prevention, and treatment strategies with the strongest evidence base, and the Department has been working diligently to develop and implement these strategies. The Department also agrees that prevention services are critical in addressing the opioid epidemic across the country. In addition to continuing support for ongoing work associated with Substance Abuse Prevention through SAMHSA's 20 percent set-aside for prevention within the Substance Abuse Prevention and Treatment Block Grant and their Strategic Prevention Framework, the fiscal year 2017 Budget includes improvements to prescribing practices as a key area where we can focus our efforts to prevent opioid misuse. While actions to address prescription opioid abuse must target both prescribers and high-risk patients, prescribers are the gatekeepers for preventing inappropriate access. Therefore, HHS is focused on increasing investments in State-based prescription drug monitoring programs and adoption of e-prescribing practices, disseminating guidelines for opioid prescribing, and training providers.

The fiscal year 2017 President's Budget proposes a \$13 million increase for Prescription Drug Overdose and Misuse Prevention, for a total of \$80 million in discretionary resources, to support improved uptake of CDC's new "Guideline for Prescribing Opioids for Chronic Pain" among providers, and to provide ongoing support to all 50 States and D.C. through the Prescription Drug Overdose Prevention to States program. In addition, the budget proposes \$5 million in new discretionary funding for the Office of the National Coordinator for Health Information Technology to harmonize technical standards in support of Prescription Drug Monitoring Programs, improve clinical decisionmaking, and further the adoption of electronic prescribing of controlled substances. In addition, the SAMHSA State Targeted Response Cooperative Agreement program, a \$920 million effort, will enable States to identify primary prevention needs in their States. The program is designed to enable States to develop holistic approaches to addressing the opioid crisis.

We must work across HHS, with our partner agencies and other stakeholders, as well as with Congress to identify and dismantle barriers as well as leverage our resources in order to effectively implement these strategies. Coordination of HHS activities addressing opioid use disorders is being led by the Office of the Assistant Secretary for Planning and Evaluation. In addition, HHS continues to coordinate its efforts to address opioid addiction and overdose with its Federal agency partners through the Interagency Workgroup on Prescription Drug Abuse Prevention/Opioid Overdose Prevention led by the Office of National Drug Control Policy. One example of the Federal coordination taking place at this level is the \$10 million fiscal year 2017 President's Budget proposal to partner with the Department of Justice to implement a new Buprenorphine-Prescribing Authority demonstration to expand the types of providers who can prescribe Medication-Assisted Treatment.

QUESTION SUBMITTED BY SENATOR TAMMY BALDWIN

NATIONAL PAIN STRATEGY

Question. Secretary Burwell, it has been 9 months since HHS closed the public comment period for the draft version of the National Pain Strategy (NPS). The NPS was developed by four of HHS' agencies, in collaboration with the Department of Defense and the Department of Veterans Affairs, and is intended to provide a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research. In light of the Nation's opioid crisis, it is critical that the NPS is released and implemented in an effort to improve pain care with alternatives to addictive medications. I understand that a final version of the NPS is awaiting your approval.

Do you have a release date for the NPS? What plans does HHS have in place to implement the NPS objectives?

Answer. The National Pain Strategy was posted for a public comment period in April 2015, which generated a robust response. The comments were carefully considered and incorporated into the report, creating a stronger plan to improve pain care. Following that important, but time consuming step, all Department of Health and Human Services (HHS) agencies, the Department of Defense, and the Veterans Health Administration, which were involved in its development, carefully reviewed and revised the report. HHS expects to release the report in March 2016. Broad ranging efforts across the Government and with private partners will be needed to

implement the objectives of the National Pain Strategy. The Office of the Assistant Secretary for Health, in conjunction with HHS operating and staff divisions, will develop a detailed implementation and evaluation plan after the release of the Strategy.

SUBCOMMITTEE RECESS

Senator BLUNT. And the subcommittee will stand in recess until 10 a.m. on Thursday, March 10.

Thanks for being here, Secretary.

[Whereupon, at 11:48 a.m., Thursday, March 3, the subcommittee was recessed, to reconvene at 10 a.m., Thursday, March 10.]