

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2014**

WEDNESDAY, APRIL 24, 2013

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

The subcommittee met at 10:05 a.m., in room SD-138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.
Present: Senators Harkin, Pryor, Shaheen, Merkley, Moran, Cochran, Alexander, Johanns, and Boozman.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. KATHLEEN SEBELIUS, SECRETARY

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education will please come to order.

Madam Secretary, welcome back to the subcommittee. I want to start by commending you for the outstanding work you're doing to implement the Affordable Care Act (ACA) since President Obama signed it into law 3 years ago.

Since 2010, some 6.3 million seniors have received more than \$6.1 billion in discounts on their prescription drugs. Last year, almost 40,000 seniors in my State of Iowa saved an average of \$650 each.

More than 3.1 million young adults are staying on their parents' insurance from graduation to age 26.

But most important of all, 105 million Americans have received a free preventative screening or service because of the Affordable Care Act.

Your Department is carrying out these reforms with great skill, and I thank you for your leadership.

More work remains, of course. The President's budget request for fiscal year 2014 includes additional funding at the Centers for Medicare and Medicaid Services (CMS) for operating the marketplaces that will allow consumers and small businesses to compare private health plans.

As chairman of both this subcommittee and the Health, Education, Labor, and Pensions (HELP) Committee, the authorizing

committee, I'm determined to do everything I can to help this effort succeed.

However, Madam Secretary, I am beyond upset—beyond upset—that the administration helped pay for the Affordable Care Act in fiscal year 2013 by raiding the Prevention and Public Health Fund.

Madam Secretary, maybe you just don't know how angry I am about this. This is a 20-year effort—a 20-year effort—I fought to get more focus on prevention and wellness. And the ACA provided the opportunity to change.

I have been saying for over 20 years, we don't have a healthcare system in America; we have a sick care system. If you get sick, you get care, and we're good at it. We have great surgeons and great doctors. Once you're sick, you get great care in America.

But where we have failed, where we have failed miserably, is keeping people healthy, preventing disease and illness in the first place. Every study, all the studies, all these years, show the payback on prevention is incredibly high.

And yet, we cut it. We cut it. And like clueless dodos, we wonder why healthcare is going through the roof.

So when the Affordable Care Act was being developed here, some of us, I included, saw it not just as a way to pay bills. How do we pay the bills more? How do we do it more efficiently and more effectively? But how do we reduce chronic diseases through prevention and wellness programs?

In other words, we need a change. To begin this change, we should think about having a true healthcare system in America where we support people from the earliest times of life, in every aspect, not just in a clinical setting, that's important, but in our workplaces, in our schools, in our communities. So we have a regime of wellness and prevention in this country.

The prevention fund is working, children are being immunized, people are quitting smoking, communities are fighting chronic diseases, more people are being screened for hepatitis C.

Robbing prevention when we know these efforts can improve people's health and lower healthcare costs goes against the very mission of healthcare reform.

Raiding the prevention fund to just figure out how we pay the bills and how we setup a structure, just perpetuates—perpetuates—our unique, costly American sick care system.

I'm sorry to say that this administration just doesn't seem to get it. They just don't seem to get it.

First of all, there was a \$5 billion raid last year on the prevention fund. This year, it's another \$332 million raid on the prevention fund.

And, Madam Secretary, I read your statement last night. Great statement, as far as it goes. It doesn't even mention prevention. It doesn't even mention it. Only in mental health, a little bit of mental health, and the Infectious Disease Surveillance Program, which the Centers for Disease Control and Prevention (CDC) has been doing for over 50 years.

It's sort of like the prevention fund and what we did in prevention is sort of an afterthought, maybe? It was not in your statement. Is that indicative of the administration's approach? That it's just an afterthought? It can be raided? It can be done away with?

Well, we are going to do another bill this year. I'm hopeful that we can get it through, and I hope that we can allocate the money as we've done in the past. But this strikes right at the heart of trying to change this system.

On other matters, the President's proposed budget does some good things. It increases key priorities like childcare and Head Start, National Institutes of Health (NIH). I'm especially interested in how the Department of Health and Human Services (HHS) and the Department of Education plan to work together on the President's Early Childhood Education Initiative, because both HHS and Education have parts of that. And we need to know more how that's going to work, in terms of how we allocate funds on this committee.

So, Madam Secretary, I look forward to hearing your testimony. But first, I yield to Senator Moran for any opening remarks he may wish to make.

STATEMENT OF SENATOR JERRY MORAN

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

Madam Secretary, welcome to the subcommittee.

I was reminiscing, at least in my own mind, that the first time you and I served in public office together was 1989, in which I, as a freshman member of the Kansas Senate, was assigned to be on the Indian Gaming Committee. And you and I spent a number of years in front of a Federal judge negotiating Indian gaming compacts in Kansas.

At least I would have never envisioned the circumstance in which we find ourselves this morning.

It's a pleasure to see you again, and welcome back to the subcommittee.

Obviously, a difficult economic environment. Congress struggling with difficult budget decisions.

The concern that I have with the Department of Health and Human Services budget is the 10.5 percent, \$6.9 billion above current spending levels. Specifically, the budget includes a significant \$1.5 billion request to set up health exchanges, insurance exchanges.

I'm concerned that we still don't yet know the full cost of the Affordable Care Act.

Last week, the Department announced it would transfer fiscal year 2013 funding from the prevention fund that Senator Harkin described to fill some of the gaps in the health insurance exchange implementation. This decision takes public health dollars and workforce development funding supported by the prevention fund and diverts it toward what I believe to be the administration's political priority, implementing the exchanges.

In fiscal year 2014, the taxpayer is handed another unexpected bill for the 33 States, including our own home State, that have declined to set up exchanges. It turns out that the blank check that was available for States to set up their own State-based exchanges does not extend to the federally implemented exchanges in the 33 States that did not implement a State exchange.

The administration struggles to find funding to implement the Affordable Care Act. It's critical that we don't continue the hap-

hazard “rob Peter to pay Paul” strategy. We need to set funding priorities to ensure balance and increased certainty across all aspects of our Nation’s healthcare system.

One of my priorities in Congress has always been to ensure that Americans have access to quality, affordable healthcare in whatever setting, whatever place in the country they live. Therefore, as a Senator from Kansas, I have a significant emphasis on rural. And I’m concerned with the proposals within the Department’s budget that would disproportionately affect Kansas and other rural States, jeopardizing healthcare access and threatening the survival of small towns.

In particular, the issues—when you transfer money from the prevention fund to fund the exchanges—rural healthcare is affected in a number of ways, including rural access to emergency devices; rural hospital flexibility grants; section 317 immunization program; the critical hospital program, that I will mention again; the continued attack on critical access hospitals; a reduction in the percentage of cost-based reimbursement; the mileage issue.

And so I raise genuine concerns with an issue that I know that you’re very familiar with—the rural aspect of transferring funds from the prevention fund to set up exchanges.

I’m also interested in hearing, and I’ll ask a question about the legality of transferring money from the prevention fund, by what authority is that possible?

Again, the President’s 2014 budget cuts Medicare reimbursement to critical access hospital programs, eliminates the designation for hospitals that are fewer than 10 miles from another hospital.

And if that’s an appropriate decision, I don’t know how it’s appropriate retroactively. It cuts funding to the programs I just outlined in large part because of the transfer from the prevention plan.

I look forward to working with you to ensure that these proposals do not adversely affect healthcare access or any American.

Finally, as we continue to work within a limited budgetary environment, funding should be targeted to programs that we know show proven results. And therefore, I’m pleased to see the Department has requested an additional \$471 million increase in the National Institutes of Health, the focal point of our Nation’s medical research capacity.

In the last 30 years, biomedical research has yielded significant scientific discoveries that have extended life, reduced illness, lowered healthcare costs, and driven economic growth. The NIH, to me, is one of those great programs that whether you come from the perspective of being the caring person who wants to make certain that everyone has access to the latest technologies and lifesaving advances, or you want to make sure that we save every penny that we can, medical research does both.

And I am pleased to see that the administration’s budget request increases the funding for NIH. I believe we need to continue that Federal commitment to advancing that research. I worry that if there’s any break in that pattern that we will lose those who are committed to scientific research on our behalf.

PREPARED STATEMENT

And we want to remain a global leader. We don't want people who are considering to pursue a career in medical research to decide that the funding is on again, off again.

So thank you, Madam Secretary, for your presence here. I look forward to our conversation.

Mr. Chairman, I'm committed to working with you to find fiscally responsible ways to address our critical Nation's needs regarding healthcare.

[The statement follows:]

PREPARED STATEMENT OF SENATOR JERRY MORAN

Thank you, Mr. Chairman.

Thank you, Secretary Sebelius, for appearing today to discuss the fiscal year 2014 budget request.

In this difficult economic environment, Congress is struggling with difficult budget decisions. I am concerned that the Department of Health and Human Services' discretionary budget request is 10.5 percent, or \$6.9 billion, above current spending levels. Specifically, the budget includes a significant \$1.5 billion request to set up health insurance exchanges. I am concerned, as I am sure many on this subcommittee are, that we still do not know the true costs or effects of the Affordable Care Act.

Last week it was announced that the Department would transfer fiscal year 2013 funding from the Prevention Fund to fill some of the gap for health insurance exchange implementation. This decision takes public health dollars and workforce development funding supported by the Prevention Fund and diverts it towards the Administration's political priority. In fiscal year 2014, the taxpayer is handed another unexpected bill for the 33 States, including our home State of Kansas, that have declined to setup exchanges. It turns out that the blank check available for States to set up their own State-based exchange does not extend to the federally implemented Exchanges in the 33 States that did not.

As the Administration scrambles to find funding to implement the Affordable Care Act, it is critical that it does not continue to use a haphazard "rob-Peter-to-pay-Paul" strategy. We need to set funding priorities to ensure balance and increase certainty across all aspects of our Nation's healthcare system. One of my priorities in Congress is to ensure all Americans have access to quality, affordable healthcare in whatever setting they may live. Therefore, I am very concerned with proposals within the Department's budget that would disproportionately affect Kansas and other rural States, jeopardizing their healthcare access and threatening the survival of small towns. I think it is critically important that Washington recognize that healthcare access is essential to the survival and success of rural communities across the country.

The President's fiscal year 2014 budget seeks to cut Medicare reimbursements to the Critical Access Hospital program and eliminate their designation for hospitals that are fewer than 10 miles from another hospital. Cuts are proposed to rural hospital flexibility grants, critical breast and cervical cancer screenings, and the foundation of our Nation's immunization program, the 317 immunization program. Madam Secretary, as a former Kansas Governor, you understand the unique nature of medical care in rural communities. I look forward to working with you on these proposals to ensure we do not adversely affect healthcare access for any American.

Finally, as we continue to work within a limited budgetary environment, funding should be targeted to programs that show proven and effective results. Therefore, I am pleased to see that the Department has requested a \$471 million increase for the National Institutes of Health, the focal point of our Nation's medical research capacity. In the last 30 years, biomedical research has yielded significant scientific discoveries that have extended life, reduced illness, lowered healthcare costs, and driven economic growth. I believe we need to continue our Federal commitment to advancing medical research to make tomorrow's breakthroughs in health possible and strengthening our Nation's position as a global leader in medical innovation.

Mr. Chairman, I am committed to working with you to develop a fiscally responsible budget that addresses the critical needs of our Nation.

Thank you.

Senator HARKIN. Thank you very much, Senator Moran.

Kathleen Sebelius became the 21st Secretary of the Department of Health and Human Services on April 29, 2009. In 2003, she was elected Governor of Kansas, served in that capacity until her appointment by President Obama as Secretary.

Prior to election as Governor, she has served as the Kansas State insurance commissioner. A graduate of Trinity Washington University and the University of Kansas.

I believe this will make the Secretary's sixth appearance before this subcommittee since her appointment. And we welcome you again.

Madam Secretary, your statement in its entirety will be made a part of the record, and please proceed as you so desire.

SUMMARY STATEMENT OF HON. KATHLEEN SEBELIUS

Secretary SEBELIUS. Thank you, Chairman Harkin and Ranking Member Moran.

It has been awhile since 1989 and the Indian gaming debate.

And it's good to see the Governor, Senator, Secretary Alexander.

And I really appreciate the opportunity to discuss the President's 2014 budget for the Department of Health and Human Services.

This budget supports the overall goals of the President's budget by strengthening our economy and promoting middle class job growth. It ensures that the American people will continue to benefit from the Affordable Care Act. It provides much needed support for mental health services and takes steps to address the ongoing strategy of gun violence.

It strengthens education for our children during their critical early years, to help ensure they can succeed in a 21st century economy.

It secures America's leadership in health innovation, so that we remain a magnet for the jobs of the future, and we help to reduce the deficit in a balanced, sustainable way.

I look forward to answering your questions about the budget. But first, I'd like to briefly cover a few of the highlights.

The Affordable Care Act, as Chairman Harkin recognized, is already benefiting millions of Americans. And our budget makes sure we can continue to implement the law.

By supporting the creation of new health insurance marketplaces, the budget will ensure that, starting next January, Americans in every State will be able to get quality health insurance at an affordable price.

Our budget also addresses another issue that's been on all of our minds recently, mental health services and the ongoing epidemic of gun violence. While we know that the vast majority of Americans who struggle with mental illness are not violent, recent tragedies have reminded us of the staggering toll that untreated mental illness can take on our society.

And that's why our budget proposes a major new investment to help ensure that students and young adults get the mental healthcare they need, including training 5,000 additional mental health professionals to join our behavioral health workforce.

Our budget also supports the President's call to provide every child in America with access to high-quality learning services. It proposes additional investments in a new Early Head Start

childcare partnership, and it provides additional support to raise the quality of childcare programs and to promote evidence-based home visiting for new parents.

Together, these investments will create long-lasting positive outcomes for families and provide huge returns for the children and society at large.

And our budget also ensures that America remains a world leader in health innovation. We make significant new investments in the NIH that will lead to new cures and treatments, and help create good jobs throughout the country. It provides further support for the development and use of compatible electronic health record systems that improve care coordination. And it includes funding to ensure that our Nation can respond effectively to chemical, biological, and nuclear threats.

I also want to especially thank the committee members for your support of our efforts to provide a safe environment for our unaccompanied children who enter our country. As you know, we've seen a growing number of children coming into the country without any parents or guardians. And our budget includes additional funds to help ensure an estimated 26,000 unaccompanied children are safe and healthy.

Even as our budget invests in these critical areas, it also helps reduce the long-term deficit by making sure that programs like Medicare are put on a stable fiscal trajectory. Medicare spending per beneficiary grew last year at just 0.4 percent thanks in part to the \$800 billion in savings already incorporated into the Affordable Care Act. And the President's 2014 budget would achieve even more savings.

For example, the budget will allow low-income Medicare beneficiaries to get their prescription drugs at the lower Medicaid rates, resulting in savings of more than \$120 billion over the next 10 years.

In total, this budget would generate an additional \$371 billion in Medicare savings over the next decade on top of the savings already in the Affordable Care Act.

To that same end, our budget also aggressively reduces waste across our Department. It includes an increase in mandatory funding for our healthcare fraud and abuse control program, an initiative that saved taxpayers nearly \$8 for every \$1 we spent last year. And it supports additional efforts to reduce improper payments in Medicare, Medicaid, and Children's Health Insurance Program (CHIP), and to strengthen our Office of Inspector General.

PREPARED STATEMENT

This all adds up to a budget guided by this administration's north star of a thriving middle class. It will promote job growth and keep our economy strong in years to come while also helping to reduce the long-term deficit.

I'm sure many of you have questions, and I'm happy to take those now.

Thank you very much, again, Mr. Chairman.
[The statement follows:]

PREPARED STATEMENT OF SECRETARY KATHLEEN SEBELIUS

Chairman Harkin, Ranking Member Moran, and members of the committee, thank you for the invitation to discuss the President's fiscal year 2014 budget for the U.S. Department of Health and Human Services.

This budget for the Department of Health and Human Services (HHS) provides critical investments in health care, disease prevention, social services, and scientific research in order to create healthier and safer families, stronger communities, and a thriving America. While it invests in areas that are critical to our long-term prosperity, the budget also helps tackle our deficit with legislative proposals that would save an estimated net \$361.1 billion over 10 years. The budget totals \$967.3 billion in outlays and proposes \$80.1 billion in discretionary budget authority. With this funding HHS will continue to improve health care and expand coverage, create opportunity and give kids the chance to succeed, protect vulnerable populations, promote science and innovation, protect the nation's public health and national security, and focus on responsible stewardship of taxpayer dollars.

IMPROVING HEALTH CARE AND EXPANDING COVERAGE

Expanding Health Insurance Coverage.—Implementation of the Exchanges, also referred to as Marketplaces, will improve access to insurance coverage for more than 25 million Americans. Marketplaces make purchasing private health insurance easier by providing eligible consumers and small businesses with one-stop-shopping where they can compare plans. New premium tax credits and the increased transparency and competition in the Marketplaces will improve affordability of private coverage. Fiscal year 2014 is the first coverage year for plans purchased through the Marketplaces; open enrollment begins October 1, 2013 for the coverage year beginning January 1, 2014. The budget supports operations in the Federal Marketplaces, as well as oversight of and assistance to State-based Marketplaces.

Beginning in 2014, consumers will benefit from a number of new protections in the private health insurance market. Most health insurers will no longer be allowed to charge more or deny coverage to people because of pre-existing conditions. These new protections will also prohibit most health insurers from putting annual dollar limits on benefits and from varying premiums based on gender or any factor other than age, tobacco use, family size, or geography. In addition, new plans in the individual and small group market will be required to cover a comprehensive package of items and services known as Essential Health Benefits, which must include items and services within benefit 10 categories. Finally, most individuals choosing to participate in clinical trials will generally not face limits in health insurance coverage for routine patient costs. This protection applies to all clinical trials that treat cancer or other life-threatening diseases.

Expanding Access to Care through Health Centers.—The fiscal year 2014 budget includes \$3.8 billion for the Health Centers program, including \$2.2 billion in mandatory funding provided through the Affordable Care Act Community Health Center Fund. In fiscal year 2014, 23 million patients will receive health care through more than 8,900 sites in medically underserved communities throughout the Nation. The budget funds new health center sites for the provision of preventive health care services, expanding outreach and care to approximately 1.5 million additional patients.

Improving Patient Safety.—HHS is committed to improving patient safety and reducing the risks and harm to patients. The budget includes \$63 million for patient safety research at the Agency for Healthcare Research and Quality (AHRQ). This research focuses on the risks of harm inherent in the delivery of health care, which helps us understand the factors that can contribute to adverse events and how to prevent them. In fiscal year 2014, AHRQ will fund projects on improving team performance, provider training, and coordination, as well as establishing cultures conducive to patient safety in health care organizations. This research will help the medical community reduce errors and improve patient safety.

INCREASING ACCESS TO MENTAL HEALTH SERVICES

The fiscal year 2014 budget includes over \$1 billion for mental health programs at the Substance Abuse and Mental Health Services Administration (SAMSHA), including the \$460 million for the Community Mental Health Services Block Grant. This block grant provides States flexible funding to maintain community based mental health services for children and adults with serious mental illnesses, including rehabilitation, supported housing, and employment opportunities. The budget also proposes funding within the block grant to encourage States to build provider capacity to bill public and private insurance. This will support States in an effective tran-

sition in the first year of the Affordable Care Act, which will include expanded coverage for mental health and substance abuse treatment services.

Expand Prevention and Treatment for Youth and Families.—While the vast majority of Americans with a mental illness are not violent, and are in fact more likely to be the victims of violence, recent tragedies have brought to light a hidden crisis in America’s mental health system. The budget addresses these issues by investing \$130 million to help teachers and other adults recognize signs of mental illness in students and refer them to help if needed, support innovative State-based programs to improve mental health outcomes for young people ages 16–25, and train 5,000 more mental health professionals with a focus on serving students and young adults.

HELPING FAMILIES AND CHILDREN SUCCEED

In his State of the Union Address, the President proposed a series of new investments to create a continuum of high-quality early learning services for children beginning at birth through age five. As part of this initiative, HHS and the Department of Education are working together to make universal, high-quality preschool available to 4-year olds from low- and moderate-income families through a partnership with States, expand the availability of high-quality care for infants and toddlers, and increase highly-effective, voluntary home visiting programs to provide health, social, and education supports to low-income families. Specifically, the fiscal year 2014 HHS budget includes:

Early Head Start—Child Care Partnerships.—The budget proposes \$1.4 billion in fiscal year 2014 for new Early Head Start—Child Care Partnerships that will expand the availability of early learning programs that meet the highest standards of quality for infants and toddlers, serving children from birth through age 3. In addition to the new Partnerships, the budget provides \$222 million above fiscal year 2012 to strengthen services for children currently enrolled in the program, avoid further enrollment reductions, and support the Head Start Designation Renewal System. Together, these investments total \$9.6 billion, an increase of \$1.7 billion over fiscal year 2012.

Child Care Quality Fund.—The request includes an additional \$700 million above fiscal year 2012 to expand early learning opportunities. Within this total, \$200 million will help states raise the bar on quality by strengthening health and safety measures in child care settings, supporting professional development for providers, and promoting transparency and consumer education to help parents make informed child care choices. In addition to this funding, the budget provides \$500 million above fiscal year 2012 to serve 1.4 million children, approximately 100,000 more than would otherwise be served.

Home Visiting.—The budget extends and expands this voluntary evidence-based program that has shown to be critical in improving maternal and child health outcomes in the early years, leaving long-lasting, positive impacts on parenting skills; children’s cognitive, language, and social-emotional development; and school readiness. The budget proposes a long-term \$15 billion investment beginning in fiscal year 2015.

Unaccompanied Alien Children.—I would like to thank the Congress for providing an additional \$248 million for the refugee appropriation in fiscal year 2013 to accommodate the increased number of unaccompanied alien children (UAC) while maintaining services for refugees. While sequestration and the across-the-board rescission still leave a shortfall, we are taking necessary action to ensure we can accommodate all UAC arrivals without reducing essential refugee services. The fiscal year 2014 budget request includes \$1.1 billion, an increase of \$355 million over fiscal year 2012, to accommodate 26,000 UAC while maintaining services for refugees. HHS has kept Congress informed about the continuing UAC increase and looks forward to working with Congress to ensure both UAC and refugees are served.

PROTECTING VULNERABLE POPULATIONS

Addressing the Unique Needs of Communities.—The Administration for Community Living (ACL) was formed in April 2012 as a single agency designed to help more people with disabilities and older adults have the option to live in their homes and participate fully in their communities. The fiscal year 2014 budget reflects the creation of ACL by bringing together the resources for the Administration on Aging, the Office on Disability, and the Administration on Intellectual and Developmental Disabilities, into a consolidated request. This newly organized agency works across HHS to harmonize efforts to promote community living, which can both save Federal funds and allow people to choose to live with dignity in the communities they call home. ACL’s Lifespan Respite Care program, as an example, focuses on pro-

viding a testbed for needed infrastructure changes and on filling gaps in service by putting in place coordinated systems of accessible, community-based respite care services for family caregivers of children and adults with special needs.

Ryan White.—The budget includes \$2.4 billion for the Ryan White HIV/AIDS program to continue its critical role in support of patients across the HIV/AIDS continuum, by linking patients to care, prescribing and improving adherence to antiretroviral medicine, and achieving viral suppression. Included in this total is \$943 million for the AIDS Drug Assistance Program (ADAP), an increase of \$10 million over fiscal year 2012 to provide life-saving and life-extending medications to 218,900 individuals. This investment will allow ADAP to serve an additional 1,600 people living with HIV/AIDS relative to the estimated number of clients served in fiscal year 2012.

PROMOTING SCIENCE AND INNOVATION

Advancing Scientific Knowledge.—The fiscal year 2014 budget includes \$31.3 billion for the National Institutes of Health (NIH), an increase of \$471 million over the fiscal year 2012 level, reflecting the Administration's priority to invest in innovative biomedical and behavioral research that spurs economic growth while advancing biomedical science. In fiscal year 2014, NIH will focus on investing in today's basic research for tomorrow's breakthroughs, advancing translational sciences, and recruiting and retaining diverse scientific talent and creativity. Investment in NIH also helps drive the biotechnology sector and assure the Nation's place as a leader in science and technology.

Alzheimer's Disease Initiatives.—The Department continues to implement the National Plan to Address Alzheimer's Disease, as required by the National Alzheimer's Project Act. In fiscal year 2014, the budget includes a \$100 million initiative targeted to expanding research, education, and outreach on Alzheimer's disease, and to improving patient, family, and caregiver support. Included in this initiative is \$80 million within the NIH budget to be devoted to speeding drug development and testing new therapies. Also, the Prevention and Public Health Fund (Prevention Fund) allocation includes \$20 million for the Alzheimer's Disease Initiative. Of this, ACL will use \$15 million to strengthen state and local dementia intervention capabilities and for outreach to inform those who care for individuals with Alzheimer's disease about resources available to help them. HRSA will use the other \$5 million to expand efforts to provide training to healthcare providers on Alzheimer's disease and related dementias.

PROTECTING THE NATION'S PUBLIC HEALTH AND NATIONAL SECURITY

Project BioShield and Advanced Development.—In fiscal year 2014, HHS will continue to support the development and procurement of medical countermeasures (MCMs) against chemical, biological, radiological, and nuclear (CBRN) threats. This funding includes \$415 million to support advanced research and development of MCMs through the Biomedical Advanced Research and Development Authority. Additionally, the Budget includes \$250 million as the first installment of a multi-year commitment to support Project BioShield, aimed to facilitate the procurement of these MCMs for the Strategic National Stockpile. Together, these efforts will enhance the nation's ability to acquire MCMs that will be vital to mitigating or preventing the effects of CBRN threats.

Infectious Disease Surveillance Modernization.—The budget invests \$40 million to modernize CDC's surveillance technology and methods to better detect and track infectious disease. This investment will allow CDC to retool its national surveillance systems and detect and respond to emerging health threats in a timely manner. CDC's infectious disease surveillance technologies are becoming increasingly outdated and threaten the basic public health mission of the agency. In an effort to keep up with advances, CDC is making substantial investments in bioinformatics, database development, data warehousing, and analytics. This initiative requires strategic and sustained investment in the following areas: pathogen identification and detection using genomics, adaptation of new diagnostics, state assistance and coordination, enhanced and integrated sustainable laboratory systems, and tool development to support prediction and modeling for early disease detection.

FOCUSING ON RESPONSIBLE STEWARDSHIP OF TAXPAYER DOLLARS

Contributing to Deficit Reduction While Maintaining Promises to All Americans.—The budget makes the investments the nation needs right now while reducing the deficit in the long term and ensuring the programs that millions of Americans rely on will be there for generations to come.

The budget maintains ongoing investments in areas most central to advancing the HHS mission while making reductions to lower priority areas, reducing duplication, and increasing administrative efficiencies. Overall, the fiscal year 2014 budget includes nearly \$2.3 billion in discretionary terminations and reductions.

Combating Fraud, Waste, and Abuse in Health Care.—The fiscal year 2014 budget makes continuing to cut fraud, waste, and abuse a top Administration priority. In addition to the \$311 million in base discretionary Health Care Fraud and Abuse Control (HCFAC) funding, the budget invests \$329 million in new mandatory funding in fiscal year 2014 to ensure that HHS and the Department of Justice (DOJ) have the resources they need to conduct critical program integrity activities. Starting in fiscal year 2015, the budget proposes all new HCFAC investments be mandatory, consistent with levels in the Budget Control Act. This investment supports fraud prevention initiatives like the Fraud Prevention System and provider screening; reducing improper payments in Medicare, Medicaid and CHIP; and HHS-Department of Justice Health Care Fraud Prevention and Enforcement Action Team initiatives, including the Medicare Strike Force teams and the Fraud Prevention Partnership between the Federal government, private insurers, and other key stakeholders.

From 1997 to 2012, HCFAC programs have returned over \$23.0 billion to the Medicare Trust Funds, and the current 3-year return-on-investment of 7.9 to 1 is the highest in the history of the HCFAC program. The budget's 10-year HCFAC investment yields a conservative estimate of \$6.7 billion in Medicare and Medicaid savings.

The budget includes \$389 million in discretionary and mandatory funding for the Office of Inspector General (OIG), an increase of \$101 million above the fiscal year 2012 level. A portion of this increase is funded through the additional mandatory HCFAC investment, which is a top priority in this budget. This increase will enable OIG to expand Program Integrity efforts for the Health Care Fraud Prevention and Enforcement Action Team and improper payments, and also enhance investigative efforts focused on civil fraud, oversight of grants, and the operation of Affordable Care Act programs.

The budget also includes \$82 million for the Office of Medicare Hearings and Appeals (OMHA), an increase of \$10 million from fiscal year 2012, to address OMHA's adjudicatory capacity and staffing levels and maintain quality and accuracy of its decisions. The increase allows OMHA to establish a new field office in the Central time zone supported by additional Administrative Law Judge teams, attorneys, and operational staff.

PERFORMANCE, EVALUATIONS, AND EFFECTIVENESS

Assessing the Impact of Health Insurance Coverage Expansions on Safety Net Programs.—The budget includes \$3 million to the Assistant Secretary for Planning and Evaluation to evaluate the impact of health insurance coverage and benefit expansions among beneficiaries of HHS direct service programs. This request supports the continuation of research and evaluation studies, collection of data, and assessments of the costs, benefits and impacts of policies and programs under consideration by HHS or the Congress.

Improving the Use of Evidence-Based Interventions.—The budget includes proposals to improve the use of evidence-based interventions in SAMHSA's Mental Health Block Grant to ensure that Federal resources are invested in strategies that work. This proposal will require States to target resources, through their formula grant allocations, to evidence-based interventions.

The budget will also substantially increase support for the National Registry of Evidence-based Programs and Practices. This searchable online system supports States, communities, and tribes in identifying and implementing evidence-based mental health and substance abuse prevention and treatment interventions. Additional funding will be used to ensure the registry includes cutting edge innovations that work.

Thank you for the opportunity to testify. I will be happy to answer any questions you may have.

Senator HARKIN. Thank you, Madam Secretary. We'll start rounds of questions.

Well, since you didn't mention it in your statement, in your written statement nor in your verbal statement, I hope you don't mind if I start talking about prevention.

Secretary SEBELIUS. Yes, sir.

RACIAL AND ETHNIC APPROACHES TO COMMUNITY HEALTH

Senator HARKIN. I'm deeply concerned by the President's plan to eliminate the Racial and Ethnic Approaches to Community Health (REACH) program. That's the Racial and Ethnic Approaches to Community Health program. African-Americans and Latinos are nearly twice as likely to have diabetes than are non-Hispanic whites in this country. A shocking 18.7 percent of all African-Americans aged 20 years or older have diabetes, according to the American Diabetes Association.

These disparities are desperately important as we think about how to improve the health of this country and bend the cost curve. Clearly, we have to work with the leaders of these communities if we're to have an impact.

REACH has been very successful in doing that. From 2001 to 2009, physical activity rates among minority populations in REACH communities increased from 7 percent to 12 percent. It may not sound like a lot, but compare that to a U.S. average in the general population of 2 percent to 5 percent.

So in the places where REACH is working, physical activity grew at two to three times the rate it grew elsewhere in the country. This is a staggering success.

So I have to ask, if the administration is truly concerned about bending the cost curve on healthcare, why would you eliminate a program doing such important and successful work?

Secretary SEBELIUS. Mr. Chairman, I, first of all, want to applaud your incredible leadership and tenacity on prevention. You have been trying to change the focus of the health system, as you say, for well over two decades and have been uniquely focused on this initiative, and have been successful in creating, for the first time ever, an ongoing stream of funding in the Prevention Fund. And that's a huge step forward.

I think there's no question that this budget represents some very difficult decisions. But in the case of the Health Disparity Initiative, what we feel very strongly, and I think has been proven by data throughout the country, is that connecting minority communities with a health home and ongoing insurance benefits may be the single most successful way to make sure that preventive benefits are available to every family, to every person, day in and day out.

And so we are, as you suggested, focusing some of the Prevention Fund dollars on not building the exchanges but on the outreach and education efforts to make sure, particularly in the most vulnerable minority communities in the most underserved communities, that they have access to the prevention benefits, which are now by law part of insurance coverage.

And we feel that those efforts, combined with our ongoing work on obesity initiatives led by the First Lady, and a number initiatives with the President's Physical Fitness and Nutrition Council, that we are changing school eating patterns, changing food deserts, driving down obesity rates, and focusing on tobacco. We feel that those efforts will be enormously successful.

Senator HARKIN. REACH was funded at \$54 million in fiscal year 2012, \$54 million in fiscal year 2012. There were \$13 million in our

bill, \$40 million from the prevention fund. I don't know what fiscal year 2013 is yet. We'll get that later this week.

But in the fiscal year 2014 budget request, the total is zero. Nothing from us. Nothing from the prevention fund for a uniquely targeted prevention program that over the last several years has proven to work.

I ask again, why are we zeroing out this program?

Secretary SEBELIUS. Again, Mr. Chairman, I think this budget reflects difficult choices, and we are focusing an enormous amount of effort on reaching people and connecting them not just with a one-time program or one-time effort but with ongoing healthcare and preventive benefits, which has been proven to be enormously important in maintaining and continuing good health.

Senator HARKIN. Well, let's see, your budget is—how much here was it this last year? How much was your budget, total HHS budget last year—this year, fiscal year 2013?

Secretary SEBELIUS. Discretionary and mandatory, or just discretionary? The total outlays are \$967 billion.

Senator HARKIN. \$967 billion?

Secretary SEBELIUS. Mandatory, \$886 billion; discretionary, \$80 billion.

Senator HARKIN. Got it. \$967 billion and yet we have to take \$54 million from the REACH program out of \$967 billion.

Well, I'm sorry. When I look at that, and I look at the other invasions of the prevention fund, again, I get back to where I started. This administration doesn't get it. We just keep trying to think about how we pay today's bills. How do we get people covered if they're sick today? That's important. But if that's all we're going to do, we're looking at the next 30, 40 years going after the same chronic diseases we've had in the last 40 or 50 years.

I'm sorry, I just can't buy that out of \$967 billion, that \$54 million has to come—I'm just talking about one program, the REACH program. I'm not talking about all the other prevention funds that are being invaded.

But, again, I don't know what the will of this committee will be. But I can tell you that, as far as this chairman is concerned, this is not good, to take that money for the REACH program out of that pot. So we'll have some say about that when we move ahead.

Secretary SEBELIUS. Mr. Chairman, again, I know another priority of yours is the Community Transformation Grant.

Senator HARKIN. That's exactly right.

Secretary SEBELIUS. And there is a lot of duplication between REACH efforts and Community Transformation efforts, which are focused on many of the same disease prevention initiatives. And the Fund does continue the Community Transformation Grant program, not only in 2013, but in 2014 it maintains the level of funding and continues those efforts focused on prevention of chronic diseases for the minority communities that the REACH program did focus on.

Senator HARKIN. Well, I'm more than willing to take a look at that. If there is some duplication, that's fine. Let's straighten that out.

But it's just one prevention program that's been uniquely successful.

Well, I'll take a look at it.
 Senator Moran.

AFFORDABLE CARE ACT IMPLEMENTATION

Senator MORAN. Mr. Chairman, thank you.

I'm going to first start with the question that I indicated I would raise, which is the authority by which you can transfer the funds to pay for the federally created exchanges.

Under the Affordable Care Act authorization, the prevention fund can be used for "programs authorized by the Public Health Service Act for prevention wellness and public health activities, including prevention research and health screenings, such as the Community Transformation Grant program, the Education and Outreach Campaign for Preventive Benefits, and immunization programs."

Health insurance exchanges are not authorized under the Public Service Act, nor do they fit any of the listed criteria. What authority does the Department use to move prevention fund dollars to health insurance exchanges?

Secretary SEBELIUS. Well, again, Senator, I think I would disagree with the characterization of your interpretation of section 4002 of the Act.

We are not using prevention dollars for building the marketplaces for the hub, or for the information technology (IT) for the call center. What we are doing is focusing some resources from the prevention fund on education and outreach to make sure that eligible individuals understand what benefits they are entitled to receive and how to actually enroll, so that they can get ongoing prevention coverage. So we think it fits very well in the education and outreach campaign regarding preventive benefits.

Every insurance policy sold in the marketplaces in every State in the country will have preventive benefits available with no copays and no insurance. That's a huge step forward, and that is what these funds will be designed to do—education and outreach in States around the country for, as you suggested, the marketplaces that the Federal Government will be operating.

Senator MORAN. So the President's budget request does not take money from the prevention fund to create the exchange, only to provide money necessary to educate people about the exchange.

Secretary SEBELIUS. It will be for education and outreach, yes, sir.

Senator MORAN. How then does the President's budget address the issue of the 33 States that have, at least at this point, decided not to create a State exchange?

Secretary SEBELIUS. Well, again, that math is a little wrong. We have 31 States and the District of Columbia who are either engaged in some kind of partnership or fully running their own exchanges. So the characterization that there are 33 States who have sort of given this over to the Federal Government is not quite accurate.

Having said that—

Senator MORAN. So the number is what, 20-something?

Secretary SEBELIUS. Well, there are 32 entities: 31 States and District.

Senator MORAN. Eighteen?

Secretary SEBELIUS. Yes.

So in the States where we are operating the marketplace, and for the Federal hub, which is a connector that every State will use, we have used the previously allocated administrative budget to actually build that infrastructure, and that is paid for.

We had \$1 billion in original administrative costs dedicated to the exchange moving forward. States have additional funding sources, if they are operating their own exchange, they can draw that funding down.

But our administrative costs have gone to not only the Department of Labor, and the Department of Treasury, but for HHS to build the infrastructure that we need for the Federal hub, for the IT center, for the call center.

Senator MORAN. So while I assume the expectation was that most, if not all, States would create a State exchange, and that hasn't happened—apparently, 18 is the number of States that have not—your ability to fund, and create a fund to create a federally created exchange, exists within existing dollars within your appropriated budget?

Secretary SEBELIUS. Well, as you know, and the chairman knows, we did ask for additional resources for 2013. There was an anomaly submitted by the administration.

Most of that funding would have been for education and outreach, and for the call center. We did not receive any additional funding from the continuing resolution, so we are still operating at the 2012 level with the original \$1 billion, which was allocated for administrative overhead.

Senator MORAN. What is the expected cost to create the Federal exchanges—instead of the State exchanges?

Secretary SEBELIUS. Well, the budget before you requests an additional \$1.5 billion. I think the good news is that when the Affordable Care Act was passed, the Congressional Budget Office (CBO) suggested that the administrative overhead should be in the \$10 billion range, as they projected the costs out.

We received \$1 billion in funding with the law, and we are requesting, at this point, an additional \$1.5 billion.

Senator MORAN. My time has expired. I assume we'll have additional rounds.

Senator HARKIN. Yes.

Senator MORAN. Thank you, Secretary.

Senator HARKIN. In order of appearance, we have Senator Alexander, Senator Pryor, Senator Cochran.

Senator Alexander.

Senator ALEXANDER. Madam Secretary, welcome. It's good to see you.

AFFORDABLE CARE ACT

Where did the definition that a full-time worker is someone who works more than 30 hours come from? I can't find it in the Fair Labor Standards Act. It sounds more like France than the United States.

Secretary SEBELIUS. I assume it was the definition. As you know, the regs were written by HHS, the Department of Labor and Treas-

ury. It was a tri-Department initiative. And if you're asking me exactly what the nexus of the 30-hour—

Senator ALEXANDER. Well, I just wonder why, you know, typically, I mean basically the basic—

Secretary SEBELIUS. It's in the statute. It's in the Affordable Care Act.

Senator ALEXANDER. It's in the Affordable Care Act.

Secretary SEBELIUS. That's what I was told by my experts.

Senator ALEXANDER. Well, I wonder where Senator Harkin got it, or whoever wrote it in the United States.

Normally, we think of a full-time workweek as a 40-hour workweek. And I was wondering about the rationale for that, because don't you think that the 30—the rule that says that if you work 30 hours, you could be considered a part-time worker, is in some cases becoming a disincentive for full-time employment, as some companies look at the healthcare law and say one way we can avoid it is to have more part-time workers. And so we have workers across the country who are going from full time at 40 hours to part time at 30 hours. And so they have not only no insurance, but no full-time job.

Secretary SEBELIUS. Well, I am hoping that that will not be a decision employers make. I think that when the law was written, there was great care taken to try and capture what is a snapshot of the small employer marketplace.

Any employer with less than 50 full-time equivalent employees is totally exempt from any aspect of the law, except for the fact that he or she may have the opportunity for the first time ever to buy affordable coverage in a larger pool without having to join an association or be a member.

I think that as people get more familiar with what the rules are and are not, we're likely to see the kind of input that at least I had heard for the couple of years before this law was passed. Certainly, as Governor, I heard each and every day from farm families and small-business owners that they had no access to affordable health coverage.

They felt disadvantaged in competing with their larger competitors, because they couldn't offer the benefits that large competitors—

Senator ALEXANDER. I was really just asking where the 30-hour came from.

Secretary SEBELIUS. It's in the law.

Senator ALEXANDER. It's in the law. But it seems to me to be providing a disincentive for full-time employment.

But I have a different sort of question I'd like to ask you to comment on. Under the new healthcare law, one of the things that can happen is a problem for those on Medicaid, which some people call "churning."

It usually affects those who make between 138 percent of the poverty level and 150 percent. And through basically no fault of their own, they might be going back and forth from the exchanges to the Medicaid program based upon their changing income.

And it has been suggested that one way to provide more certainty for those lower income working people would be a plan that would help them own their own insurance, so that as they went

back and forth from different income levels, their lives would be simpler, which would be good for them.

Arkansas has made an interesting proposal, which you've seen to have approved in concept—a lot of people are watching—that incorporates some different ideas.

And Governor Haslam of Tennessee has watched that very closely. I know he's talked with you about what he calls his Tennessee plan for using the money that would be otherwise available for many of those Medicaid recipients.

I try to follow the rule that there can only be one Governor of Tennessee at a time, and I'm not it right now. But I would be interested. I don't want to interfere with your discussions with Governor Haslam, is what I'm trying to say, and I hope they continue and I hope they're successful.

But I wonder if there's anything you might say about the general idea of the Arkansas plan and the Tennessee proposal that Governor Haslam has made and any report that you might have on its status.

Secretary SEBELIUS. Well, Senator, I think you're absolutely correct that I have been in close touch with Governor Haslam. I think we've had a couple of meetings in person and several phone conversations in the last couple of months.

I think he is evaluating whether or not expansion of Medicaid is beneficial for Tennessee, looking at all the cost estimates and looking at the health benefits for individuals. And he has asked for a lot of information that we've been providing him.

We are waiting to receive the specific proposal from Arkansas. But, certainly, we're in very close touch with Governor Beebe, as well as Governor Kasich in Ohio and Governor Scott in Florida and some others, around the notion that Medicaid dollars could be potentially used to purchase coverage from a company offering coverage on the exchange, and, as you say, kind of eliminating people going back and forth.

As you know, and I'm sure that Tennessee has a similar situation to Kansas—most of the Medicaid program is offered right now by managed care companies. Their contracts are already there. Those companies will be providing benefits on the exchange.

So we are working around sort of premium assistance plans. There is more flexibility in the original Medicaid law for cost sharing, for a different kind of benefit package for those above 100 percent of poverty.

And I think Governors are very intrigued by creating a format where, particularly for the higher income low-income workers there would be a package that looked very similar to what's in the private market and have the ability, if someone's wages continue to rise, that they would stay with that plan.

So we're waiting to receive the specific proposal from Arkansas. We've made it clear that we would be open to some waivers from States looking at this kind of interpretation and are interested.

And I have told Governor Haslam that very clearly. So I think he's waiting to see exactly what Arkansas submits.

But as I shared with you, the Arkansas bill did pass, both the House and the Senate, by a three-fourths vote. And they will now submit a proposal to Medicaid.

Senator ALEXANDER. Thanks, Madam Secretary.

Thanks, Mr. Chairman.

Senator HARKIN. I will say to my friend in Tennessee, he asked where I got this, so I had to check with my staff. And the Secretary was right, refreshing my memory on this. We obviously checked with the Department of Labor, trying to figure out who is a full-time employee.

And as the Secretary said, quite correctly, that the snapshot was taken at that time. What do employers, writ large, what do they use as a cutoff for employee benefits, for who is a full-time employee and who is not? And it came in at, basically, 30 hours. So that's what was written in.

So that's kind of where it came from. That's what employers were using at that time to decide whether someone was a full-time employee or not.

Senator ALEXANDER. Thank you.

Senator HARKIN. That's all I can figure out.

Okay, Senator Pryor.

Senator PRYOR. Thank you, Mr. Chairman.

And thank you, Secretary Sebelius, for being here. We appreciate your service very much.

I want to follow up on Senator Alexander's question. I want to say thank you. Thank you for working with Governor Beebe.

CHILDREN'S GRADUATE MEDICAL EDUCATION

I know that you all have a good working relationship, and he signed an important bill into law yesterday. I'm sure there's a lot more work to be done.

But I want to say thank you for your help, because you are innovative, and were trying to get to yes. We appreciate that very much. It's going to make a huge difference for the people in my State.

Second thing I want to talk about is pediatrician graduate medical education. I think what a lot of people don't completely understand is that a very large portion of our funding for training of physicians across the country comes through Medicare. Not much of that is for pediatrics though. But nonetheless, a very high percentage of doctors get their training through funding in Medicare.

I would like to visit with you about the pediatric graduate medical education provision as we are looking to recruit more primary care physicians, and for ways to train more doctors and get more doctors in the field. States are under tremendous budget restraints and constraints. How do you think we can train enough pediatric care physicians to meet the needs that we have in this country?

Secretary SEBELIUS. Well, Senator, first of all, I want to say that I was pleased to work with my old colleague Mike Beebe. And not only has he been very innovative about Medicaid expansion ideas, but we are doing some really exciting work in Arkansas around sort of an all-payer transformation of the whole healthcare system. And Arkansas has been a real leader in that effort.

In terms of the children's graduate medical education, certainly, training pediatricians in the future and the whole workforce issue is of critical importance. What this budget reflects is funding for

the direct costs of the medical education and not the indirect costs, which often are up to 40 percent on top of the original costs.

We think it's critical to keep those slots in pediatrics and, in fact, have done some work to shift additional slots used for specialty care into primary care, geriatric care, and pediatric care.

But the budget, as I said, does reflect the direct costs. And we are hopeful that the same number of resident slots will be available going into the future.

AREA HEALTH EDUCATION CENTER

Senator PRYOR. Thank you. I think that many of my colleagues here would share that same concern, not just about pediatric slots, but general educational slots, to try to make sure that we train and equip the very best physicians we can.

And, hopefully, a lot of them will end up in rural America. As you know, depending on how you count it, about 20 percent of the Nation's population is in rural America, but only 9 percent of the doctors. So the challenge there continues.

Let me ask about the Area Health Education Center (AHEC) program. As we discussed a moment ago, Arkansas is in a process of a big expansion of private healthcare in our State. AHEC is a program that for years has worked in Arkansas, and it has worked very well. I'm concerned that through the President's budget that we may be jeopardizing or at least stunting some of that progress that we're seeing in my State through AHECs.

So are we going to continue the AHEC funding?

Secretary SEBELIUS. Senator, I'm not sure I can directly answer that question, but I'd love to come back to you and respond in writing with some details.

[The information follows:]

The fiscal year 2014 President's budget prioritizes allocating Federal resources to training programs that directly increase the number of primary care providers. Given the lean fiscal climate, HRSA had to make difficult choices regarding program funding levels. While HRSA has made longstanding investments in these activities to enhance health professions training since 1972, they do not directly increase the supply of providers. Given the most AHEC programs have been in place for many years and have State and local support, it is anticipated that the AHEC program grantees will continue much of their efforts relying on these other funding sources.

Senator PRYOR. Okay, that'd be great.

CRITICAL ACCESS HOSPITALS

With regard to rural hospitals, critical access care hospitals, there have been some changes for those hospitals. When I talk to rural hospitals in my State, they tell me that budgets are tight, and that some of the changes in Medicare are making them even tighter. And then you throw the sequester on top of that. And now we're talking about a 1-percent cut here in the President's fiscal year 2014 budget.

Critical access care hospitals really impact rural America. And I would like to get your thoughts on how we can help these hospitals.

I know they're working on efficiencies. They're trying to do all they can. But how can we help these hospitals keep their doors open?

Secretary SEBELIUS. Well, Senator, as Ranking Member Moran already suggested, coming from Kansas, we do like to refer to your State as “Ar-Kansas” as much as possible.

I am fully aware of how critical hospitals are to a community. If you close a school, if you close a hospital, you close a town. Nobody wants to live without a healthcare facility. So it’s something that I take very seriously.

This budget submission is the same as it was in 2013, which reflects that critical access hospitals would be paid at 100 percent of cost, not paid more than 100 percent, but it reflects that they would have their cost fully reimbursed. And we felt that that was an appropriate way to deal with making sure that they did keep their doors open and had the ability to serve patients in their communities.

Senator PRYOR. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Pryor.

Now Senator Cochran, and Senator Boozman, and then Senator Johanns.

Senator Cochran.

Senator COCHRAN. Mr. Chairman, Madam Secretary, thank you very much.

CRITICAL ACCESS HOSPITALS

Because Arkansas and Mississippi have a lot in common, except football prowess—that kind of goes back and forth—but we have a large number of poor people living in our States. And many of them have benefited from Department of Health and Human Services’ sensitivity to the challenges that many of our small-town hospitals face in our two States.

And they’re worried now, though, about how these new regulations or new programs might affect them in an adverse way.

So I refer to a letter that our delegation sent to your office, wondering if you could let us know what your plans are for critical access hospitals, and whether or not certain payments of reimbursement of cost will reflect the fact that some of these in the Mississippi River Delta region may not be able to keep their emergency rooms open as they are now and available to people who need medical attention.

What concerns can you address today that will be good news for them that it isn’t going to have as bad a consequence as many down there fear?

Secretary SEBELIUS. Well, I think, Senator, a couple of things, hopefully, will give you some assurances.

First of all, as I suggested to Senator Pryor, the budget request before this committee has 100 percent of costs for critical access hospitals, recognizing that keeping the doors open in small communities is really essential. So it does reduce from 101 percent to 100 percent, but it is a full reimbursement for cost.

Secondly, the debate that is underway in many States around the country has caught the attention of hospitals. In anticipation of full implementation of the Affordable Care Act, whether it’s people who will be enrolled in private health plans in marketplaces in a State like Mississippi, or if, indeed, the Mississippi Governor chose to expand Medicaid, hospitals would be looking at a dramatic

reduction in uncompensated care that right now is threatening, certainly, the lowest margin hospital.

Hospitals deliver care if somebody comes through the door. But if that person does not have either health insurance or an ability to self-pay the bill, that really adds to the hospital's bad debt. And we see that all over the country, which is why, I think, hospital executives and leaders have been so engaged in the discussions in State legislatures and also in communities about expansion of affordable health coverage—knowing that their bottom line will be dramatically and positively impacted by that change starting in 2014.

OFFICE OF MINORITY HEALTH

Senator COCHRAN. Our State advises me that partnership grants from the Office of Minority Health are going to be done away with under the new budget request submitted by the Department. Is that true or not?

Secretary SEBELIUS. We have eliminated some of the grants that come directly through the Office of Minority Health but have increased funding through some of our other programs in the area of health disparities.

So there's an overall increase in the budget in those programs and grants that will go into communities, but not funded directly through the Office of Minority Health.

Senator COCHRAN. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Cochran.

Senator BOOZMAN.

Senator BOOZMAN. Thank you, Mr. Chairman.

And thank you for being here. We really do appreciate your hard work. You've got a big job to do.

SMALL BUSINESSES AND THE AFFORDABLE CARE ACT

I hear a lot from Arkansas businesses that have perhaps 75 employees. Their concern is competing with the business that has 49. One group is under the mandate's increased costs. The other doesn't have those costs—that makes for a difficult situation.

And again, America, Arkansas, Kansas, wherever, is made up of those kinds of, you know—so I guess what I tell them—the other thing is, isn't that an incentive for those that are a little over the 49 to downsize?

And again the question I would ask is: What do we tell those employers that are losing hours or perhaps losing jobs as a result of that?

Secretary SEBELIUS. Well, Senator, I have heard those same concerns expressed by folks and, again, heard over and over again, the snapshot of the current market prior to the Affordable Care Act being implemented. What I hear is that small-business owners are paying about 20 percent more than their large competitors for exactly the same benefit package.

What we know is about 94 percent of employers who have 50 or more employees are offering health coverage, because it's the best recruitment and retention package they can have for their employees. But they still lose employees to the big guys who have more leverage in the marketplace.

So I think the law is attempting to capture what the snapshot of the market was and to put together a larger negotiated pool of benefits, so small employers can finally have the leverage that some of their large competitors have enjoyed for years.

What we saw in Massachusetts, which is the only State with a fully functional marketplace that's been in place, was a lot of the same business fears were expressed before they got up and running. They have a similar employer responsibility provision, a similar penalty. And the fear that was expressed was lots of employers would just drop coverage, drop out of the market.

What has happened is just the opposite. More employers right now in Massachusetts offer coverage than before. The small market has actually increased. And so we are hopeful that with affordable comparative rates, with competitive choices in a shopped plan, that those small employers will now have some choices to make for their employees.

Senator BOOZMAN. I'd like to see kind of the white paper, the research or your data to back it up.

You've got a situation in Washington State that is thinking about shifting a lot of employees into the exchange. Is that something that you intended? Evidently, when they——

Secretary SEBELIUS. In Washington State?

AFFORDABLE CARE ACT

Senator BOOZMAN. Yes, considering moving some State employees into the healthcare exchanges. This will shift healthcare costs from the State to the Federal Government. If others follow suit, this could cost the Federal Government billions. That's what the Associated Press (AP) is reporting. So that's something you need to look into, if you're not aware of.

Secretary SEBELIUS. Well, that's certainly something we'll look into. I've had many communications with the new Governor of Washington State, and I'm unaware of any conversation or decision——

Senator BOOZMAN. Well, let me read the first—again, this is an AP article. This is Olympia, Washington. "In a move that would capitalize on provisions under President Obama's healthcare law, but could cost the Federal Government millions of dollars, Washington State lawmakers have found a creative way to pass a large chunk of their healthcare expenditures along to Washington, DC—analysts say others are likely to follow suit."

So again, that's something that is being considered.

Evidently, as they do their white papers, their analysis, they're finding that it's, perhaps, to their advantage to do as the employers with a little bit higher, the 51 as opposed to 49.

My last question is that the President said the healthcare law would bring down premiums by \$2,500 for the typical family. What year can Arkansas families expect to see that savings?

Secretary SEBELIUS. Well, Senator, what we're seeing, prior to the full implementation, is actually one of the slowest growth trends over the last 3 years in private benefits. And I think that's due to a couple of things.

It's due to more rigorous insurance commissioner oversight. And a lot of commissioners both asked for and got new authorities from

their legislatures, hired actuaries, and are doing much more intensive rate reviews at the commissioner level.

We have in place, thanks to the law, the so-called 80/20 rule, where insurance companies for the first time have to make sure that 80 percent of their dollars collected are for health-related costs, not for overhead costs. And we saw last year about \$2 billion sent back to consumers around the country.

So some of those Arkansas families got checks last year to lower their benefit costs, because their companies didn't meet that ratio.

And the third step will be: The new marketplaces will provide families competitive choices, for the first time ever and if you're below 400 percent of poverty, the ability to get an accelerated tax credit as an assistant to purchase that without the overhead and administrative costs that a lot of companies added on.

And it wasn't President Obama. It was really the Congressional Budget Office who looked at that implementation, looked at both what competition can do, what transparency can do, what the new rules could do, and what the subsidy would do for families, and made that \$2,500 estimate.

But as you know, the markets aren't up and running. That will be next year, and we'll report back to the committee.

Senator BOOZMAN. Thank you, Mr. Chairman.

Senator JOHANNIS. Mr. Chairman, thank you.

Good to see you again.

Secretary SEBELIUS. Nice to see you, sir.

Senator JOHANNIS. Do you prefer to be called Governor or Secretary?

Secretary SEBELIUS. Either works. You missed Senator Alexander. He has three titles. But you only have two, Governor and Senator. Oh, that's right. You were Secretary. I'm so sorry. You are Governor, Secretary, Senator, too.

Senator JOHANNIS. That's right. Let me, if I might—

Secretary SEBELIUS. Probably a diplomat, I don't know.

Senator JOHANNIS. No, never a diplomat. I've never been accused of being diplomatic.

AFFORDABLE CARE ACT AND EMPLOYERS

CBO in a recent report, actually in February, estimated that 7 million people are expected to lose their employer-provided coverage due to the healthcare law. This estimate, as you know, continues to grow. CBO estimated 4 million in its August report.

CBO also estimated that the worst case is that as many as 20 million Americans could lose their employer-provided coverage under the healthcare law.

I think CBO is simply recognizing the reality of one of the features of this healthcare law. That reality very simply is this: That an employer looks at the cost of the healthcare plan, looks at the cost of the penalty, and makes a decision.

Now you and I can recognize that there's maybe a competitive advantage, in terms of recruiting employees, to provide them a healthcare plan versus paying the penalty and sending them to the exchange.

But I think the reality of what Senator Boozman was saying, and what the CBO is saying, is that the promise—if you like your

healthcare coverage, you're going to get to keep it; we can almost all quote that word for word—it's not fulfilled under this law.

And people who did like their healthcare coverage, who wanted to keep their healthcare coverage, they might have argued that it was costly and they wished that it was less costly, but having said that, they liked their coverage, wanted to keep their coverage. These people aren't going to be given that option.

What can you do, your Department do, to this phenomena that CBO recognizes is occurring and could get a lot worse, 20 million, I mean, just the impact on the subsidies would be rather breath-taking. So how do you stem that tide?

Secretary SEBELIUS. Well, Senator, a couple of things.

First of all, I think that it is correct that CBO did adjust the baseline. I think what is incorrect is the assumption that meant people would lose their employer coverage.

They were really adjusting the baseline based on the Supreme Court decision that made Medicaid expansion voluntary. And they readjusted, suggesting that some of the people who were in States where a Governor chose not to expand Medicaid would be coming into the exchange at above 100 percent of poverty. And that was the basic baseline adjustment.

So fewer States would have the full expansion. More States would have people in the exchange based on the Governor's decision not to expand.

I think also that if you look at the 155 million people or so who are currently provided employer coverage, or are dependents of someone who is provided employer coverage, as you know, that market was totally voluntary. And the part of the market that worked the least well for both employers and often employees was the small group market. That is certainly the case for the entrepreneurs or self-employed or family business folks who were shopping in and out. Coverage for that population, over a 10-year period prior to the Affordable Care Act, has gotten more and more expensive and fewer and fewer people were covered.

So that is the segment of the market that will be most affected by the new marketplaces. Most large employer plans are grandfathered in. Most medium employer plans are grandfathered in. The new market benchmark captures the most popular employer plan in the marketplace, allows a State to set the benchmarks and the flexibilities.

As Senator Harkin said, with 30 hours, we have tried to actually capture the snapshot of what was going on in the market, and allow States to make a lot of choices that fit—what fits Nebraska may not be the same as what works in Iowa or in California. So it is a very State-based choice.

And we're hopeful that choice will be reflected in more affordable coverage, but the snapshot is what's going on in the business community right now in those States.

Senator JOHANNIS. I'm out of time, which is always one of the challenges in a hearing like this.

But there has been a tremendous amount of disagreement about this law from day 1. And I cannot emphasize enough, Madam Secretary, how much I disagree with what you just said.

I don't think that accurately reflects what CBO is getting at. People are going to lose their insurance. They already are.

The other thing that I would tell you, just by defining a plan and forcing everybody to offer that plan, the thought that you're somehow going to impact the price of that plan really doesn't make one wit of economic sense to me.

The problem these small businesses are having is that they are trying to insure a very small pool. But what small businesses are now doing, if they're at 48 people or 49, they just tell me, "Look, I'm not going to go over 50. I don't want to deal with this healthcare mess."

The other thing that I think is going to happen is the economics of a large employer taking people off a healthcare plan are huge. It's huge. And I think it will happen.

And I think once the dam breaks, it's going to be a mess. And there isn't anything you will be able to do about that. And I am just convinced it's going to happen.

The economics are just too big for that not to happen at some point, but we can continue this discussion.

Now, I'm way out of time. Thank you for your indulgence.

Senator HARKIN. Did you have a response?

Secretary SEBELIUS. I think I heard the Senator.

PREVENTION AND PUBLIC HEALTH FUND

Senator HARKIN. Okay, we'll start a second round.

Again, Madam Secretary, we know this. More than 75 percent of our Nation's health costs come from chronic diseases, many of which are preventable. That's part of the prevention title. That's why we have it there.

A lot of people focus on prevention as just being in the doctor's office. That's one part of it, the clinical setting. But it must be done in a broader setting in our society—communities, workplace, schools.

If we are really going to get ahead of this curve, we have to make it easier for Americans to make healthy choices. I've always said, "In America, it's easy to be unhealthy and hard to be healthy."

Why shouldn't that change? Why shouldn't it be easy to be healthy and harder to be unhealthy?

So anyway, we put in all the things like smoking cessation, diabetes prevention, wellness programs in the workplace. The Trust for America's Health has had a lot of reports in the past showing the return on investment to be 5- or 6-to-1.

So again, I'm back to where I started: The President's request for the prevention fund in fiscal year 2014.

Now, here is what's interesting. In the budget, there is money in the fund for things like newborn screening, cancer screening, birth defects prevention, things I think we can all agree on. At the same time, the budget proposes to cut these programs in the base Labor-HHS bill.

For example, the budget includes \$28.5 million in the fund for newborn screening. Everyone will say, well, that's great. But the budget cuts \$28.5 million from newborn screening in the base bill, our bill.

So there's no increase. We're just swapping it from one account to the other.

That was not the purpose of the prevention fund, to allow money to be just swapped out. It was to increase over and above what we have been doing for prevention.

We have the same situation with funding for teen pregnancy prevention, poison control centers, and other programs.

So, again, what's the thought behind this idea of swapping it out rather than having an increase, which is what was supposed to be in the prevention fund?

Secretary SEBELIUS. Well, Senator, I think that what we are in the process of trying to evaluate as we move into calendar year 2014, with the full implementation of the Affordable Care Act, is what assets will now be part of an individual's health insurance plan that won't need to be duplicated by special programs either in the base budget or special programs in the prevention fund.

So screenings will become more routinely part of a family's healthcare. Prevention activities that deal with cancer detection and colon cancer screening, even some of the smoking cessation efforts, will be actually funded through private health insurance and through the Medicaid program in ways that currently are not available to a lot of people.

So I think what we are trying to reflect in 2014 is, yes, these initiatives are important moving forward, focusing prevention funds on activities that are known to have proven success. But also recognizing that what's not reflected in the budget is that, for millions of Americans, they will actually have access to prevention benefits as part of their insurance package that they do not have now and so don't need to draw down those Federal funds or program dollars at the State level.

Again, I agree with you that trying to get to the underlying causes of chronic disease are the best ways to save dollars in the long run. So we've tried to make sure that the smoking programs are not only included but ramped up through various efforts, and that community transformation efforts focusing on chronic disease management and prevention actually continue forward.

Senator HARKIN. Well, again, I would just say I would like to see that happen before you start cutting the money. I'm not certain that it's going to happen just like that overnight in 2014. Maybe 2015, maybe 2016, maybe 2017. Okay, when that happens—well, I'm not going to be here, but it seems to me, when that happens, then we can talk about shifting it over to where people have it on their insurance exchange. But that's not going to happen in 2014.

So we'll take another look at that.

ADMINISTRATION FOR COMMUNITY LIVING AND THE DISABLED

Let me just also say that, again, the fiscal year 2014 budget is the first for the Administration for Community Living (ACL). You created this, the ACL, bringing together programs to provide services to people with disabilities and older Americans.

I am all for it. I think it's a great idea. I think what you've done is commendable. But now that it is formed, I am not certain exactly how it's going to carry out the mission to promote the independence of persons with disabilities as well as older Americans.

So, again, I just want to know briefly—I guess, I’ve gone over my time, too—how you’re going to get this agency really moving to fill in all those gaps, so to speak.

Secretary SEBELIUS. Well, first of all, Mr. Chairman, I want to recognize your incredible leadership on behalf of Americans with disabilities.

That’s been part of your career achievements and, certainly, a voice that will be terribly missed when you leave the United States Senate.

We were really pleased to work with you to establish what we think is a model that can be incredibly effective moving forward.

Senator HARKIN. I agree.

Secretary SEBELIUS. And it was to take our various disparate disability programs, and the Administration on Aging, and put them under one umbrella. And actually, what is very exciting is it kind of models the best practices that are going on in States around the country.

So ACL just had a first anniversary. It’s now been an entity for a year. And in visiting with the leadership, with not only Administrator Kathy Greenlee, but certainly Henry Claypool, and others representing the disability community, they are very enthusiastic about the opportunity to build a real network of services and supports at the community level, because whether you’re thinking about someone aging in place or someone from the disability community being fully productive in the community, a lot of the individual needs are fairly similar—transportation needs, supportive housing needs, access to mobile medical services, the medical home model.

So the combination of these two important communities doesn’t mean that we’re going to have a one-size-fits-all package of services. But it does mean, I think, that we leverage services and supports that were operating in silos.

We have some real administrative efficiencies. And we actually are encouraging and creating at the State level a network of community services that I think can more effectively serve people from the disability community, but also that we take advantage of the money follows the person and we continue with our Olmstead efforts to get people out of a restrictive setting and into the community.

But that doesn’t work very well unless you have support services in the community. And I think that is the exciting thing about ACL, and that’s really what’s happening on the ground.

Senator HARKIN. Well, good for you. I think it was a great idea, and I commend your leadership in pulling this together and starting this entity. And I look forward to working with you to—

Secretary SEBELIUS. Thank you.

Senator HARKIN [continuing]. Invigorate it and keep it strong.

Senator Moran.

Senator MORAN. Chairman, thank you.

MARKETPLACE FUNDING

Madam Secretary, just a few follow-ups. I want to try to ask them briefly in hopes that I can get through three or four things in 5 minutes.

Your response to my question, your response that the Department requested \$1.5 billion for exchanges was not answering the question I was asking.

What is the amount necessary for the Federal Government to pay for the federally created exchanges in States that did not create an exchange?

So I think what you were telling me is that it's \$1.5 billion for exchanges, generally. But what do you estimate the cost to be to solve the problem where States have decided not to create a State exchange?

Secretary SEBELIUS. Well, again, Senator, it's some of the same. Part of what those dollars are for is the set up and original operation of the Federal hub, which is the data system that will verify income levels and provide the tax credit and enrollment information. And that will be for every State in the country, whether they're operating their own exchange or not.

For the States where HHS is operating at least one part or all of the exchange, some of those dollars are used for that. And the dollars that come from the Federal Government will also begin to be replaced by user fees, so that in every State in the country, whether it's the federally operated market or a State-operated market, insurers who are providing plans on that marketplace will pay a fee. And those fees will make the market self-supporting.

But I can get you a more detailed breakdown in writing.

Senator MORAN. That would be fine. We can follow up on this topic.

I think what I'm asking you is: What is the unexpected cost as a result of States not operating State exchanges?

Secretary SEBELIUS. We always assumed, Senator, that we would operate some exchanges. What we can tell you, and try to get those numbers nailed down, is what additional costs there are. But we were always going to have to build the hub.

Senator MORAN. Okay.

Secretary SEBELIUS. We were always going to build a portion of the infrastructure. And the cost estimates have differed.

We weren't ever sure, as the deadlines passed, how many States would be in or out, and now we finally know.

AFFORDABLE CARE ACT AND EMPLOYERS

Senator MORAN. In response to Senator Alexander's question, and I don't know that there's a question for you in this, but you indicated that you hope employers don't do what Senator Alexander was suggesting.

I just would indicate to you that it seems to me, and Senator Boozman pointed this out, it's a Washington Post article this morning in which the State of Washington is looking for ways to have more part-time employees and get their employees out of the—get the State out of the requirement of providing insurance for them.

But that's happening in the private sector as well. The interesting thing to me is it's now expanding to the public sector, the State of Washington.

But those conversations are occurring all the time. I mean, the anecdotes in Kansas of people who are either trying to get below 50 full-time equivalent employees or to have more of their employ-

ees be part-time is really prevalent. Again, anecdotes of a small business who is closing a couple of their businesses so that they fit that criteria, I think it's out there.

CRITICAL ACCESS HOSPITALS

I wanted to ask you about rural healthcare again. You are supportive of the President's budget request in reducing the 101 percent to 100 percent of cost base reimbursement for critical-access hospitals?

Secretary SEBELIUS. That is our budget proposal, yes, sir.

Senator MORAN. And you are supportive of the change in the mileage limitation from 20—well, for the hospitals that have been granted a waiver and are less than 10 miles apart, you believe they should not receive the reimbursement as a critical access hospital?

Secretary SEBELIUS. Yes, that is the proposal, again, that was made last year and this year.

Senator MORAN. We have a number of examples, many of which you are aware of. There are a number of critical access hospitals that would meet the criteria that you're now creating.

And while I said in my opening remarks, I can see that being prospective, how do you take away the critical access hospital designation for both hospitals, which in my view means that neither succeed. I can't remember who you were responding to, but you indicated in response to this issue—maybe it was Senator Cochran—was that they're already getting 100 percent of costs.

But the reality is that not all costs are included in the calculation of costs. There's a definition of what costs are, and you get, presumably, 100-percent reimbursement of those costs. But they're not all costs of the hospital.

At least according to the National Rural Health Association, 41 percent of all critical access hospitals are in the red now. There's less access to capital for small hospitals. They treat older, poorer, and sicker patients. And in addition to their specific and unique needs, they represent such a very small portion of any money spent on healthcare, so when you reduce the payments to critical access hospitals, it doesn't have a significant corresponding impact on the overall budget.

And so I was interested in any response you want to make to that? How do you explain to two hospitals who would now no longer be eligible to be critical access hospitals that neither one of them are going to be designated as a critical access hospital, presumably losing the status and closing both hospitals?

Secretary SEBELIUS. Senator, I will share with you that I had a similar conversation in a budget briefing the other day. And frankly, I would love to work with you on that aspect of this proposal, to really drill down a little bit in terms of how it impacts people. If they got a designation being 10 miles apart, how far away are they from the next critical access hospital, the typical is 35 miles. How did this 10-mile structure occur? But I would love to continue that discussion.

Senator MORAN. Great. I would guess that as Governor, you granted some hospital waivers—in days gone by, Governors got to grant exemptions to 35 miles. I would not be surprised that you granted a number of those exceptions.

Secretary SEBELIUS. That could be.
 Senator MORAN. That could be.

AFFORDABLE CARE ACT IMPLEMENTATION AND ENROLLMENT

I've run out of time. I just wanted to—I didn't know whether you ever had the opportunity to respond to Senator Baucus on the train-wreck comment.

Anything that you would respond to what was at least reported about Senator Baucus's description of implementation?

Secretary SEBELIUS. Well, I think the Senator was describing a situation where he felt far too few people were aware of the benefits that they were going to be entitled to receive, and there wasn't enough outreach and education going on, which I would agree is a challenge.

And it's one of the reasons that, again, we made what is a very difficult decision to use some of the prevention funding when we were not given additional resources for education and outreach. We will use some of the prevention funding so that there will be now navigators on the ground in States around the country to begin to educate folks, community groups, and others.

We know that worked on Part D when Medicare expanded the program. In Part D, there was a series of steps taken that we're watching very closely. One of them was on-the-ground help and assistance. We did not have the funding in our budget. We did not get a 2013 budget, so we made a very tough choice.

But I think that's what the Senator was expressing, is that too few people know what's happening, and he is not sure that anybody will be able to enroll. And that's what we are trying to get out ahead of and address.

Senator MORAN. Madam Secretary, thank you, and I look forward to working with you on critical access hospitals.

Senator HARKIN. Madam Secretary, I'm sorry. I have to go over to the floor, so I'm going to turn the gavel over to Senator Moran.

In order, it would be Senator Boozman and Senator Shaheen. And then more people are showing up.

But thank you very much for your testimony.

Senator MORAN. Now that you're leaving, Mr. Chairman, members are showing up.

Senator HARKIN. That's right.

Thank you, Madam Secretary, for your forthrightness and your answers to our questions. You exhibit an encyclopedic knowledge of our healthcare system, and we appreciate that.

I sent a letter to the Inspector General of the Department of Health and Human Services, Daniel Levinson, in which he sent his response. I would like to submit both letters to be included in the record.

APRIL 17, 2013

Hon. DANIEL R. LEVINSON
Inspector General, Department of Health and Human Services
Washington, DC.

DEAR INSPECTOR GENERAL LEVINSON: Thank you for your leadership of the Office of Inspector General (OIG) and your efforts to promote the efficiency, effectiveness and integrity of the Department of Health and Human Services programs and activities. Your office plays a critical role in ensuring the taxpayer resources are spent in the most efficient and effective manner possible.

To that end, I am interested in receiving your view of the greatest threats and vulnerabilities to the discretionary programs and activities of the Department of Health and Human Services. I would also like you to provide the status of recommendations from the OIG's work for each of the past 4 years and discuss any recurring issues within the Department that need to be addressed by the Department. I am particularly interested in seeing the results of your oversight over programs funded through the American Recovery and Reinvestment Act of 2009. Lastly, I would like to receive specific information about the impact of sequestration on the OIG's staffing and work in the current fiscal year. I will make your response to these issues a part of the hearing record for the April 24, 2013, hearing with Secretary Sebelius.

Thanks again for your leadership of the OIG and for the role you play in making sure that resources provided to the Department are spent as intended.

Sincerely,

TOM HARKIN
 CHAIRMAN

*Subcommittee on Labor, Health and Human
 Services, and Education, and Related Agencies.*

MAY 1, 2013

Hon. TOM HARKIN
*Chairman, Subcommittee on Labor, Health and Human
 Services, Education and Related Agencies*
Washington, DC.

DEAR MR. CHAIRMAN: I am writing in response to your April 17, 2013, letter requesting that the Office of Inspector General (OIG) report on the greatest threats and vulnerabilities to the discretionary programs of the Department of Health and Human Services (HHS or the Department), provide status of recommendations for each of the past 4 years and discuss recurring issues, provide the results of our oversight of programs funded through the American Recovery and Reinvestment Act of 2009 (ARRA or Recovery Act), and provide information on the impact of sequestration on OIG.

VULNERABILITIES IN HHS DISCRETIONARY PROGRAMS

OIG has identified numerous threats, vulnerabilities, and management challenges for HHS related to the Department's discretionary programs. In summary, here are five of the most important challenges for HHS:

1. Effectively Administer Grants and Contracts

HHS is the largest Federal grant-maker and the third largest Federal contracting agency. Effective management of these outlays must be a priority. OIG has identified vulnerabilities in HHS's oversight of grantees, particularly with respect to deficiencies in grantees' internal controls, financial stability, organizational structures, procurement and property management policies, and personnel policies and procedures. OIG has also identified vulnerabilities in HHS's internal oversight of its contract funding to avoid Antideficiency Act violations, on the basis of problems identified with certain contracts at the National Institutes of Health (NIH).

2. Protect the Security and Integrity of Data, Systems, and Technology

As reliance on information technology and data grows, so do the challenges and importance of ensuring the security and integrity of systems and data. Through our annual audits, we have identified vulnerabilities in HHS's information security controls. These include deficiencies in computer inventory management, logical access controls (e.g., weak passwords); outdated software, and patch management that could allow unauthorized access to HHS systems and sensitive data. HHS should heighten its management focus on strengthening information security across the Department to minimize threats to the systems.

3. Reduce and Report Improper Payments

HHS should make every reasonable effort to ensure that vital Federal dollars are spent for their intended purposes and in accordance with program requirements. In fiscal year (FY) 2012, the Department reported \$64.8 billion in improper payments across eight programs deemed as high risk by the Office of Management and Budget. Medicare and Medicaid programs accounted for the vast majority of these improper payments. Foster Care, Head Start, and the Child Care Development Fund (CCDF), run by the Administration for Children and Families (ACF), accounted for about \$0.5 billion of those improper payments.

The positive news is that Head Start's improper payment rate was less than 1 percent, and HHS met its error rate reduction goals for Head Start and CCDF. The challenge remains for HHS to meet error rate reduction goals for Foster Care and to further lower CCDF's improper payment rate from 7.9 percent. In addition, HHS did not meet its requirement to report an improper payment rate for the ninth high-risk program, Temporary Assistance for Needy Families, citing limitations in its authority to require States to provide the requisite information.

4. Prevent, Prepare for, and Respond to Public Health Emergencies

HHS is integral to preventing, preparing for, and responding to public health emergencies resulting from a wide spectrum of natural and man-made disasters. HHS needs to continue its focus on fulfilling this responsibility effectively and implement the specific management improvements that OIG has identified to avoid a threat to public safety. In recent years, OIG has recommended management improvements in planning, coordination, and communication during pandemic influenza and hurricanes. Most recently, OIG reviewed local public health preparedness for radiological and nuclear incidents and found vulnerabilities in the Centers for Disease Control & Prevention's (CDC) guidance and coordination with other entities involved in preparedness and response.

5. Effectively Manage Public Health Programs and Oversight of Food, Drugs, and Devices

Effective oversight and management of public health resources is essential to ensure that vulnerable populations receive the full benefit of public health programs. Vulnerabilities in the oversight of certain public health programs hinder them from meeting their missions effectively. For example, CDC needs to continue its efforts to work with State health officials and medical organizations and change its vaccine ordering and inventory systems to address problems OIG identified with providers inappropriately storing vaccines. OIG has also recommended that the Health Resources and Services Administration (HRSA) strengthen its oversight of community health centers' provision of required primary care services. In addition, HRSA should strengthen oversight of the 340B Drug Discount Program, including improving the accuracy and reliability of program data to address deficiencies we have identified.

Through the Food and Drug Administration (FDA), HHS also plays a critical role in protecting public health by overseeing the safety of food, drugs, and medical devices. With respect to food safety, OIG has found that FDA conducts infrequent inspections of food facilities and has not ensured that States conduct adequate inspections; food facilities and dietary supplement manufacturers too often fail to comply with registration and recordkeeping requirements; and improvements are needed to ensure efficient and effective food safety recalls. OIG has also raised concerns about FDA's followup on adverse events involving medical devices and about the transparency of FDA's process for reviewing and approving devices. Finally, FDA needs to strengthen its Risk Evaluation and Mitigation Strategies, a program for monitoring drugs with known or potential risks that may outweigh the drugs' benefits.

STATUS OF OIG RECOMMENDATIONS

Additionally, you asked for the status of OIG recommendations to HHS for each of the past 4 years. Here are the counts of recommendations that OIG has made to HHS, along with implementation status.¹

¹These are recommendations stemming from OIG audit and evaluation reports and memoranda to HHS. These include recommendations to CMS related to Medicare and Medicaid. The unit of analysis is recommendations, not reports; a single report may include several recommendations.

Calendar Year	Recommendations Made to HHS that Year	Implemented or Closed to Date ²	Still Open to Date ³
2009	216	117	99
2010	393	234	159
2011	445	161	284
2012	454	57	397
Cumulative Totals	1,508	569	939

² OIG may close a recommendation if an alternative action has addressed the underlying issue or a change has superseded or made the recommendation moot.

³ This figure includes some recommended actions with which HHS has disagreed, but that OIG continues to recommend.

RECURRING ISSUES

With respect to the HHS discretionary programs, the recurring issues include those discussed above as top management challenges and vulnerabilities. With respect to the Medicare and Medicaid programs, we have identified additional recurring issues related to improper payments, contractor oversight, and the availability and quality of program data.

Medicare and Medicaid Improper Payments

Despite departmental efforts to reduce improper payments, they persist in many Medicare and Medicaid program areas. For example, Medicare improper payments to skilled nursing facilities totaled more than a billion dollars in 2009. Skilled nursing facilities frequently billed for more intensive services than were provided or needed by beneficiaries. In another example, OIG identified hundreds of millions of dollars in improper Medicaid payments for personal care services across several States. OIG also found that home health agencies submitted 22 percent of claims in error because services were unnecessary or claims were coded inaccurately, resulting in \$432 million in Medicare improper payments. For FY 2012, HHS reported improper payments totaling more than \$64 billion in the Medicare and Medicaid programs.

Medicare and Medicaid Contractor Oversight

OIG reviews have uncovered recurring issues that hinder the successful performance and oversight of Medicare and Medicaid contractors. Examples include limited results from contractors' proactive data analysis to detect improper payments and fraud; contractors' difficulties in obtaining from Centers for Medicare & Medicaid Services (CMS) the data needed for fraud detection; inaccurate and inconsistent data reported by contractors; limited use by CMS of contractor-reported fraud and abuse; and lack of identification and resolution of program vulnerabilities. OIG's recommendations to CMS include: oversee contractors' proactive identification of fraud, provide contractors timely access to data during times of contractor transitions, improve accuracy of contractor-reported fraud data, include more quantitative results in contractors' performance evaluations, ensure vulnerabilities identified by contractors are tracked and promptly resolved, and improve contractor overpayment identification and collection of overpayments.

Utility of Medicaid Claims Data for Oversight

The Medicaid Statistical Information System is currently the only national system containing Medicaid claims information. However, we have found that the system is not an effective tool for program integrity purposes because it does not contain all the data elements needed to help identify fraud, waste, and abuse. In addition, the system does not always contain data that is accurate and up to date. Without a reliable system containing Medicaid claims data, the detection of fraud, waste, and abuse in the program is difficult. CMS is taking steps to improve the Medicaid Statistical Information System, and we will continue to monitor its progress.

OVERSIGHT OF PROGRAMS FUNDED BY ARRA

Your letter asked about OIG's oversight of programs funded by ARRA. OIG has conducted significant work to oversee the programs funded through ARRA, such as the more than 200 ARRA-related audits and evaluations issued over the last 3 years. These included numerous preaward and post-award reviews of ARRA applicants.

For example, of 83 Early Head Start program grant applicants that OIG assessed, 75 had problems with financial stability; inadequate systems to manage and account for Federal funds; and inadequate organizational structures, procurement and property management procedures, and personnel policies and procedures. Using our find-

ings, ACF awarded \$15 million in ARRA funds to the 8 applicants who had no deficiencies; did not award \$31 million requested by 15 of the 75 deficient applicants; and attached conditions to the \$126 million awarded to 60 of the 75 applicants to require that they receive increased ACF oversight, training, and technical assistance. OIG recommended and HHS implemented front-end controls to mitigate grantees' risks and better protect these funds.

With respect to post-award reviews of ARRA grantees, OIG identified instances when grantees claimed unallowable costs, indicating that better oversight was needed. For example, OIG performed a series of audits to assess the financial capability of HRSA's community health centers receiving ARRA funds to account for and manage Federal funds. The assessments identified problems with inventory, cash management, and financial systems controls. In response, HRSA has increased its efforts in monitoring, assisting grantees, and ensuring program integrity.

OIG also focused on the ARRA provisions encouraging the use of Electronic Health Records (EHR) by health care professionals and establishing protections against medical identity theft. In early assessments of CMS oversight of the Medicare and Medicaid EHR incentive programs, we identified obstacles to effectively overseeing the \$13.7 billion in incentive funds to health care professionals. We recommended that CMS and the National Coordinator for Health Information Technology (ONC) help ensure the integrity of EHR incentive payments. We also identified the number of identity breaches requiring notification under ARRA and recommended improvements in CMS's oversight of the notification process.

In addition, OIG investigated complaints related to programs affected by ARRA. OIG received hundreds of complaints alleging inappropriate use of ARRA funds, which resulted in more than 50 investigations.

ARRA established the Recovery Accountability and Transparency Board (RATB), consisting of 12 Inspectors General, including the HHS Inspector General, to coordinate and conduct oversight of Recovery Act funds; prevent fraud, waste, and abuse; and promote accountability and transparency. At the request of RATB, OIG completed a series of reviews to assess the Department's process, oversight, and effectiveness in performing data-quality reviews of information reported by recipients of ARRA funds. OIG found that the Department had designed an adequate process for performing limited data-quality reviews that identify material omissions and significant errors in recipient-reported ARRA information. In another RATB-requested review, OIG reviewed the staffing, training, and qualifications of Department personnel responsible for overseeing ARRA funds. HHS OIG and other OIGs concluded that staffing qualifications at the largest Federal agencies, including HHS, were inadequate.

IMPACT OF SEQUESTRATION ON OIG

Finally, your letter asked for specific information about the impact of sequestration on OIG's staffing and work. Sequestration, in addition to pre-existing expirations of OIG funding streams, puts OIG's ability to oversee HHS programs at risk. Before sequestration was enacted, OIG had implemented a hiring freeze and offered a buyout for voluntary separation, and we are on pace to downsize by hundreds of positions. Since FY 2012, OIG has reduced our staff by 160 positions. Additionally, before sequestration was enacted, OIG reduced non-pay budgets across the agency.

Sequestration ups the ante and further impacts the agency. With sequestration, OIG will continue our hiring freeze and staff reductions. Our funding levels and trajectory necessitate a 20-percent reduction in staff from our FY 2012 level. We will be unable to retain talent needed to oversee the nation's expanding health care system or upgrade aging data systems and implement new technologies critical to our mission. The FY 2014 HHS OIG budget request would restore funding to OIG and enable us to further invest in our mission to meet the substantial challenges that lie ahead.

Thank you for your continued interest in our work. If you have any questions, please contact me or your staff may contact Chris Hinkle, Director of Congressional and Regulatory Affairs.

Sincerely,

DANIEL R. LEVINSON
INSPECTOR GENERAL
Department of Health and Human Services.

Senator HARKIN. Thank you for your leadership on so many of these vital issues. I have some more questions I'll submit for the record.

Senator MORAN [presiding]. Senator Boozman.

Senator BOOZMAN. Thank you, Senator Moran.

RESIDENCY AND FOREIGN MEDICAL STUDENTS

I'd like to get your comments on a few things that aren't concerned with the Affordable Care Act but really about just good governance.

I think Senator Pryor mentioned the concern about the slots for people in the specialties. Right now, we're in a situation in the residency programs where we have a lot of foreign medical students. They're filling those slots.

To me, it really makes no sense, in the sense that if we're going to train foreign medical students, we should have the ability to allow them to stay once we subsidize their education. And that's a real problem.

I think we all agree. Maybe we can argue about the extent of the problem, but residency problems are a real problem. Since we have more students going to medical school now, we haven't increased the residency programs.

We do have a lot of foreign students. It would make sense to make it such that there were an easy way, if they choose to stay in the United States and practice, for that mechanism.

Can you comment on that?

Secretary SEBELIUS. Well, Senator, I think that's one of the components of the President's proposal, and the Senate bipartisan proposal on immigration reform. It really is an immigration issue to increase the number of visas for highly skilled, highly trained workers, particularly those workers in critical areas who were, as you say, educated in the United States.

I think sometimes called a component of the program of "staple the green card to your diploma," and that is one of the components of the bill that will come before the Senate.

Senator BOOZMAN. I understand, right. And I don't mean to interrupt. But again, in this case, we really do have a critical situation.

Secretary SEBELIUS. I agree.

RECOVERY AUDIT CONTRACTORS

Senator BOOZMAN. We are adding all of these patients into the system, and it makes sense. If that can be done, on the context of the other, if the other doesn't get done, it's something that we simply have to address as a standalone or whatever.

But I think where you can really help is by really illustrating the extent of the problem. I don't think most Members of Congress understand that. I know our providers do. I know that our hospitals do.

The other thing is the Recovery Audit Contractor (RAC) audits, and I believe very much that we need to have accountability on things. When you have a situation, though, where 70 percent of the audit is overturned, that's not a good situation.

So I would really encourage you to look at that again. Nobody hammers harder on waste and fraud, and we all agree that there is a tremendous amount of waste and fraud in the system. But I would appreciate it if you look at it and make sure that we're not

spending an inordinate amount of time on people who are trying to get it right as opposed to the bad actors.

I was visiting with a lady at a medical center recently, her analogy was like one of the kids in the family acting out and you spank all of them. And I think we've got some of that going on.

SUSTAINABLE GROWTH RATE

The last thing that I'd like for you to comment on is Sustainable Growth Rate (SGR). And I'm a former optometrist, former provider. I know that we are not going to cut providers by 20 percent, 30 percent, whatever we're up to now, but they don't know that.

Healthcare is 17 percent, 18 percent of the economy. It's a huge deal. We've essentially frozen those offices that some of them are doing well, but they can't plan, they can't do that with that hanging over. And it's going to take leadership from all of us to come up with a plan.

But we talk a lot about the economy and the importance of growing the economy, providing economic opportunity. But that is one of the things that truly is a wet blanket that's hanging over us.

Secretary SEBELIUS. Well, Senator, let me tell you, I'd be happy to follow up on the RAC issue that you raised and any specific example. I mean, your case of a 70-percent overturn, that's always helpful, just so we can drill down on a case and use that as an example. So I would appreciate getting that.

In terms of the residency program, again, we are focusing on a whole array of workforce issues, because with or without the Affordable Care Act, the aging of the population and the demands on providers is different and if we're really—

Senator BOOZMAN. And the aging of providers.

Secretary SEBELIUS. You bet. The aging of providers.

So we have a whole series of workforce initiatives underway and take that very seriously. We can't, at the Department of Health and Human Services change the visa situation.

But finally, on the SGR, I don't think there is any bigger single threat to Medicare than the constant threat that Medicare providers will be cut, year in and year out. Far too much time and energy is spent.

The President's budget every year since I've been appointed Secretary has included a long-term fix for the SGR. This budget does the same.

We think that a transition period for a couple of years, which gets rid of the looming threat, and then actually working with Congress on a more pay-for-performance strategy moving forward, is the best transition underway. And that's what's incorporated into this budget.

But I couldn't agree more. We would love to work with you and other Members in Congress to get rid of this yearly kind of kabuki dance that takes providers' time, scares patients, and is really not very beneficial to the notion that healthcare needs to be planned for in the future.

And particularly for small provider offices, what we hear is that people are taking out loans and they don't have any idea if they're going to have a payment the following week or the following month. And last year, we actually had to implement pay cuts. So

we have seen this up close and personal, and actually gone over the edge a few times.

So I'd love to work with you on that.

Senator BOOZMAN. Thank you, Madam Secretary.

Secretary SEBELIUS. Sure.

Senator MORAN. Senator Shaheen.

Senator SHAHEEN. Thank you, Mr. Chairman.

I'm a new member of this committee, and it's very nice for my first hearing to be here with you, Secretary Sebelius, and very much appreciate the work that you're doing and that you're at the helm of the Department of Health and Human Services at this critical time, as we change our healthcare system in this country. So thank you very much for all of the work that you are doing.

OUTREACH TO SMALL BUSINESSES AND AFFORDABLE CARE ACT

I want to follow up a little bit on the issues that Senator Moran raised about how we educate people in this country about what's available to them through the new healthcare law, particularly small businesses who I'm hearing a lot from in New Hampshire as they're trying to figure out just how they comply with all of the new requirements of the law.

And I wonder if you could talk about to what extent you're cooperating with the Small Business Administration, the Internal Revenue Service (IRS), the Department of Labor, all of the other agencies within Government that are also involved in trying to implement the law.

Secretary SEBELIUS. Well, Senator, we have had extensive collaboration, particularly with the Small Business Administration in terms of outreach. They have a very effective and active network. Their number one issue from their employer base for years has been affordable healthcare. That is the biggest challenge that small-business owners face.

So our regional offices around the country, as well as a whole army of folks from HHS, are doing a lot of joint presentations. We have done trainings for Small Business Administration employees at their request, so they can actually give information, hold business meetings. We're using their networks of newsletters and outreach. And I think those efforts will ramp up as we get closer to open enrollment in October of this year.

Senator SHAHEEN. Well, I would urge you to do whatever you can to make sure that we are aware here of those efforts, because we can also help in our home State—

Secretary SEBELIUS. You bet.

Senator SHAHEEN [continuing]. To educate people.

Secretary SEBELIUS. Yes.

ENROLLMENT AND OUTREACH FOR THE MARKETPLACES

Senator SHAHEEN. One of the other issues that was raised with me recently by some folks who were involved in implementing the Massachusetts healthcare law was the extent to which those people who had been uninsured had never been part of the healthcare system, had no idea how to navigate the system, and the challenges of trying to provide assistance to them as they were being brought into health insurance coverage.

So are you anticipating that? And is there funding in the budget to do things like help lines and all of the assistance that we'll need to provide to people who have no idea how to operate in a healthcare system that gives them health insurance?

Secretary SEBELIUS. Well, I think you've just given a snapshot of some of the challenges that we know are very real and that we will face—everything from language barriers, to cultural competency, to a lack of familiarity with terminology.

You can't make choices unless you actually understand the system. So we will have a variety of assistance available on the ground, help from trained individuals who come from community groups and advocacy groups and neighborhood groups. And those grant applications are out in States around the country, the so-called navigators. We will use our Federal employees at a variety of points of contact in health centers, hospitals, in housing units, and in programs where they have contact with individuals, and, again, with training and materials.

We are trying to create the easiest, most consumer friendly Web site to use in multiple languages with a help line that will pop up when you're shopping online. If a consumer wants to pick up the phone and call along the way to get questions answered, our help line will make sure that's available.

We have up to 150 languages that people anticipate will be necessary. We are kind of mirroring what we know comes in through the Medicare line, as well as recognizing that a lot of people are going to need help actually filling out forms and answering questions.

Many States will have agents and brokers involved, and that really is a kind of marketplace-by-marketplace decision.

So I think we're anticipating a lot of challenges. We will have a lot of educating during the summertime and then, hopefully, a motivation to enroll period.

But you're right, if you've never dealt with health insurance before, if you don't know what it is that you're looking for, it's pretty difficult to make a decision.

Senator SHAHEEN. Thank you. My time has expired, but hopefully, I can do another round in a few minutes.

Senator MORAN. Senator Merkley.

Senator MERKLEY. Thank you very much, Mr. Chair.

And thank you, Madam Secretary. Wonderful to have you here. And there are so many programs you have responsibility for that touch lives of folks in so many different ways. So I'll just pick out a few to ask about.

COMMUNITY SERVICES BLOCK GRANT

One is the Community Services Block Grants. These block grants, I do a lot of town halls, one in each county each year, so I've done more than 160. And beforehand, I hold a meeting with the city and county leaders. And inevitably, they raise the flexibility of block grants, and they use them in so many different ways in different parts of my State.

I believe that the President's request is \$350 million, if the numbers I have are right. And the fiscal year 2013 enacted amount was

\$682 million, so roughly a 50-percent decrease in those block grants.

If those numbers are right, I just wanted to get your thinking about it, because I see communities advocating all the time for the huge amount of flexibility to address vital needs and the value of that.

Secretary SEBELIUS. Well, Senator, I think there's no question that those programs play a critical role in delivering services at the local level. I think this budget reflects some very difficult choices in a tough budget time, and we're trying to balance needs across a wide array of services, as you say.

So in a different budget year, we would certainly not suggest or recommend a reduction in the Community Services Block Grant, but that was a choice that was made for this year's budget.

Senator MERKLEY. And I very much appreciate the challenge and pressures and choices that you're wrestling with as you prepare your budget. It doesn't sound like there was any particular critique of the program, feeling it didn't work well or anything of that nature.

Secretary SEBELIUS. It was not. Unfortunately, most of our service areas were cut back. We are looking at a 2012 baseline. And I would say, the only sort of plus-up areas were areas where we actually have new authorities, new challenges. And we're trying to, again, allocate resources as strategically as possible.

BREASTFEEDING

Senator MERKLEY. Second one I want to turn to, under the Affordable Care Act, the issue of reasonable break time for nursing mothers. This is a provision based on a law that we adopted in Oregon when I was Speaker that worked incredibly well, because, essentially, it asked businesses to provide both the privacy and flexibility and break time for mothers to continue to express breast milk for their small children.

The result was happier mothers, less sick time, healthier children, and actually good health effects. Senator Coburn has really emphasized more positive health for the women as well.

So it's one of those things that doesn't cost much, and actually the businesses are very happy, because they have both less sick time and higher morale.

So the Department of Labor has responsibility for enforcing it, but there's also a role for HHS. And I believe that the Administration for Children and Families is putting up a Web site on breastfeeding. And also, there is a role for the Centers for Disease Control in the hospitals promoting breastfeeding budget proposal.

This is a case where a little bit of education and working with hospitals to change long-ingrained habits like giving mothers a kind of an implied encouragement to not breastfeed by free samples and so on and so forth, and making sure staff can help mothers through the first couple of days of breastfeeding, to get them going on this.

Is there enough money in that program to kind of do the work that is necessary, given the great value that stems from it?

Secretary SEBELIUS. Well, Senator, first of all, I share your strong commitment that not only does this have tremendous health

value, but it has proven to be enormously effective in terms of bonding mothers and children together. And as the new grandmother of an 8-month-old who is the beneficiary of breastfeeding, I can tell you, it has been great to have this opportunity for my daughter-in-law to go back to work but have a place set aside.

And two things have happened in addition to what you're saying. We will focus on it. We have a lot of agencies who feel that it has enormous benefits.

We also had a surgeon general implement a call to action around breastfeeding, and a very high profile rollout of all of the health impacts. And we are working closely with hospitals, for instance, to discourage the free gifts of formula that is sort of a cease and desist, and really working, as you say, with new mothers.

The Affordable Care Act, as you know, also has recommended a set of preventive benefits, specifically for women's health that the Institute of Medicine recommended to us. And one them is lactation help and support for new mothers, and that will now be part of every new health plan available with no copays, no co-insurance.

And I think, again, it reflects the fact that we're trying to address this issue at the public education level through our Administration for Children and Families and CDC, through private insurance now covering support and help, and certainly working with hospital leaders on what they can do to make sure that new mothers get off to the best possible start, and know how beneficial this can be.

Senator MERKLEY. Thank you very much.

Secretary SEBELIUS. Sure.

317 IMMUNIZATION PROGRAM

Senator MORAN. We will try, as I heard Senator Shaheen say that she'd like another round of questions, we have votes in about 15 minutes. And so if we can rapidly have one more round, Madam Secretary, we should conclude by noon.

And I'm interested in doing that because I have a couple of questions.

First of all, let me talk about immunization, the 317 immunization program. The budget recommends a \$61.3 million reduction. The budget justification indicates that that's possible because immunizations will be covered for more people under private healthcare and under the Affordable Care Act public insurance programs.

I would point out to you, and you would know this as a Kansan, that the 317 immunization program is more than just vaccines. It's infrastructure and trained workforce for our public health departments across our State and others. And I want to make certain that any reduction in that 317 program would not deter the quality and availability of the infrastructure in public health.

Secretary SEBELIUS. That's certainly our intent, Senator.

Senator MORAN. And then let me raise one or two more.

OFFICE OF MEDICARE HEARINGS AND APPEALS' CASES

Senator Boozman, I'd like to just again accentuate what he said about the workload increase that the Office of Medicare Hearings

and Appeals workload increased 247 percent from fiscal year 2006 to 2013. We've had an aging population, more Medicare recipients.

But I am concerned, as Senator Boozman indicated—his question was more on the side of the Finance Committee, but I also am concerned that this increase may be due to overzealous audits that are occurring through the Recovery Audit Program.

And here's at least the facts that I've been told. Over half the cases that are sent to the Office of Medicare Hearings and Appeals are overturned, and the remaining 37 percent were overturned by the Department, which suggests that there's lots of allegations, cases filed. They are appealed, and the hospital or provider is found not to be committing fraud or abuse.

And the point I make, and perhaps it goes back to the critical access hospital issue, but to hospitals and other providers generally, we've got a lot of people in healthcare who are out there spending time, money, and effort in regard to these audits that ultimately the provider is, in many instances, determined to be successful.

We need to figure out to have a threshold by which the case not brought in the first place.

Secretary SEBELIUS. Well, Senator, I think there are two issues. You're absolutely right that the number of Medicare beneficiaries has increased fairly dramatically since the last time we had any increase in resources for that office. So we will continue to ask for resources to try and get rid of the backlog.

Having said that, I think there are also a category of cases that deal with the difference of inpatient and outpatient coding that apply across the board that we are actually working to solve administratively. I also think that we should, at least, prospectively, help with some of those issues where there are issues and challenges and overturned by the Medicare board and—

Senator MORAN. Inadvertent errors.

Secretary SEBELIUS. We are fixing it on the front-end, but I hear you.

Senator MORAN. Good.

EARLY LEARNING INITIATIVE

And finally, Secretary Duncan was before us last week. We haven't spent any time, I think we talked all about healthcare today, on the education, in particular the pre-kindergarten proposal that's in the budget. I don't yet fully understand what happens at Department of Education, and then what happens at your Department with regard to Head Start; how they come together in this new proposal. Unfortunately, I don't have time in the remaining few minutes to have you explain that to me.

But I wanted to point out to you that Secretary Duncan stated that the Head Start teachers' ". . . qualifications are too low to be what is really needed for quality early education." Can you discuss how pre-kindergarten programs would affect Head Start, and how we're making certain that we have quality programs at Head Start?

Secretary SEBELIUS. Well, just in a snapshot, what the President is putting forth is a 10-year infrastructure that would actually be birth to 5. And the notion would be that the children under the age

of 4 would be primarily in settings and programs more funded by HHS, childcare settings, Early Head Start, Head Start. And this anticipates 4-year-olds and 5-year-olds would be in pre-K and kindergarten more under the umbrella of the Department of Education, expanding the access to pre-K and then working with States on full-day kindergarten.

Senator MORAN. Would the programs under the Department of Education be administered by the local school district?

Secretary SEBELIUS. Yes. And I think the President has outlined a State-Federal partnership where the funding would go to the State level who chooses to expand into a universal access to pre-K.

Many States are choosing to do that well ahead of the Federal Government, and there would be some increased funding in our budget for both Early Head Start-childcare partnerships to raise both quality and increase the slots available to children who are less than 200 percent of poverty. It would also increase the evidence-based home visitation program, which has proven to be a very effective early start to successful parenting, reducing violence, getting kids off to good language starts.

So those are the pieces that are in our budget. The pieces in education really deal with 4- and 5-year-olds, and really very much in a State partnership. This wouldn't be triggered unless a State chose to actually take advantage of the partnership.

Senator MORAN. Thank you. That was helpful.

Senator Shaheen.

SEQUESTRATION

Senator SHAHEEN. Thank you. As I know you're well aware, sequestration went into effect about 6 weeks ago on March 1st. And I understand that your office has been in touch with the Office of Management and Budget (OMB) about how the cuts will be implemented for various programs.

And we've been told that OMB has instructed agencies to develop a plan by the end of April, and then each grantee will be called by their funding agency.

On Friday, I got a letter from New Hampshire's Commissioner of Health and Human Services, Nick Toumpas, who was very concerned and frustrated, I think is fair to say, about the lack of guidance that he has received about how to implement the sequester cuts.

And he's very concerned that because the instructions have taken awhile and still are not totally there, that he's going to have to implement those cuts in the last 2 months of the fiscal year.

So I wonder if you could tell what information you all have received about the timeline on the cuts, and what further instruction might be available? And can you work with us to try and help Commissioner Toumpas as he figures out how to deal with this?

Secretary SEBELIUS. Well, Senator, let me just start by saying, we'd be happy to work with you and have whoever needs to get in touch with the commissioner.

This is a little bit of a catch-22, because what we're trying to do, as you would appreciate as a former Governor, is give States some flexibility as they look program-by-program, and not impose a one-

size-fits-all, “you must do this in a Head Start program, you cannot do this in a childcare program.”

Having said that, we are communicating with them pretty clearly what the budget reductions look like, and as you know, we were given no flexibility program-by-program, department-by-department. So we can communicate the numbers. We can communicate our goal is really mission first, so maximizing the dollars that are available for services and looking first to any kind of administrative cost that could be cut, any kind of travel, any kind of training, any reduction in overhead costs, and keeping as many service dollars as possible available, is sort of where we’re going.

But we’d be glad to work further with the commissioner.

Senator SHAHEEN. Thank you very much.

And let me just be clear, I think sequestration is outrageous. We need to fix it. This Congress needs to act, and it’s totally unacceptable that we haven’t done that.

Secretary SEBELIUS. I appreciate that.

Senator SHAHEEN. So I appreciate the bind that this puts you and all the other agencies in.

Secretary SEBELIUS. It’s about \$15.5 billion out of our budget for 7 months of a fiscal year, and \$11 million of that comes directly out of Medicare—

Senator SHAHEEN. Right.

Secretary SEBELIUS [continuing]. Services.

DIABETES PREVENTION PROGRAM

Senator SHAHEEN. One of the chronic illnesses that I’ve been very concerned about is diabetes. I have a personal connection to that. My oldest granddaughter has Type I. And so I’ve seen very directly both the costs in dollars and the personal toll that diabetes takes on families.

And one of the programs that I think has been very successful is the Diabetes Prevention Program. And looking at the budget, it appears that it eliminates the previous funding for this program and consolidates it into a larger category of diabetes funding.

Is that a correct interpretation? And can you talk a little bit about how you’re approaching, addressing diabetes in the budget?

Secretary SEBELIUS. Well, I think, Senator, diabetes is clearly one of the chronic disease conditions that is getting more attention both at the prevention level and, certainly, at the management level. And it’s been missing, I’d say, in both of those.

The budget for 2014 includes the same amount of dollars for diabetes as we had in the 2012 budget. But what we do see is a new coordinated chronic disease funding opportunity. We’re not combining the programs, but we’re, again, allowing States the flexibility and the opportunity to identify ways that they would use the funding to fill in the gaps that they may have in the State, which might be different from another State.

We’ve heard it from a lot of State health officers and others that this is a welcome change, that they won’t have to fill out five different applications for five different disease programs, and really can tailor the Federal dollars to the chronic disease initiatives that they find most effective.

So while there's a coordinated funding application, there will be line items for specific disease funding in the budget.

We're just trying to simplify, really at the administrative level, and allow States to, frankly, be a little more strategic, because if they can apply some attention to coordinating what are often comorbidities—it may not be, certainly, the case in your granddaughter, but a lot of diabetic patients also have a series of other issues like having high blood pressure. They may be obese. They have a series of things.

And having the opportunity to really focus some dollars on all of those conditions simultaneously we think is a step forward.

Senator SHAHEEN. Well, thank you. I look forward to seeing that work—

Secretary SEBELIUS. Sure.

Senator SHAHEEN [continuing]. As we go forward.

ARTIFICIAL PANCREAS

My time is up, but I just wanted to also say how pleased I was that the Food and Drug Administration (FDA) finally issued the guidance on the artificial pancreas and hope they will continue to move that, because that offers tremendous hope for diabetes patients.

Senator MORAN. Secretary Sebelius, unless you say something that causes me to have some level of outrage, the final questions will be provided by Senator Merkley.

Secretary SEBELIUS. I'll do my best not to do that, Senator Moran.

BREASTFEEDING

Senator MERKLEY. Thank you. Thank you very much.

Before going to another topic, I just wanted to go back a moment to the promoting breastfeeding line, because I had this information handed to me.

In the CDC, it was dropped from 2012 from \$7 million, which is a modest amount, to \$2.5 million. And I just want to again kind of anchor my concern that this is one of those prevention high win—win for the babies, win for the mothers, win for the workplace—that merits attention. And I don't think there was an advocacy group that is there in the same way there is for any particular disease or so on and so forth. And I want to make sure that when we have an incredibly effective tool that we draw attention to it even if there isn't an organized advocacy side to this.

Secretary SEBELIUS. Well, again, Senator, I think some of the changes in the 2014 budget reflect the fact that the CDC's focus and attention may have been on a number of pregnant women and patients who did not have health insurance, did not have access to their own benefits.

And with the full implementation of the ACA coming online in 2014, we hope that that will reduce the number of people who need to rely on just Government services for that kind of help and support.

But certainly, I take this issue very, very seriously.

Senator MERKLEY. And if I understand right, this is really about folks who work to leverage the capability of hospitals and clinics

to then work with the women themselves, so that it is a highly leveraged education training.

I may not have it quite right, but I just want to flag it as something that—

Secretary SEBELIUS. Thank you. Okay.

Senator MERKLEY [continuing]. Merits attention.

ASSETS FOR INDEPENDENCE

I want to turn for a moment to the Assets for Independence program, AFI. This is often called IDAs, Individual Development Accounts.

This is essentially strategies where folks with low to moderate incomes save money and receive matching grants to engage in the three pathways toward middle class, one being education, one being small business, and one being homeownership.

And it's a very small amount of money at this point. Your request is \$20 million.

I just want to note that a "for example" is that we spend \$80 billion-plus in the home mortgage interest deduction to promote homeownership, but almost none of that goes to lower income families buying starter homes, because their interest does exceed their standard deduction and, therefore, there's no actual boost, if you will, to assist them.

So those who need the most help to actually become homeowners only get the help through something like the IDA program. And \$20 million is a tiny drop in the bucket. And that's split between folks launching small businesses, going back to school. Again, three major pathways into the middle class.

The reason I wanted to raise this is this is really a strategy that gets people started in homeownership which has a huge impact on the success of families. Children have higher graduation rates from high school. Families take more of an interest of the community that they live in, because they now have a stake in it. The equity they build becomes powerful equity for them to be able to strengthen their family in other ways and assist their children going to college.

So I just wanted to flag that program as one which has very little funding but is a very powerful—what's been a very powerful bipartisan strategy.

Secretary SEBELIUS. Well, I'd love to have an opportunity follow up with you and your staff on that program, and see what we could do to make sure we maximize the limited funding that is available.

CENTERS FOR DISEASE CONTROL AND PREVENTION BUDGET

Senator MERKLEY. As I was looking at, for example, the line items within the CDC, do you have the flexibility to move money between line items, or are these pretty well locked in by what we do at the appropriations level?

Secretary SEBELIUS. I think the CDC director has some ability, some flexibility, but my guess is not very much.

OLDER AMERICANS ACT

Senator MERKLEY. Okay.

Well, I want to use my last minute just to flag, if you will, that the Older Americans Act program, we have an increase—substantial increase—over the 2-year period from 2012 to 2014 in a population of 10,000 folks a day surpassing the age of 60, plus growth in the cost of the goods that they face in those programs.

That program, the Older Americans Act, has been flat funded despite the growth in population and the growth in inflation.

So are we going to be able to find ways to deliver similar services with the funding flat while the number of folks and inflation are eating away at it?

Secretary SEBELIUS. Well, I think there's no question that there's a higher demand on services with an aging population.

I shared with Senator Harkin, we are really pleased with the additional community assets that we think we can leverage with the creation of the Administration on Community Living, a lot of the support services that older Americans need, and also those in the disability community need at the community level. So we're trying to be as strategic as we possibly can about the transportation, food needs, medical needs, supportive housing, that are really essential to a wide variety of populations.

ADDITIONAL COMMITTEE QUESTIONS

Senator MERKLEY. You have an incredibly difficult and challenging task, and I thank you for your dedication to public service and for your extensive knowledge and work with these programs.

Secretary SEBELIUS. Thank you.

Senator MORAN. Madam Secretary, thank you for your testimony and for answering our questions for the last 2 hours. We're appreciative of your presence here.

[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 TOM HARKIN

REDUCING HEALTHCARE FRAUD AND ABUSE

Question. Secretary Sebelius, I know you share my disappointment about the lack of any additional funding the past 2 years for eliminating waste, fraud, and abuse in Medicare and Medicaid. This is an area where we know we can find savings. In your testimony you say the return on investment is \$7.90 for every \$1 invested.

The Budget Control Act included cap adjustments that encouraged Congress to increase this funding by \$569 million over the past 2 years—an amount that would have saved taxpayers more than \$4 billion. Madam Secretary, can you give this subcommittee an idea of what has been lost over the last 2 years, by not taking advantage of the additional funding in the Budget Control Act?

Answer. The lack of additional Health Care Fraud and Abuse Control (HCFAC) funding as envisioned by the 2011 Budget Control Act has set back our Medicare, Medicaid and Children's Health Insurance Program (CHIP) efforts to combat fraud, waste, and abuse in the following ways:

—*Strike Forces.*—HHS and Department of Justice (DOJ) cannot expand beyond the existing nine Medicare Fraud Strike Forces. Our data show that there are other geographic areas where healthcare fraud is high. The lack of funding increases means there remain areas with high incidents of Medicare fraud that we are unable to target in partnership with DOJ. Since its inception, Strike Forces have been responsible for over 1,023 defendants pleading guilty or being convicted of fraud, and have charged defendants in cases where over \$4.6 billion was billed to the Medicare program.

—*DOJ Civil Cases.*—DOJ cannot hire additional attorneys and personnel who support civil healthcare fraud investigations. Civil healthcare fraud settlements

are the main source of returns to the Medicare Trust Fund and to Federal agencies which have been harmed by fraudsters. In fiscal year 2012, these efforts returned over \$4.2 billion to the Medicare Trust Fund, Federal agencies, and others, and the 3-year average return on investment was \$7.90 to every \$1 spent on healthcare fraud efforts. The lack of increases means that DOJ has fewer attorneys and can take on fewer cases of suspected healthcare fraud.

- OIG Staffing.*—Our Office of Inspector General (OIG) has been hit most directly by the absence of these investments. Since the beginning of 2012, OIG has lost over 160 people due to a hiring freeze as well as Voluntary Early Retirement Authority and Voluntary Separation Incentive Payments. The reduced staffing levels for OIG mean less resources for:
 - Making recommendations to save money and improve programs;
 - Investigating instances of fraud and abuse; and
 - Identifying overpayments for collection.
- CMS Prevention.*—Reduced funding has limited CMS's ability to accelerate new initiatives aimed at preventing fraud, waste, and abuse in Medicare, Medicaid, and CHIP. Specifically, the lack of increases means:
 - CMS has not been able to integrate the Fraud Prevention System (FPS) and Automated Provider Screening system.
 - Starting in fiscal year 2014, CMS will be hampered in its ability to maintain the current level of antifraud, waste and abuse activities, and expand upon its current predictive analytics initiatives like the FPS.
 - Medicaid program integrity efforts have been delayed, including updating Federal Medicaid claims systems and developing and implementing Web-based tools for enhanced oversight; which leaves CMS's ability to fight Medicaid fraud, waste, and abuse limited by outdated systems, incomplete data, and inadequate tools.

BREAST AND CERVICAL CANCER SCREENING

Question. I was pleased to see the proposal to expand flexibility in the Breast and Cervical Cancer Screening program so that 10 States can spend more of their grants on education and outreach. With the expansion of coverage in the Affordable Care Act, we all expect that more women will have access to these important screenings but it might take some work to get them through the door. My question is: Why only 10 States? Wouldn't all States benefit from this added flexibility?

Answer. The National Breast/Cervical Cancer Early Detection Program (NBCCEDP) authorization allows HHS to waive for up to five States the requirement that at least 60 percent of program funds be used to provide direct screening services and up to 40 percent of funds be used for screening promotion practices such as outreach and education. Recent modeling estimates show that increased insurance coverage provided by the Affordable Care Act (ACA) would increase the number of women covered by private insurance or Medicaid and therefore, decrease the number of women eligible to receive screening services through the NBCCEDP. However, estimates also show that there will continue to be some women who remain uninsured and in need of services provided by the program. CDC believes expanded flexibility is necessary, but that in the early phase of ACA implementation, States will likely continue to need resources to provide screenings and other clinical services.

SECTION 340B DRUG DISCOUNT PROGRAM

Question. The Affordable Care Act requires that HHS post a secure Internet Web site file containing the ceiling prices of 340B covered outpatient drugs. This is a critical program integrity provision, ensuring that eligible entities like clinics and safety net hospitals can see if they are being overcharged for the drugs that they purchase. But it is also a cost-efficient means of doing program integrity—a small investment in transparency will allow participants in the system to conduct their own oversight and identify problems that HHS can then follow up on. When is HRSA going to post this file to its Web site?

Answer. HRSA is proposing a modest user fee in order to pursue regulations to define these requirements and provide the necessary funding to implement this requirement. The posting of the Web site is dependent, in part, on the final regulation being published and the availability of resources.

PREVENTIVE SERVICES BILLING

Question. As you know, I am a long-time proponent of expanding access to preventive services as a way of reducing healthcare costs. I am interested in hearing more

about the initiative in the President's budget to build the capacity of public health and community-based organizations to bill insurers for these services.

In particular, I'm concerned that moves toward managed care and restricted networks of providers will limit the reach of these vital services. If the President's budget wants to increase the billing capacity of more local organizations, can I take that as a commitment to allowing preventive service reimbursement to the widest range of providers? How does HHS expect to ensure that community-based providers are reimbursed under Accountable Care Organizations?

Answer. The President's budget contained proposals to increase the billing capacity of more local organizations that have traditionally delivered a variety of preventive services. Increased billing capacity, combined with an increase in the insured population thanks to the Affordable Care Act may allow such local organizations to be reimbursed for delivering these services. The President's budget supports the infrastructure that enables these types of organizations to seek reimbursement; however, it is important to note that public and private payers have their own rules relating to coverage of individual services and inclusion of providers in their networks.

CMS is implementing the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO).

Healthcare providers participating in ACOs are paid for services furnished to Medicare beneficiaries on a fee-for-service basis, like traditional Medicare. But, providers in the Shared Savings Program ACO are eligible for additional Medicare payments for improving the quality and coordination of care their assigned beneficiary population receives while reducing the rate of growth in Medicare expenditures and providing efficient, cost-effective care.

Examples of ACO participants are a group practice, an acute care hospital, a pharmacy, a solo practice, a federally qualified health center, a critical access hospital, a rural health center, and other entities that are Medicare-enrolled and bill Medicare for services. Roughly half of all ACOs participating in the Shared Savings Program are physician-led organizations that serve fewer than 10,000 beneficiaries. Approximately 20 percent of ACOs include community health centers, rural health clinics and critical access hospitals that serve low-income and rural communities.

With respect to preventive services, a key way for ACOs to accomplish the objectives of reducing the rate of growth in Medicare expenditures and providing efficient, cost-effective care is to encourage beneficiaries assigned to them to take advantage of Medicare covered preventive services such as annual flu shots. Additionally, some of the key quality measures to assess performance of ACOs are preventive health quality measures. For example, influenza immunization, tobacco use assessment, mammography screening, and depression screening are quality measures that ACOs are required to report in the Shared Savings Program.

When the Affordable Care Act's coverage expansions begin in 2014, the uninsured population who often rely on community health providers will decrease significantly. By the end of 2014, the number of uninsured people is expected to decrease by 14 million people, according to the Congressional Budget Office (May 2013). Many of these previously uninsured populations may be eligible to enroll in Medicaid or in qualified health plans (QHPs) offered in the Marketplaces. With an expansion in insurance coverage community health providers may be able to seek reimbursement for covered services for which they previously could not bill because the individuals were uninsured. To this end, CMS has issued rules requiring QHPs offered in the Marketplace to include a sufficient number and geographic distribution of essential community providers (ECPs) in their network to ensure reasonable and timely access to a broad range of such providers for low-income, medically underserved individuals . . . As part of CMS's ongoing technical assistance efforts to ECPs, CMS recently sent a letter with frequently asked questions (FAQs) to these providers about their potential role in the Marketplaces. These FAQs are available at <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ecp-faq-20130513.pdf>.

U.S. PREVENTIVE SERVICES TASK FORCE

Question. As you know, the work of the U.S. Preventive Services Task Force (USPSTF) is central to the preventive benefits covered under the Affordable Care Act. Preventive services that receive an A or B recommendation from the Task Force will be covered by Medicare and new insurance plans without any cost sharing. Pre-

ventive services receiving less than an A or B recommendation are not required to be covered by the health plans offered through the State and Federal healthcare exchanges.

For the past several years, the Department has received funding from this subcommittee and the Prevention Fund to increase the transparency of the Task Force's work, as well as to increase the number of its evidence reviews and recommendations. Yet I continue to be concerned about the consequences of delays on those at high risk of certain diseases. For example, lung cancer is the number one cancer killer of men and women in the United States, yet the USPSTF has not updated its recommendation on lung cancer screening since 2004, despite new evidence from NIH's National Lung Screening Trial (NLST).

Can you provide an update of the Task Force's efforts to improve transparency as well as increase the number of its recommendations? Please include an update on lung cancer in your response.

Answer. Over the last 2 years, the United States Preventive Services Task Force (USPSTF) has expanded its efforts to engage stakeholders and the public in every step throughout its recommendation making process. This expansion was a direct response to the need for a more open and transparent process regarding the USPSTF's recommendations. The public, including scientists, health professionals, business and industry, health advocates, families and individuals, can nominate new members to serve on the Task Force and propose new topics for consideration. All draft research plans, evidence reports, and recommendation statements are made available for public comment.

In an additional effort to increase the public's understanding of the Task Force, USPSTF has produced a series of materials explaining its mission, composition, and process, including an introductory slide show "USPSTF 101" and two short videos. The USPSTF also produces plain language fact sheets for each of its draft and final recommendations to help consumers understand what each recommendation means for them. These materials complement the comprehensive USPSTF procedure manual that remains available to the public on the USPSTF Web site.

AHRQ has also invested significantly in ensuring that the USPSTF has the evidence it needs in order to make its recommendations. In fiscal year 2011 and again in fiscal year 2012, AHRQ commissioned 15 systematic evidence reviews on topics prioritized by the USPSTF which will lead to updated and new recommendations in the years to come.

The USPSTF postponed updating its 2004 recommendation on screening for lung cancer in order to incorporate the findings of the National Lung Screening Trial (NLST), published in 2011. In the fall of 2011, the USPSTF posted a draft research plan for public comment and expanded the scope of its planned review to meet the demands of healthcare professionals and the public for additional information. While focusing on the timeliness of this recommendation, the Task Force is committed to following its processes so that its recommendations will be valuable to clinicians and their patients. On average, the USPSTF requires between 30 and 36 months to complete a systematic, rigorous review of evidence and publish a final recommendation statement. Despite the size and complexity of this topic, due to the efforts of its members the USPSTF is significantly ahead of its own schedule. The Task Force anticipates posting its draft recommendation statement for public comment late this summer.

PROJECT BIOSHIELD

Question. The BioShield Special Reserve Fund (SRF) was designed to incentivize biopharmaceutical companies to develop and manufacture medical countermeasures for national security threats by providing a substantial guaranteed market for these products, many of which have no commercial market. As you know, the SRF previously was funded through an advance appropriation of \$5.6 billion over 10 years and your Department is projecting that these funds will be spent by the end of fiscal year 2013. PAHPA reauthorization, which passed in March, authorized a new advance for the SRF of \$2.8 billion over 5 years. However, the President requested an annual appropriation of \$250 million for this program along with new multiyear contracting authority. How can the President's request provide the same kind of market guarantee and certainty that is needed to attract and retain industry partners going forward?

Secretary Sebelius, please provide an analysis of how your Department derived the budget request of \$250 million for fiscal year 2014. Please include estimated costs for new acquisitions for the stockpile, as well as any possible options on existing contracts that may be exercised in fiscal year 2014.

Answer. The Department agrees that providing industry with a clear indication of long-term support of medical countermeasure development is important to the success of Project BioShield. The budget explicitly states the fiscal year 2014 request represents a multiyear renewed commitment to Project BioShield. Additionally, as an added incentive, the fiscal year 2014 President's budget proposes language to provide BARDA with the authority to modify the standard government-wide authority for multiyear contracting (41 U.S.C. 3903). The modified language included in the fiscal year 2014 President's budget authorizes BARDA to enter into an "incrementally funded", multiyear contract for up to 10 years. Additionally, the language modifies the existing authority's requirement of set-aside contract termination costs by allowing BARDA to repurpose any unused termination costs to pay contract invoices in subsequent years. This differs from traditional multiyear contracting authority, which specifies termination costs can be used for that purpose alone. These modifications allow BARDA to effectively utilize multiyear contracting authority to engage in long-term contracts with companies that develop medical countermeasures.

Based on MCM development and procurement across multiple years and relevant PHEMCE priorities, BARDA determined that \$250 million was needed for procurements in fiscal year 2014. This funding request will support the replenishment of modified vaccinia Ankara (MVA) vaccine (smallpox), vendor-managed inventory (VMI) costs for an antineutropenia cytokine acquisition to treat acute radiation syndrome, and a new BioShield award for artificial skin to treat thermal burn patients.

CHILD CARE QUALITY INITIATIVE

Question. The budget request includes an approximately \$155 million increase in discretionary funding for the Child Care and Development Block Grant (CCDBG). This would be used for competitive grants to States to improve the quality of child care programs. Over the last decade the number of children served through the Child Care and Development Fund has decreased from about 1.74 million to 1.4 million. As I know you agree, we need to improve both access to and the quality of early childhood care and education, for which the CCDBG plays a critical role. How will these new competitive grants under the CCDBG help achieve that goal? Further, how will they work in conjunction with proposed investments in new Early Head Start/Child Care Partnerships and other early childhood care and education initiatives included in the President's budget to do the same?

Answer. Improving access to child care is an important role of the Child Care and Development Block Grant (CCDBG), but equally important is ensuring that low-income children supported by tax-payer dollars are in safe settings that promote their healthy development and school readiness. For millions of children, child care is the primary preschool setting and yet many child care teachers and programs do not have access to the training, assistance, and support they need. Child care should be a place that engages children's minds, sparks their curiosity, and begins to develop their cognitive, language, and social skills. Child care is more than a work support for parents, and while it is important to focus on the number of families receiving assistance, investing in high-quality child care is a key opportunity to give our most vulnerable children the support they need to reach their full potential and lay the foundation for future prosperity.

The proposals included in the fiscal year 2014 budget reflect the Administration's commitment to providing access to high-quality child care to more low-income families. Included in the fiscal year 2014 proposals is an increase of \$500 million in mandatory funding. This increase would support 100,000 child care subsidies and help maintain access for low-income working families.

To complement this investment in preserving and expanding access, the fiscal year 2014 President's budget request for the Child Care and Development Block Grant (CCDBG) includes an additional \$200 million in discretionary funding for an initiative that would provide competitive grants to help States raise the bar on quality for child care statewide through improved regulation, monitoring, and transparency for parents, along with efforts to enhance the continuity of care. This proposal to raise the quality of child care would be aimed at helping children already in the CCDBG population, not expanding the overall population.

The budget also requests \$1.4 billion to create Early Head Start/Child Care Partnerships that will help accomplish the dual objectives of expanding access and improving the quality of care, by supporting States and communities in expanding the availability of early learning programs that meet the highest standards of quality for infants and toddlers, serving children from birth through age 3. Funds will be competitively awarded to new and existing Early Head Start programs that will partner with child care providers that serve a high number of children with child

care subsidies. The proposed \$200 million child care quality initiative would support systemic reform of policies at the State level that will support and strengthen the community-level Early Head Start/Child Care Partnerships.

The proposed competitive grants to improve child care quality and the new Early Head Start/Child Care Partnerships are part of the President's Plan for Early Education for All Americans, a series of new investments that will create a continuum of high-quality early learning services for children beginning at birth and through age 5. The President's Plan also includes a mandatory initiative that would provide high-quality preschool for all 4-year-olds in low- and moderate-income families through a new Federal-State partnership at the Department of Education and additional mandatory funding to extend and expand current Federal investment in voluntary home visiting programs.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

EARLY HEAD START/CHILD CARE PARTNERSHIP

Question. As you know, I strongly support the Administration's goal of expanding access to high-quality early learning opportunities. Your budget calls for a new Early Head Start/Child Care Partnership competitive grant. What type of entities would be eligible to apply for those grants? How will this program provide a pathway toward raising child care quality and access?

Answer. As part of President Obama's Early Education Plan, we would expand high quality early learning by approximately 110,000 full-day full-year high-quality Early Head Start slots through the Early Head Start—Child Care Partnerships. All entities currently eligible to apply for Early Head Start including State, local and tribal governments, not for profit and for profit organizations and other community based organizations would be eligible to apply for this competitive grant program. These partnerships will provide a pathway for improving child care access and quality as Early Head Start grantees will partner with center-based and family child care providers who agree to meet Early Head Start Program Performance Standards and provide comprehensive, high-quality services to infants and toddlers from low-income families.

HEAD START RESEARCH

Question. Some have suggested reducing or eliminating Head Start, a program serving about a million of our most at-risk children and families because of a misinterpretation of the Impact Study and the conflicting results shown when the children were in third grade. In fact, some of the best lasting impacts of a two-generational intervention like Head Start, including those elements that stabilize families and teach kids how to persevere, are shown by researchers to be present later in life. Can you please speak to the research that has been done on Head Start? What are the short-, mid-, and long-range outcomes? Did the Head Start Impact Study not find statistically significant differences between the Head Start group and the control group on every measure of children's preschool experiences? One report that is often under the radar is the 2010 report out of Maryland's Montgomery County Public Schools—showing that students who went to full-day Head Start pre-K needed only half the special education services as their fellow kindergartners. Given our recent bad practice of cutting indiscriminately, rather than wisely investing in what works and produces a good return on investment, the study estimated a savings of \$10,100 per child for each child who went to full day Head Start. What other such savings is the Department aware of?

Answer. The 1998 reauthorization of the Head Start Act required the Secretary of Health and Human Services to study the program's impact on children and families. In 2000, the Department commissioned the first large-scale randomized control trial of the national Head Start program from an independent contractor: The Head Start Impact Study. A report of interim findings was submitted to Congress in 2005 and a final report with findings through children's first grade year was provided to Congress in January 2010. The third grade study was not required by Congress but was undertaken by ACF in order to understand longer term impacts on children and families. This report, presenting findings through third grade, was completed in December 2012.

The Head Start Impact Study includes a nationally representative sample, including programs at all levels of quality; employs a randomized design; and examines all domains of children's development and achievement as well as parenting through third grade. It examines the average impact of providing children access to one program year of Head Start at age 3 or age 4. It compares children randomly assigned

to receive Head Start in 2002 to children who were denied Head Start but could—and often did—attend other early childhood programs. The study is unique from other studies of early care and education in that it includes a nationally representative sample, a randomized control design, and examines a comprehensive set of outcomes for children and families through third grade.

The study indeed found that there were statistically significant differences between the Head Start group and the control group on every measure of children's preschool experiences measured in this study. These effects were found both for the 4-year-old cohort and for the 3-year-old cohort during the year in which they were admitted to Head Start. The measures that were examined included, but were not limited to, teacher qualifications, including their training and education; classroom literacy and math instructional activities; classroom teacher-child ratios; the nature of teacher-child interactions; and global measures of the care environment as measured by research based observation tools.

Looking at impacts on child and family well-being in the short and longer term, the study found that there were initial positive impacts of Head Start, for both age cohorts and across domains of development, but by the end of first grade and again at third grade there were very few impacts found for either cohort in any of the four outcome domains examined: Cognitive, social-emotional, health and parenting practices. The few impacts that were found did not show a clear pattern of favorable or unfavorable impacts for children.

While the Head Start Impact Study cannot speak to impacts beyond third grade, the Advisory Committee on Head Start Research and Evaluation's final report reflects on the interpretation of this and other studies of Head Start and the implications of the body of evidence on Head Start for longer term outcomes. Further, one possible explanation for the perceived "fade out" of effects of early childhood programs may be that children who did not attend early childhood programs "catch up" to their peers later in elementary school. The committee concluded that both the Head Start and Early Head Start impact studies show immediate impacts on child and family well-being, and that while those immediate impacts do not persist into elementary school in the two impact studies conducted by HHS, the broader literature suggests that longer term impacts might still be found in adulthood. To support this conclusion, the committee cited both evidence from nonexperimental longitudinal studies of Head Start that have found beneficial effects into adulthood, as well as studies of other early childhood intervention programs that have found long-term impacts in adulthood despite diminished or no impacts during earlier follow-ups.

Regarding your question on the savings of full-day Head Start versus other options, we do not have rigorous studies that can speak to the benefits of providing access to full-day Head Start. However, we do have research from quasi-experimental studies (Currie and Thomas, 1995; Garces, Thomas and Currie, 2002; Ludwig and Miller 2007) that suggest that the long-term benefits of Head Start have outweighed the costs for cohorts of children, with a benefit-cost ratio as large as 7-to-1.

SEQUESTRATION

Question. How has sequestration impacted LIHEAP, Head Start, Early Head Start and child care beneficiaries? Besides the immediate effects on families, what are the wider-reaching effects of cutting these programs on communities?

Answer. Like almost all programs at HHS, sequestration reduced funding for LIHEAP, Head Start, and Child Care under the Child Care and Development Block Grant by approximately 5 percent. HHS is working with States and grantees as they make decisions about how to administer programs in light of the reduced funding level, and in many cases, the full impact of sequestration will not be known until the fiscal year has ended.

In the case of Head Start, the impact of reduced funding is being felt across the Nation, with community and faith-based organizations, small businesses, local governments and school systems facing potential layoffs for teachers, teacher assistants, and other staff who work in Head Start programs. Services for children and families are being disrupted, with some Head Start centers shortening their service days, closing their classrooms early this school year, or reopening their programs later in the fall.

We expect that some programs are choosing not to fill openings as children age out of the program, and reducing the number of children and classrooms through attrition. Working families participating in Head Start rely on a regular school calendar in planning their work schedules, and early closures could impact parents' ability to retain jobs.

Question. Because the sequester impacts every program and activity the same amount, can you describe how cuts will impact CDC grants to State and local communities, NIH-funded research, Community Health Centers, the National Health Service Corps, and AHRQ Institutional Training Grants? Will some communities be hit harder than others, and in what areas?

Answer. The cuts mandated by sequestration will have a significant impact on States and local communities across the country, leading to lower investment in public health system and biomedical research. Because the law mandates that most programs be reduced proportionately, programs that serve vulnerable and underserved populations will see decreased funding, impacting communities across the country.

At the Centers for Disease Control and Prevention (CDC), the cuts will result in less funding to State and local communities and research institutions, leading to reduced technical assistance and surveillance activities within States. For example, each State's funding for HIV testing will also be cut, which could result in increased future HIV transmissions, costs in healthcare and leave vulnerable communities at risk.

The National Institutes of Health (NIH) sequester was applied evenly across all programs, projects, and activities (PPAs), which are primarily the Institutes and Centers. This affects every area of medical research. Approximately 700 fewer research project grants (RPGs) will be awarded compared to fiscal year 2012 and existing grants will be reduced by 4.7 percent, on average. These cuts will delay medical research progress in all disease areas and the development of more effective treatments for common and rare diseases affecting millions of Americans. In addition, while patients currently participating in research protocols at the NIH Clinical Center will continue to receive care, about 750 fewer new patients are anticipated to be admitted to the Clinical Center for the remainder of the fiscal year due to these reductions.

Approximately 176 fewer awards for loan repayment and scholarships will be provided to National Health Service Corps (NHSC) clinicians who are integral to building healthy communities by providing primary healthcare services in federally designated Health Professional Shortage Areas throughout the Nation.

In the case of the impacts of sequestration on Institutional Training Grants funded by the Agency for Healthcare Research and Quality (AHRQ), Congress funds AHRQ using Public Health Service Act authority that is not reduced by this sequester, so no reductions were taken to these grants.

Question. Unlike premium assistance subsidies, cost-sharing subsidies are not provided to individual taxpayers, but paid directly to insurers. As such, they appear to be subject to sequestration. How will sequestration affect the ability to protect lower income people from high out-of-pocket costs at the point of service, as intended by the Affordable Care Act?

Answer. We share your concern about the potential adverse impacts of the payment cuts mandated by sequestration, both with regard to low-income individuals, and more broadly across all government programs. That is why the Administration has indicated that we stand ready to work with Congress on balanced approaches to replace sequestration to avoid its adverse impacts.

REPRODUCTIVE HEALTH

Question. Accessible and affordable family planning services have helped reduce the rates of unintended pregnancy and abortion in the United States. CDC has even included family planning on its list of the top 10 most valuable public-health achievements of the 20th century—along with childhood vaccinations and fluoridation of drinking water. More recently, a panel of women's health experts convened by the Institute of Medicine agreed that family planning is basic preventive healthcare for women that should be covered at no extra cost in the new health system. Do you agree that family planning improves public health, and if so, how?

Answer. Yes, family planning is an integral component in public health and healthcare service delivery. As you have indicated, family planning has had a significant impact in improving the public's health, from allowing women the ability to safely space their pregnancies—improving their children's physical and cognitive development, improving access to screening for diseases and cancers of the reproductive tract to increasing access to other related preventive health screening. Ensuring access to preventive health services, including family planning, as the Institute of Medicine's 2011 Report on Clinical Preventive Services for Women recommended, is of great benefit to the health of men and women of all ages.

Family planning clinicians provide information, counseling and clinical services to women and men of reproductive age to ultimately assist in maintaining healthy re-

productive lives. Ensuring healthy fertility is a process that requires regular preventive health screening, physical activity and all of the body's systems to be healthy. Couples seeking pregnancy can do many things to ensure that they have the best chances to achieve a pregnancy. Family planning providers and clinics are ideal for providing regular preventive health screening and other related services to help begin a healthy family. A mother who is physically active, routinely screened for or adequately managing chronic disease is most likely to have a healthy pregnancy with lower risks resulting in a safer delivery and healthier baby. These outcomes are not just felt by the new or growing family but are shared by the community, State and Nation as a whole. Prenatal care, healthy birth weights and other benefits of family planning and planning a pregnancy are associated with reduced risk of future chronic disease, improved educational and economic attainment, fewer behavioral problems and other positive developmental outcomes. Being a strong proponent of access to family planning services is a necessity for helping to ensure the strong, supportive and sustained development of our youth, families, and communities of this Nation.

Question. Studies show that every \$1 invested in family planning services saves nearly \$4 in government healthcare expenditures. How will increased access to affordable birth control affect healthcare costs overall under the Affordable Care Act?

Under the Administration's no-cost birth control policy, religiously affiliated organizations like charities, universities, and hospitals will not have to pay or refer for contraceptive coverage. Is it your opinion that private employers that are not religiously affiliated should not be able to refuse this coverage for their employees?

Answer. Ultimately access to affordable birth control under the Affordable Care Act will lower healthcare costs, in part, by reducing unintended pregnancies. This factor is pointed out by the findings from the Institute of Medicine's 2011 report entitled "Clinical Preventive Services for Women: Closing the Gaps," specifically the recommendation that a "fuller range of contraceptive education, counseling, methods and services so that women can better avoid unwanted pregnancies and space their pregnancies to promote optimal birth outcomes," is needed. Through the provision of contraception with no cost sharing, access to a broad range of contraceptive options will improve, especially to the more effective and longer acting forms of contraception (Intrauterine Device, Intrauterine System, and implants), and equally as important, the consistent use of contraceptive methods will also increase. Ensuring the health of women and their families was one of the many reasons HHS adopted these recommendations as part of the guidelines for women's preventive services under the ACA.

We know that unintended pregnancies occur at alarming rates; approximately half of the pregnancies in the United States are unintended (Unintended pregnancy in the United States: incidence and disparities, 2006, 2011; 84(5)). We also know that pregnancies which are not planned may result in a delay of prenatal care as well as slower adoption of healthy behaviors such as being physically active, quitting tobacco use, taking dietary supplements like folic acid, and screening for and the management of chronic diseases. All of these elements increase the risk of physical and cognitive impairments, resulting in elevated healthcare and other costs at birth and later in life. In addition, there are also large ethnic, age and income disparities in women who experience unintended pregnancy. Poorer women are more likely to have an unintended pregnancy and thus need to rely on Federal and State assistance to cover the costs of prenatal care and the births (Unintended pregnancy in the United States: incidence and disparities, 2006, 2011; 84(5)). It is estimated that the total public expenditure for births resulting from unintended pregnancies in the United States was \$11.1 billion (\$6.5 billion Federal and \$4.6 billion State expenditures) in 2006 (Sonfield, 2011, 43(12)).

In addition, family planning services provided at publicly funded family planning clinics are of significant social and financial value. While access to these services helped women avoid 1.48 million unintended pregnancies, about a third (450,000) of the unintended pregnancies prevented were among Medicaid enrollees (Gold, RB, 2009). The services provided at publicly funded clinics saved the Federal and State governments an estimated \$5.1 billion, of which Title X-supported clinics accounted for \$3.4 billion (Contraceptive Needs and Services, 2008 Update, 2010). The ratio of every \$1 invested in family planning services saving approximately \$4 in government healthcare expenditures is the result of the investments in family planning (Contraceptive Needs and Services, 2008 Update, 2010).

QUESTIONS SUBMITTED BY SENATOR MARY L. LANDRIEU

TOPIC 1: SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM

Question. Numerous studies and news reports have documented the re-employment struggles of out-of-work older Americans. For example, the General Accountability Office found in a 2012 study (GAO 12-445) that the unemployment rate for older adults increased by 145 percent during the recession and that it took unemployed older workers, on average, 35 weeks to return to the workforce, much longer than for younger jobseekers. Despite this growing need, the Administration has proposed a drastic cut to the only Federal program designed to help older workers from Louisiana and across the country return to the workforce. Two hundred fewer Louisianans will get service if this proposed cut was enacted.

Can you explain the Administration's rationale for targeting this older adult employment program that the GAO (12-445) noted "has done a reasonably good job at accomplishing its goals"?

Answer. As in prior years, the budget proposes to transfer the Senior Community Service Employment Program (SCSEP) to ACL in order to strengthen the integration of SCSEP with the other supports provided by ACL's existing Aging Services programs and ACL's service network connections. The budget does propose to reduce funding for the program based on attrition, and to prioritize funding to serve those with the greatest need. The Administration is also concerned about the growth in unemployed older workers, and wants to improve the ability of the existing workforce system to meet the needs of these individuals. The budget proposes to retain \$25 million at the Department of Labor to pilot and evaluate potential low-cost structural changes to the workforce system that will improve outcomes for seniors. In particular, DOL is interested in testing two policy changes that the GAO recommends in the report that you cited (GAO 12-445): (1) developing job search assistance programs that address skill deficiencies common among seniors; and (2) changing the performance measures to eliminate the disincentives to place older workers in part-time employment.

We believe that this dual strategy will allow ACL to provide improved and integrated support to the most vulnerable seniors, while also improving the services that seniors receive through the broader workforce system.

Funds will continue to be used to provide formula grants to States and competitive grants to national organizations. This funding will also provide necessary administrative support, monitoring, and technical assistance.

TOPIC 2: PROSTHETIC AUDITS

Question. In September 2011, immediately following the release of the OIG Report entitled "Questionable Billing Practices in Orthotics and Prosthetics," CMS's DME MAC contractors issued a "Dear Physician" letter that announced new documentation requirements for orthotic and prosthetic devices provided to Medicare beneficiaries. It also adopted a "zero tolerance" policy, so that if there was any imperfection in the claim submission, no matter how immaterial, payment of the claim should be denied. In the past, when the preponderance of evidence indicated that there was no fraud or abuse present, the claim would be approved. I am hearing from my constituents that small prosthetics businesses which provide care to seniors who need prostheses, are having as many as 90 percent of their claims denied for minor technicalities or paperwork that hasn't been completed by physicians. In the meantime, small prosthetics businesses are carrying hundreds of thousands of dollars' of legitimate, but unreimbursed costs—or limiting the number of seniors they care for under Medicare—or are going out of business altogether. In light of this crisis, I would like to ask the following questions:

What is CMS's policy to ensure that RACs and other anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?

Answer. CMS strives to reduce audit burden on providers. The Medicare Administrative Contractors (MACs) process claims and follow a process known as Progressive Corrective Action (PCA). The PCA process starts with the MAC reviewing a small number of claims on a pre-payment basis to determine if any of the claims would have been paid improperly. Based on the results of those reviews, if a provider has a high improper payment rate, the MAC increases the number of medical reviews for that provider and performs educational activities in an effort to improve their compliance with CMS policies. Conversely, if the PCA process shows the provider consistently bills correctly, the MAC suspend the reviews and focuses on other priorities.

The Recovery Auditors review claims mostly on a post-payment basis. The CMS has implemented several measures to ease provider burden and to ensure accurate RAC decisions. First, all new areas to be reviewed are approved by CMS before the Recovery Auditors can begin review. Second, the Recovery Auditors lose their contingency fee if their decision is overturned at any level of appeal. Third, CMS has limited the number of additional documentation requests a Recovery Auditor can send to a provider. On April 3, 2013, CMS created a separate additional documentation request limit category for prosthetists/orthotists. Recovery Auditors can request a maximum of 10 medical records per prosthetist/orthotist every 45 days. Before, Recovery Auditors could request up to 10 percent of their records.

Question. What policies does CMS employ to ensure that providers that are suspected of fraud are the primary targets of the audits?

Answer. Payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding and payment rules is an improper payment. It is important to keep in mind that all fraud is considered to be improper payments, but not all improper payments are fraud. In 2011, the Department of Health and Human Services Office of Inspector General (OIG) released a report that found that there was a significant amount of improper payment for lower limb prosthetics. Since the publication of the report, the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have begun reviewing these claims as recommended by the OIG. CMS also offers a range of educational materials through online manuals and Web sites to assist prosthetists and orthotists, providers and suppliers with Medicare policies, billing procedures and required documentation. If the DME MAC suspects that the supplier is participating in fraud, they are required to refer the case to CMS's Zone Program Integrity Contractor who is responsible for investigating potential fraud.

Question. Does CMS have any policies in place that take into account longstanding Medicare providers with a history of dedication to high-quality integrity, without documented or suspected fraudulent activity? Is it appropriate for Medicare to subject them to the same level of scrutiny, payment delay, and payment denial as high-risk providers?

Answer. The Medicare Administrative Contractors process claims and follow a process known as Progressive Corrective Action. As explained in chapter 3, section 3.7.1 of CMS's Program Integrity Manual, CMS's contractors "shall ensure that actions imposed upon Medicare providers or suppliers for failure to meet Medicare rules, regulations and other requirements are appropriate given the level of non-compliance." The manual offers examples of "minor," "moderate," and "major" concerns and discusses the type of corrective action appropriate for each.

Question. What length of time does CMS believe it is appropriate to withhold payment to prosthetics providers for minor documentation technicalities, or for documentation failures that are the responsibility of the physician, not the prosthetics provider?

Answer. Payment made for the furnishing of an item that does not meet one or more of Medicare's coverage, coding and payment rules is an improper payment. Section 1833(e) of the Social Security Act states that "[n]o payment shall be made to any provider of services or other person [under Medicare Part B] . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person" Documentation is essential to meet the requirement in the statute. Chapter 3, section 3.3.1.1 of CMS's Program Integrity Manual discusses the timeframe for certain medical review activities.

In regard to prepayment review, this section states, in part, that when one of CMS's Medicare Administrative Contractors (MACs) "receives requested documentation for prepayment review within 45 calendar days, the MAC shall . . . within 60 calendar days of receiving the requested documentation . . . make and document the review determination."

Question. Where providers have the financial and legal resources to appeal RAC payment denials to the Administrative Law Judge level, those RAC determinations are overturned at a very high rate—in some cases, more than 80 percent of the time. At what point does CMS examine RAC determinations—including costs to the agency—that are consistently being overturned upon appeal?

Answer. Through oversight to ensure Recovery Auditors make accurate improper payment decisions, CMS continually strives to reduce the appeal rate, which, in turn, decreases provider burden and administrative costs. The fiscal year 2011 Recovery Audit Report to Congress reported that more than 90 percent of Recovery Audit overpayment determinations were not appealed, and that just 2.9 percent of all Recovery Auditor overpayment determinations were overturned on appeal.

CMS has multiple layers of oversight and incentives to ensure Recovery Auditors make accurate payment decisions. Every month, for example, CMS, through an independent review contractor, reviews a random sample of claims from each Recovery Auditor to determine an accuracy rate representing how often the Recovery Auditors accurately determine overpayments or underpayments. The Recovery Auditors' accuracy scores are consistently above 90 percent. The CMS reports appeal statistics in the annual Report to Congress and on its Web site at: www.cms.gov/rac. Moreover, Recovery Auditors are required to return any contingency fee if an improper payment is overturned.

Question. Manufacturer records show practitioners have retreated to less advanced, less costly, less functional artificial limbs and components, reflecting aversion to risk of nonpayment. Has CMS measured the impact of contractor actions on patient care in prosthetics since August 2011, including how delivery times may have slowed in the face of these new requirements? Is Medicare satisfied to see the program reducing the level of care provided to Medicare amputee beneficiaries?

Answer. Medicare beneficiaries are receiving high-quality prosthetics and orthotics that help them live active and healthy lives, and CMS continues to ensure they have access to appropriate prosthetics and orthotics. In 2011, the HHS Office of Inspector General Daniel R. Levinson released a report that there was a significant amount of improper payment for lower limb prosthetics. CMS is working to educate providers and suppliers on Medicare coverage and documentation requirements for lower limb prosthetics to reduce the level of improper payments. In addition, CMS is developing a clinical template in consultation with prosthetic and orthotic suppliers to assist providers in complying with Medicare coverage policies. There is no data available to CMS to suggest any access to care issues.

Question. The current "all or nothing" approach to audits, where a minor paperwork flaw may block the entire payment on a \$35,000 prosthetic limb, seems inequitable and unnecessarily punitive to small businesses that are providing necessary, high-quality services to disabled senior citizens. In other settings, CMS has limited its audit/claw back to the specific challenged codes/components, while paying for those codes/components which are not contested. Why hasn't a similar policy been implemented for O&P?

Answer. In 2009, the U.S. Court of Appeals issued a decision in *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) regarding the application of the least costly alternative. The Court of Appeals held that the Medicare coverage decision is binary: An item or service is either reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all. Similarly, if a supplier bills for a level 3 prosthetic but the beneficiary only qualified for a level 1 prosthetic, the review contractor cannot simply reduce the payment to the level 1 payment amount; the review contractor must issue a full denial.

TOPIC 3: CENTER FOR DISEASE CONTROL

Question. In December, the Administration released the Action Plan for Children in Adversity to help increase coordination between 7 agencies and 30 offices on international programs working with children.

What is the Center for Disease Control doing to ensure that there is an implementation plan in place by the required 180 days? What, if any, challenges do you see in meeting the Action Plan's objectives of providing strong beginnings for children, a family for every child, and protect children from abuse, exploitation, violence, and neglect?

Answer. CDC is currently coordinating input across agencies and offices to ensure that an implementation plan will be in place by the required 180 days. CDC's implementation plan is comprised of activities that address all three of the Action Plan's objectives, and includes programs that aid in healthy physical and emotional development, as well as data collection activities addressing sustainable approaches to reducing sexual, emotional, and physical violence against girls and boys. Three main challenges for CDC include: (1) supporting the objectives of the Action Plan in non-PEPFAR countries; (2) addressing populations of children living outside family care, such as street children and those in institutions; and (3) lack of dedicated appropriations for implementation of the Action Plan.

Question. The Action Plan places a strong emphasis on the use of evidenced-based research and data to achieve measurable outcomes. What role do you anticipate CDC being able to play in meeting this objective?

Answer. The foundation of CDC's work is scientific excellence, putting into place public health programs based on the highest quality research and data. Regarding children in adversity, CDC emphasizes the fact that exposure to childhood adversity

has been linked with serious long-term emotional and health effects, including risk for HIV. Thus, CDC can provide technical expertise and scientific leadership for the Action Plan. For example, CDC has been providing technical assistance to countries to conduct national Violence Against Children Surveys (VACS), with support from PEPFAR, the CDC Foundation, UNICEF, and the Together for Girls Public Private Partnership. Once completed, countries conducting the VACS link these data to evidence-based National Action Plans to create and evaluate violence prevention efforts and to assist victims and their families. Demand for these surveys, along with CDC technical assistance to meet this demand, is strong and growing. CDC is able to play a major role in meeting these requests under the leadership of CDC's PEPFAR activities.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

CONGENITAL HEART DISEASE

Question. Congenital heart disease (CHD) is among the most prevalent birth defects in the United States and a leading cause of birth defect-associated infant mortality. With medical advancements, more people with congenital heart defects are living into adulthood, but our Nation has not had a population-surveillance system that captures adults living with CHD. The healthcare reform law authorizes the CDC to expand surveillance and track the epidemiology of CHD across the life-course, with an emphasis on adults. The Consolidated Appropriations Act of 2012 provided the CDC with \$2 million in new funding for enhanced CHD surveillance across the lifespan.

CDC is making commendable efforts to close the knowledge gap in adult congenital heart disease by using this funding for three grants to pilot adolescent and adult surveillance. I also appreciate CDC's efforts to use expert consultation to develop ongoing research priorities through the Expert Meeting convened in the fall of 2013. Moving forward, how does the CDC plan to implement the outcomes from the expert meeting? Further, how does CDC plan to use CHD surveillance funds in fiscal year 2013? If additional money is appropriated for CHD surveillance in fiscal year 2014, how would that funding be utilized?

Answer. The expert meeting provided helpful input from 50 participants representing diverse specialties, priorities, and perspectives: Physicians, surgeons, epidemiologists, public health officials, advocates, and patients. The summary of input from the meeting has been submitted for publication in a peer-reviewed journal so that it is accessible to all expert meeting participants, other HHS operating divisions, and other stakeholders. CDC used this summary to guide its strategic plan revision, which will guide future work as resources permit.

In fiscal year 2013, CDC will use CHD resources to:

- Fund the second year of the three CHD surveillance cooperative agreements to pilot innovative methods for CHD surveillance among adolescents and adults. The grantees are Emory University (Atlanta, GA), the New York State Department of Health, and the Massachusetts Department of Health. Grantees will link data from multiple existing sources, and will begin submitting de-identified surveillance data to CDC in year two.

- Support intramural public health science on CHDs that will form an evidence base about the health and economic costs of CHDs. Projected topics include estimating hospital costs across the lifespan for those with CHDs, the role of insurance type and demographic factors in survival of those with CHDs, and estimating the total number of individuals in the United States living with CHDs.

In fiscal year 2014, CDC will continue these efforts. CDC could enhance these activities in fiscal year 2014 by:

- Funding additional sites for CHD surveillance among adolescents and adults, and potentially add a research component to better identify the factors associated with improved longer term outcomes.

- Linking existing birth defects surveillance data to other available datasets to evaluate longer term outcomes, including medical care use and survival. This model has been successfully piloted in one State, and could be implemented in additional States to provide more complete evidence.

- Collaborating on research opportunities with the National Heart, Lung, and Blood Institute to improve outcomes for CHD survivors.

Question. The CDC is in position to move beyond primary detection to addressing the life-long needs of those living with congenital heart disease. What does the CDC propose for further addressing this public health burden of congenital heart defects across the life-span?

Answer. CDC has identified several areas for further addressing CHD burden across the lifespan:

- Expand and modernize surveillance practices to provide prevalence estimates across the life span and to collect longitudinal data on health outcomes and services use that could identify opportunities to improve longer term outcomes for those with CHDs.
- Expand current research efforts to identify modifiable causes of CHDs to increase capacity to prevent CHDs.
- Identify current barriers impacting access to care which might contribute to existing disparities in survival, and explore opportunities to reduce or eliminate barriers.
- To better address the lifelong needs of those with CHDs, partner with the National Heart, Lung, and Blood Institute to follow up on a cohort of individuals with CHDs to understand their longer term outcomes.
- To better understand the impact on families, conduct a family survey to assess out of pocket and nonmedical costs, loss of work time, impact on siblings, and other consequences to pinpoint opportunities to mitigate the adverse effects for families.

Question. Recent data suggest that the number of infant deaths related to CHD is decreasing, and successful intervention in infancy and childhood is resulting in an adult population of congenital heart disease survivors. How are you systematically responding to this new population of survivors reaching adolescence, adulthood and advanced age? How are you utilizing adult congenital heart disease research experts in these efforts?

Answer. With newborn screening for critical CHDs, survival is expected to improve. CDC is actively preparing ways to assess and address the needs of the population of CHD survivors. CDC is funding three pilot surveillance programs to track CHDs among adolescents and adults, and better understand the needs of the population. The grantees are Emory University (Atlanta, Georgia), the New York State Department of Health, and the Massachusetts Department of Health. New methods are being tested in order to develop the most successful approaches for this surveillance. We will pool data across the sites to develop more robust estimates of the prevalence of CHDs among adolescents and adults, and will examine characteristics of those with CHDs. We will use this data to inform our current understanding of the national prevalence of CHDs across the lifespan.

CDC is engaging researchers with expertise in both pediatric and adult congenital CHDs. For the pilot CHD surveillance programs among adolescents and adults, CDC has established an External Guidance Committee to provide this input to both CDC and the grantees. This committee includes individuals with expertise in adult CHD research. In addition, each of the three grantees has included researchers with this expertise as part of their key personnel.

PREVENTION AND PUBLIC HEALTH FUND

Question. Smoking causes nearly one in every five deaths in the United States and costs the country about \$193 billion each year in healthcare expenses and lost productivity. An estimated 43.8 million American adults smoke cigarettes and about 3,800 young people under the age of 18 smoke their first cigarette every day. Congress created the Prevention and Public Health Fund, a dedicated funding stream for crucial investments in prevention for a healthier America, to begin addressing these challenges. The Fund represents a rare opportunity to reverse decades of increasing healthcare costs attributable to ever-growing rates of obesity, chronic disease, and other preventable illness.

Please summarize investments made through the Prevention and Public Health Fund to promote tobacco prevention and control. What measurable economic and health benefits have resulted from those investments? A portion of the fund went toward the Centers for Disease Control and Prevention Tips from Former Smokers campaign. Please summarize the status of this initiative and health and economic benefits of this campaign. If Prevention and Public Health Fund dollars are reallocated toward non-public health prevention initiatives, how would that reallocation of funds impact investments in tobacco control and prevention and the returns on those investments?

Answer. Since the enactment of the Prevention and Public Health Fund in fiscal year 2010 through fiscal year 2013, HHS has invested approximately \$229 million in tobacco activities predominately within the Centers for Disease Control and Prevention (CDC), and some additional resources within the Office of the Secretary.

From fiscal year 2010 through fiscal year 2013, the Prevention Fund has supported a range of strategic programs to reduce tobacco use, support cessation efforts,

and to prevent the initiation of tobacco use. Funds have supported: Tobacco media activities within the office of the Assistant Secretary of Public Affairs in fiscal year 2011 and fiscal year 2012 to execute innovating local, regional, and national health marketing campaigns, develop effective outreach strategies to target audience groups, and to develop and promote educational tools; efforts within the office of the Assistant Secretary for Health in fiscal year 2010 to coordinate and implement tobacco cessation activities consistent with the HHS Tobacco Control Strategic Action Plan and to fund projects focused on cessation services in partnership with other HHS agencies; and, CDC tobacco prevention and control programs that aim to reduce initiation and the prevalence of tobacco use. Specifically, CDC has supported a nationwide media campaign to increase awareness of the risks of smoking and to encourage smokers to quit. In addition CDC has supported and enhanced the capacity of State telephone tobacco quit line services. These activities were initiated in fiscal year 2010 and continue to be supported in fiscal year 2013.

Research has shown that well-designed tobacco education media campaigns with adequate reach prevent initiation, increase cessation and reduce tobacco use. Evidence reviews of tobacco education media campaigns have found that advertisements that employ strong imagery and personal testimonials showing the negative health consequences of smoking are especially effective in motivating smokers to quit. The CDC TIPS from Former Smokers (TIPS) is a nation-wide education campaign that was launched during several months in 2012 profiling individuals living with the effects of smoking related disease. The intent of the campaign was primarily to encourage smokers between the ages 18 through 54 years to quit smoking by increasing awareness of the health risks caused by smoking, and to raise awareness about services through the CDC quit lines and the National Cancer Institute (NCI) smoking cessation Web site. As a result, the CDC quit line received more than 365 thousand calls during the campaign which reflected a 132-percent increase from a comparable period of time in 2012, and visits to the NCI smoking cessation site also increased significantly. The fiscal year 2013 allocation of the Prevention Fund supports the TIPS campaign in fiscal year 2013.

HHS continues to support tobacco cessation and prevention efforts not only with resources from the Prevention Fund but with base resources appropriated to agencies across HHS as well. The fiscal year 2014 budget includes \$95 million from the Prevention Fund to CDC, in addition to CDC base resources, to continue tobacco prevention efforts.

MENTAL HEALTH

Question. According to USDA, 50 million people live in rural America. This rural population is disproportionately affected by mental health disorders, with higher levels of depression, domestic violence, and child abuse, compared to their urban peers.

Unfortunately many families in rural American find themselves cut off from mental health services because of geographic and cultural barriers. As of January 2013, there are 3,800 Mental Health Professional Shortage Areas nationwide, as defined by HRSA. More than 85 percent of MHPSAs are located in rural areas. As a result of the scarcity of mental health professionals, primary care providers in rural communities typically have a larger role in mental healthcare than their urban peers.

Studies have shown that stigma is a significant concern for many in rural America. People suffering from a mental disorder are less likely to seek treatment if they fear being recognized.

Recognizing this stark data, what steps is the agency taking to increase the mental health workforce in rural settings?

Answer. HRSA is implementing a variety of projects to increase mental and behavioral health providers, place such providers in rural and underserved communities, and increase the primary healthcare workforce.

HRSA is increasing the number of mental and behavioral health providers through the Graduate Psychology Education program and the Mental and Behavioral Health Education and Training program. The Graduate Psychology Education program supports doctoral-level psychology education. The Mental and Behavioral Health Education and Training program increases the number of behavioral health professionals at the masters and doctoral-level through support for clinical training (internships, field placements) required for practice. Both programs include an emphasis on vulnerable and underserved populations, such as rural populations, older adults, children and adolescents, victims of abuse, veterans, military personnel and their families.

HRSA is also supporting the placement of behavioral and mental health professionals through the National Health Service Corps. The Corps has increased the

number of behavioral and mental health providers that it supports over the past 5 years. In fact, nearly one in three clinicians in the Corps (2,919 as of September 2012) is a behavioral and mental health practitioner, which includes psychiatrists, health service psychologists, clinical social workers, licensed professional counselors, marriage and family therapists, and psychiatric nurse specialists. The distribution of all NHSC clinicians across the country is generally even between rural and urban areas. Rural: 45 percent. Urban: 55 percent.

HRSA is also increasing the ability of the primary healthcare workforce to address mental and behavioral health needs by partnering with SAMHSA on the Center for Integrated Health Solutions (CIHS). The Center is a national training and technical assistance resource center which promotes integrated primary and behavioral health services to address the needs of individuals with mental health and substance use conditions, whether seen in specialty behavioral health or primary care provider settings. CIHS has formulated trainings for health center primary care providers, many of whom serve in rural areas, around the topic of providing mental health services.

Question. What steps is HRSA taking to better integrate mental health and primary healthcare in rural hospitals and FQHCs?

Answer. Today, more than 1,200 health centers operate nearly 9,000 service delivery sites that provide care in every U.S. State, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. Nearly half of all health centers serve rural populations. In 2011, 70 percent of health centers in rural areas offered behavioral health services to their patients in addition to serving as a key access point for primary care. Also in 2011, over 1 million people across the Nation received behavioral health treatment at health centers. This represents a 35-percent increase in patients seeking behavioral health treatment at health centers since 2009.

While not a required service, HRSA actively encourages health centers to provide mental health and substance abuse services, such as Screening, Brief Intervention and Referral to Treatment (SBIRT) services. Another example of integrating mental and primary healthcare at health centers is the use of tele-behavioral health which is used to enhance outreach and education.

HRSA's Rural Workforce Development Program supports the development of rural health networks that focus on activities relating to the recruitment and retention of primary and allied healthcare providers, including mental and behavioral health providers, in rural communities. For example, one grantee is currently implementing a training program in which students may complete their clinical programs in psychology, social work, or counseling in the community health center setting in the rural area. This innovative program has the potential to be replicable at a regional and State level.

Question. What ideas does HRSA propose for further addressing the scarcity of mental providers in rural settings?

Answer. In fiscal year 2014, HRSA will partner with SAMHSA to support a \$50 million initiative, included in SAMHSA's fiscal year 2014 budget request, to expand the behavioral health workforce as part of the President's plan to prevent gun violence. The initiative will include \$35 million to expand the Mental and Behavioral Health Education and Training program by supporting training for masters level social workers, psychologists and marriage and family therapists as well as behavioral health paraprofessionals. Applicants will be asked to focus on vulnerable and underserved populations, such as rural populations, older adults, children and adolescents, victims of abuse, veterans, military personnel, and their families.

ORAL HEALTH

Question. According to HRSA, 108 million Americans today lack access to dental coverage. In fact, many people with dental coverage lack access to dental care. The U.S. has roughly 141,800 working dentists and 174,100 dental hygienists. However according to HRSA data, there are 4,230 dental health professional shortage areas nationwide with 49 million people living in them.

More than 16 million children in the United States go without seeing a dentist each year. Particularly vulnerable are children living in rural areas. Although the Children's Health Insurance Program (CHIP) provides comprehensive oral health coverage, dental care is the greatest unmet health need among children. More concerning, many dentists refuse to treat Medicaid beneficiaries, citing low reimbursement rates and administrative burdens.

In 2009, HRSA embarked on an Oral Health Initiative, which included a series of Institute of Medicine reports. Based on this work, what concrete steps has the

agency taken to implement the recommendations from the initiative to close the coverage gap?

Answer. HRSA is addressing many of the recommendations by supporting training programs to increase the oral health workforce.

—The Training in General, Pediatric and Public Health Dentistry program builds on the recommendation to increase access to oral health services by increasing the oral health workforce. The program supports schools and universities' financial assistance programs for oral health students and dental residents, as well as loan repayment programs for full-time faculty.

—The State Oral Health Workforce Improvement Grant program addresses the initiative's recommendation for greater coordination with States to improve core oral health services. The program provides grants to support States in their efforts to develop and implement innovative programs (including programs that integrate oral health services in primary care settings) to address their dental workforce in underserved areas.

In fiscal year 2011, these programs combined trained over 2,700 oral health students, including over 600 primary care dental residents. Data showed that the training of pre- and post-doctoral oral health students 1 out of every 2 sites used for clinical training were located in medically underserved communities or dental health professional shortage areas. Also, a total of 175 faculty members were trained through the faculty development activities within these two programs.

Question. Even in States with the highest Medicaid reimbursement rates. Children enrolled in Medicaid are not getting adequate oral healthcare. Has the agency looked at expanding the number of mid-level professionals to provide care in underserved areas as an option for addressing this need? Please explain.

Answer. HRSA does not have a position on the use of mid-level professionals, such as alternative oral health providers. However, a number of HRSA programs do include activities related to a variety of alternative oral health providers within State licensure laws.

—For example, the State Oral Health Workforce grant program currently funds ten States for activities related to dental therapist, dental hygienist with expanded functions or less restrictive supervision requirements, medical providers, community oral health coordinators, and expanded-function dental auxiliaries.

—Among HRSA's Training in General, Pediatric, and Public Health Dentistry and Dental Hygiene programs, six dental residency programs have incorporated training medical residents and primary care providers into their dental residencies' curricula.

—In Minnesota, a collaboration between a nonprofit dental clinic and two academic institutions provides clinical rotations for 25 dental hygiene trainees, including 20 trained on a Restorative Expanded Functions clinical curriculum, and five on an Advanced Dental Hygiene (Advanced Dental Therapists) curriculum.

QUESTION SUBMITTED BY SENATOR JON TESTER

Question. The Area Health Education Consortium (AHEC) programs are a cornerstone of the development, recruitment and retention of a full range of much needed healthcare professionals—from physicians to the whole range of ancillary service positions upon which facilities and providers rely in order to provide quality care to their patients, especially in rural and frontier communities. It has become clear that the best option is to develop talent from those who want to learn or hone their healthcare professional skills at a program in the State, serving Montanans while developing skills in their chosen profession. Without the AHEC program in Montana we would not have a new Family Medicine Residency program starting in Missoula this summer which will train 10 new physicians each year. We would lose the mentorship of the Health Occupation Students of American programs and the scholarships given to high school seniors who plan to pursue a career in health professions at a Montana institute of higher education. We'd also lose the MedStart Camps that encourage current sophomore and junior high school students who come from disadvantaged backgrounds, low-income families, rural areas, minorities, or will be first in their family to attend college to pursue a career in a healthcare field. The Federal AHEC investment in Montana was \$826,112 last year; this money goes a long way in the small, close-knit communities across the State.

The need for diverse, well-prepared and supported primary healthcare providers and related ancillary services is ever-increasing, and the AHEC program is a vital element in the development, recruitment and retention of healthcare professionals.

Given the increasing need—due to ACA implementation—of healthcare professionals, especially primary care providers—what is the rationale for proposing the elimination in the HHS fiscal year 2014 budget of the Area Health Education Consortium (AHEC) Program which has a long and successful history of recruiting, training, and retaining primary care providers and other health professionals to work in rural, frontier, and other underserved communities throughout the U.S.?

The AHEC Program plays a key role in meeting numerous HHS/HRSA strategic priorities including: (1) Inter-professional Education and Practice (the new national Inter professional Education Coordinating Center is housed at the Minnesota AHEC and University of MN); (2) Veterans' Mental health: AHECs are training 10,000+ community-based providers re: PTSD/Substance Abuse/behavioral health issues throughout the country for returning Veterans; (3) The development of Community Health Workers and Patient Navigators: NAO and the AHEC network are taking the lead on CHW/navigator training, curriculum development, and are developing a national advisory board to create some standardization of the profession. AHEC funding is important to maintaining this vital program; (4) Diversity in the health professions: AHECs throughout the country are engaged in exposing underrepresented minorities to the health professions and are working diligently to increase the diversity of the health professions; and (5) Linking Public Health to Primary Care: Medical school-based AHECs are working to ensure that health professions students are developing connectivity to public health schools in order to enhance the public health knowledge and skill base. Taken together, how can you rationalize eliminating the AHEC Program that is so clearly aligned with key HHS/HRSA objectives and how with HHS/HRSA continue to meet these critical objectives in the absence of the AHEC Program?

With a fiscal year 2011 investment of \$34 million, AHECs leveraged six- to seven-times that much money from local and other sources to create and share robust training and mentorship programs. Without the Federal investment, local resources are insufficient, and therefore the recruitment, training, and retaining of health professionals in underserved areas does not occur. Why would you propose eliminating such a program that generates jobs, creates vital healthcare access enhancements, and is a proven return on investment?

Answer. The fiscal year 2014 President's budget prioritizes allocating Federal resources to training programs that directly increase the number of primary care providers. Given the lean fiscal climate, HRSA had to make difficult choices regarding program funding levels. While HRSA has made longstanding investments in these activities to enhance health professions training since 1972, they do not directly increase the supply of providers. Given that most AHEC programs have been in place for many years and have State and local support, it is anticipated that the AHEC Program grantees will continue much of their efforts relying on these other funding sources.

QUESTIONS SUBMITTED BY SENATOR JERRY MORAN

PUBLIC HEALTH AND PREVENTION FUND

Question. Madam Secretary, a portion of the Prevention and Public Health Fund (Prevention Fund) is being used to backfill the implementation of the health insurance exchanges. I have been concerned that the Administration creates budgets that rely on these Prevention Fund dollars to backfill critical public health programs. This fear has now been realized with your decision to remove Prevention Fund funding for public health programs in favor of implementing the Affordable Care Act. Under your revised Prevention Fund distribution that allocates funding to health insurance exchanges, the CDC loses \$357 million in fiscal year 2013, including significant cuts to the 317 Immunization Program and surveillance programs. In fact, had it not been for additional funding being transferred with your 1 percent transfer authority, CDC would have a \$440.3 million reduction in fiscal year 2013. Could you explain why you made such a significant reduction to critical public health programs in order to fund your other priorities?

Answer. The purpose of the Prevention and Public Health Fund is to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector healthcare costs. Assisting Americans in gaining affordable healthcare aligns with the purpose of the Prevention Fund, which may be used for prevention, wellness, and public health activities. Implementing the health insurance marketplace is the Administration's top public health activity which has a great potential to improve prevention and public health in the next year by enabling individuals

to enroll in coverage through private health insurance and have greater access to primary and preventive care. For example, the Navigator program, in the federally facilitated marketplaces, is intended to help increase access to coverage, including by assisting with eligibility determinations and enrollment into the marketplace. Various other activities funded by the Prevention Fund help Americans get the information they need by building awareness and sharing information. These activities include the education and outreach campaign regarding preventive services as well as funding for tobacco prevention like the media campaign and quitlines. Just as quitlines help smokers navigate tobacco cessation, Navigators help consumers navigate the health insurance marketplace. Increasing access to care and in particular preventive services is a component of our national efforts to restrain the cost of healthcare by encouraging healthier lifestyles, which is a key intent of the Prevention Fund. One of the proven ways to improve health outcomes is to improve access to insurance coverage. Not only does it provide security and peace of mind, but several studies have shown that health insurance coverage improves health outcomes. For example:

- In a 2008 study, the Urban Institute noted that the absence of health insurance creates a range of consequences, including lower quality of life, increased morbidity and mortality, and higher financial burdens.
- A 2009 study in the American Journal of Public Health found that a lack of insurance is associated with mortality and that the uninsured are more likely to go without needed care than the insured. It also found that the chronically ill uninsured are also less likely to have a usual source of medical care, decreasing their likelihood of receiving preventive and primary care.
- A study by the Institute of Medicine showed that working-age Americans without health insurance are more likely to: Receive too little medical care and receive it too late; Be sicker and die sooner; Receive poorer care when they are in the hospital even for acute situations like a motor vehicle crash.

In addition to funding the marketplaces, the fiscal year 2013 allocation also continues other important public health and evidence based programs such as tobacco prevention and the Community Transformation Grant program. In recognition that some key prevention and public health activities should be continued in fiscal year 2013, HHS is providing additional base resources for specific programs within CDC and SAMHSA through the use of transfer authority within the Department. The fiscal year 2013 allocation totaling \$949 million, after accounting for sequestration reductions, reflects a broad and strategic portfolio of activities that supports the Administration's highest prevention and public health priorities.

Question. Over the past 3 years, the Prevention Fund has been used to supplant budget authority throughout the Department's budget. As we have seen with the fiscal year 2013 Prevention Fund allocation, your proposed distributions in the budget request are not always followed. By making last minute changes to the Prevention Fund's allocations, program funding becomes uncertain. After learning of the significant changes to this distribution of the Prevention Fund in fiscal year 2013, how can Congress rely, with any certainty, on the Department funding Prevention Fund programs at the level proposed in the fiscal year 2014 request?

Answer. The Prevention Fund allocation is developed following the annual Federal budget process. HHS considers comments, stakeholder input, and current priorities in developing a yearly strategy for these resources. This year presented circumstances which resulted in HHS revising the initial allocation developed for fiscal year 2013. The fiscal year 2013 President's budget presented a planned allocation for resources totaling \$1.25 billion. After the budget was released, the Middle Class Tax Relief and Job Creation Act of 2012 reduced this funding to \$1 billion. The Prevention Fund was then further reduced by \$51 million in sequestration reductions. As a result of these changes in law and because the fiscal year 2013 appropriation did not provide the resources requested by the Administration for implementation of the health insurance marketplace to fully enable individuals to access affordable health insurance coverage, the Department is leveraging and reallocating existing resources from multiple sources to provide short term and immediate funding for these efforts.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) EXCHANGE

Question. Madam Secretary, some States, for example our home State of Kansas, have decided against setting up a new State-based exchange. If a State elects not to establish an exchange, under law, the Affordable Care Act requires that Centers for Medicare and Medicaid Services (CMS) must establish a federally facilitated exchange in that State. Are these Federal exchanges on track to begin enrollment on October 1, 2013?

Answer. Yes, we are on track to begin open enrollment on October 1, 2013.

Question. How much discretionary funding will the Department have spent to implement exchanges through fiscal year 2013?

Answer. In fiscal year 2011 and fiscal year 2012, HHS spent approximately \$33 million and \$290 million in discretionary funding on marketplace activities, respectively. In fiscal year 2013, HHS is planning to spend approximately \$879 million in discretionary funding. These totals are from multiple discretionary sources, including CMS Program Management, General Departmental Management, the Non-recurring Expenses Fund, and the Secretary's Transfer Authority.

Question. The Affordable Care Act provided "such sums as necessary" language to set up State-based exchanges. How much money have you used thus far under that authority?

Answer. As of April 5, CMS has awarded \$3.84 billion in planning grants, early innovator grants, and establishment grants for State-based marketplaces under the authority provided by section 1311 of the Affordable Care Act.

Question. CMS issued Establishment grants to 37 States as planning money to set up exchanges. How many of the States that received this award established a State-based exchange?

Of the States that received an Establishment grant that did not decide to establish a State-based exchange, how much money was spent?

Answer. CMS has awarded 49 States and the District of Columbia a planning grant under the authority of section 1311 of the Affordable Care Act. To date, CMS has conditionally approved 17 States and the District of Columbia to operate marketplaces in 2014, and an additional 7 States are conditionally approved as State Partnership Marketplaces. Lastly, another 7 States are managing plan management functions.

In addition to the planning grants, grant funding appropriated in section 1311 of the Affordable Care Act is available to States for their costs related to "establishment" of marketplaces. States may apply for Level 1 and Level 2 establishment grants. States may also seek approval of a State-based marketplace in future years, and grant funds must be awarded by December 31, 2014. A comprehensive list of grant awards by State is available here: <http://www.cms.gov/ccio/resources/marketplace-grants/index.html>

NAVIGATORS

Question. The Department designated \$54 million in Prevention and Public Health Fund dollars for "navigators," a program whose stated objective is to help consumers understand health insurance options under the health insurance exchanges created pursuant to the Affordable Care Act. Could you please provide further information to the committee regarding the following:

Will the \$54 million in Prevention and Public Health Fund be the only source of funding for navigators in fiscal year 2013? If there will be other sources of funding, please provide details.

Answer. In fiscal year 2013, the Navigator program in federally facilitated marketplaces is primarily funded from the Prevention and Public Health Fund. However, CMS spent about \$750,000 out of Program Management for a support contract to assist in administering the grants in February.

Question. Neither the fiscal year 2013 nor fiscal year 2014 budget requests allocate Prevention Fund dollars to the navigator program. While the fiscal year 2013 budget proposal did not request Navigator funding from the Prevention Fund, in the end, Prevention Fund dollars were used. Do you expect fund this program in fiscal year 2014 through the Prevention Fund?

Answer. The fiscal year 2014 President's budget does not allocate funding from the Prevention Fund to CMS for the Health Insurance Marketplace. While the health insurance marketplaces are set to be operational in fiscal year 2014, it is critical we invest now in outreach activities that will increase awareness and enrollment.

Question. How many navigator employees and/or contractors do you expect to hire with the \$54 million?

Answer. In the federally facilitated Marketplace, including Partnership Marketplace States, CMS may award grants to private and public entities and self-employed individuals within those States to perform Navigator duties. We are not hiring any employees or contractors.

Question. How many navigator employees and/or contractors will be maintained once exchanges are in operation on October 2013?

Answer. In the federally facilitated marketplace, including Partnership Marketplace States, CMS may award grants to private and public entities and self-em-

ployed individuals within those States to perform Navigator duties. We are not hiring any employees or contractors.

PROJECT BIOSHIELD

Question. Madam Secretary, while a commercial market for medical countermeasures is small, Federal investments in biodefense have proven fruitful and are critical to the continuing defense of our Nation. The Project BioShield Act resulted in the procurement and stockpiling of nine medical countermeasures in its first 7 years. Given current funding challenges, what steps are you taking to make sure that innovations in medical countermeasures continue?

Answer. Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multiyear budgeting practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies (e.g., Amgen, GlaxoSmithKline, etc.) are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress's continued support for these future activities.

Question. What steps are you taking to make sure that the Project BioShield Special Reserve Fund is available for the next 5 years to give confidence to companies that are developing and delivering essential medicines to our national stockpile to use in the event of an emergency?

Answer. The Department agrees that providing industry with a clear indication of long-term support of medical countermeasure development is important to the success of Project BioShield. The budget explicitly states the fiscal year 2014 request represents a multiyear renewed commitment to Project BioShield. Additionally, as an added incentive, the fiscal year 2014 President's budget proposes language to provide BARDA with the authority to modify the standard government-wide authority for multiyear contracting (41 U.S.C. 3903). The modified language included in the fiscal year 2014 President's budget authorizes BARDA to enter into an "incrementally funded", multiyear contract for up to 10 years. Additionally, the language modifies the existing authority's requirement of set-aside contract termination costs by allowing BARDA to repurpose any un-used termination costs to pay contract invoices in subsequent years. This differs from traditional multiyear contracting authority, which specifies termination costs can be used for that purpose alone. These modifications allow BARDA to effectively utilize multiyear contracting authority to engage in long-term contracts with companies that develop medical countermeasures.

HEAD START

Question. How is the Department working to improve quality of services to provide better outcomes for Head Start and Early Head Start children?

Answer. HHS is committed to ensuring program excellence for the families and children we serve and has put in place a number of reforms and improvements to further improve the programs' quality.

Designation Renewal System

This Designation Renewal System is the largest reform that has taken place in Head Start's history. By laying out quality benchmarks and requiring any program that falls short on those benchmarks to compete for continued funding we ensure that the children Head Start serves will get the best early education that each of their communities can offer. We have already conducted competitions in more than 100 communities and notified more than 100 additional grantees that they will be required to compete.

CLASS

The Office of Head Start is now using a valid reliable research based tool to assess the quality of Head Start classrooms across the country. The Classroom Assessment Scoring System (CLASS) was developed based on years of research by experts at the University of Virginia and assesses the quality of teacher-child interactions, the thing that matters most in the quality of early childhood classrooms. We are using CLASS in Training and Technical Assistance, programs are using it for professional development of their teaching staff and we are also using it in for account-

ability. As part of the Designation Renewal System, agencies that score below a minimum threshold or in the lowest 10 percent of all Head Start programs reviewed in the same monitoring year which received a CLASS evaluation during their on-site Federal monitoring review for any domain are required to compete for continued funding. We believe using CLASS throughout Head Start will continue to strengthen the most critical elements of quality.

School Readiness

Head Start programs are required to establish goals for enhancing the school readiness of children, including school readiness goals that are aligned with Head Start Child Development and Early Learning Framework, and State Early Learning Standards as appropriate. We also require that programs assess how children are progressing, and regularly analyze that data to better support each child's individual progress in the classroom and collectively to make program improvement decisions about necessary changes to curriculum or teacher training.

Training and Technical Assistance (T/TA)

We have strengthened our Training and Technical Assistance System to better support program improvement. The system consists of three components: Direct funding to grantees; State, Migrant and Seasonal Head Start (MSHS), and American Indian and Alaskan Native (AIAN) Centers; and National Centers. The State T/TA System provides Head Start programs access to professional development providers at the State, tribal, and local level. Six National Centers work together to provide Head Start grantees with consistent information and "best practices" from OHS across all service areas.

Question. Will the increase in Head Start funding in fiscal year 2014 reflect more full-day service?

Answer. The President's budget request for fiscal year 2014 does reflect more full-day service. The expansion for the Early Head Start/Child Care Partnerships would expand high-quality early learning by approximately 110,000 full-day, full-year, high-quality Early Head Start slots.

STRATEGIC NATIONAL STOCKPILE

Question. The budget proposes to reduce funding for the Strategic National Stockpile by \$38.2 million. This reduction could result in fewer people receiving treatment during an influenza pandemic and fewer people receiving post-exposure treatment following exposure to anthrax. The proposed reduction is more than an efficiency cut; it affects our capability to respond in the event of a terrorist attack. At this proposed funding level, are you concerned in the Federal Government's ability to adequately respond should there be a bioterrorist attack or disease epidemic?

Answer. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is responsible for defining and prioritizing requirements for public health emergency Medical Countermeasures (MCMs) and establishing deployment and use strategies for SNS products. Furthermore, the PHEMCE formulates and maintains an intra-agency 5-year budget plan that takes into consideration requirements and lifecycle costs of SNS products throughout HHS. Timely procurement of new and replacement MCMs is necessary to achieve established PHEMCE goals and protect the public from health security threats. CDC coordinates with PHEMCE to prioritize and identify which expiring products need to be replaced to maintain current capabilities with available funding.

CRITICAL ACCESS HOSPITALS

Question. As a follow up to our discussion about Critical Access Hospitals during the hearing, I ask for further details on the following:

How did the Department come up with the 10-mile limit and how many hospitals will be at risk of losing their designation based on your proposal? If these facilities lose their designation pursuant to this policy, do you think their survival will be jeopardized?

Answer. The Critical Access Hospital (CAH) program was created in 1997 through the Balanced Budget Act with the intent to ensure beneficiaries in rural communities had access to inpatient hospital and emergency care. This proposal would limit CAH designation to those facilities that are located more than 10 miles away from the nearest hospital and would ensure that only hospitals whose communities depend upon them for emergency and basic inpatient care receive the generous cost-based reimbursement afforded to CAHs. A distance restriction is already in place for most CAHs (which generally must be at least 35 miles from the nearest hospital or 15 miles in the case of mountainous terrain); however, there are some CAHs that

qualified under the “Necessary Provider” rule that, before 2006, allowed States to waive the distance requirement.

In general, if a facility does not meet the minimum distance requirement, it will have the option to meet the conditions of participation and convert into a certified Medicare hospital. The facility would no longer be paid under the cost-based reimbursement structure and would instead be paid under the same system as other Medicare hospitals. Accordingly, there would be program savings as well as beneficiary savings since the outpatient cost-sharing for beneficiaries would no longer be based on the higher CAH payment structure for the CAHs affected by this proposal.

Question. How will the fiscal year 2014 proposal affect a 10-mile area where there are two facilities that are already designated as Critical Access Hospitals?

Answer. As stated in response to the previous question, in general, if a facility does not meet the minimum distance requirement, it will have the option to meet the conditions of participation and convert into a certified Medicare hospital. The facility would not have to close down; however, since the Critical Access Hospital (CAH) was not the sole provider of inpatient care, it would no longer receive the generous cost-based reimbursement as a CAH and would instead be paid as a Medicare hospital the Medicare rate that other hospitals receive. In the case of two CAHs within 10 miles of one another, if both continued to operate as an independent Medicare acute care hospital, then neither could continue to be paid as a CAH.

Question. How will the fiscal year 2014 proposal affect Critical Access Hospitals located across State lines, but within a 10-mile radius of each other?

Answer. The driving distance between a CAH and a certified Medicare-participating hospital is already taken into account under current law, but under current law, the distance requirement is longer than 10 miles. Neither the distance requirement under current law nor under this proposal take the existence of State lines into account since the controlling factor is distance from another CAH or hospital. The purpose of the CAH program is to ensure access in rural communities that depend upon these facilities for emergency and basic inpatient care. The generous cost-based reimbursement system is reserved for those facilities that are the sole provider of inpatient hospital care for the community. In areas where there are two or more hospitals serving the same community, Medicare payment would be made at the same rate that is paid to other hospitals.

Question. How will the fiscal year 2014 proposal affect Critical Access Hospitals when they are located within 10 miles of a Veterans Affairs-run hospital or Indian Health Service operated hospital?

Answer. This requirement for CAH certification pertains to the distance between a given facility and a CAH or Medicare-participating hospital. If the facility does not meet the minimum distance requirement, it would be given the opportunity to meet the conditions of participation and to convert into a certified Medicare hospital.

Question. In addition to the impact that this proposal will have on Critical Access Hospitals, I am concerned with the unintended consequences this proposal will have in the larger rural health delivery system. For example, if a Critical Access Hospital loses this designation and becomes a normal, subsection D hospital, other facilities with alternative Medicare designations, such as Medicare Dependant or Sole Community Hospital status might lose their status and all of the sudden multiple hospitals in one rural area are faced with massive Medicare cuts. Has your office considered these ripple effects?

Answer. CMS has determined that this proposal would not adversely affect the larger rural health delivery system, including Medicare Dependent hospitals and Sole Community hospitals. These hospitals face different certification criteria from Critical Access Hospitals. This proposal was designed with the intent to reserve the cost-based reimbursement system for those CAHs that are truly the sole provider of inpatient hospital care and preserve beneficiary access in rural areas.

Question. Are you concerned about how these proposals regarding Critical Access Hospitals will affect access to healthcare for Americans living in rural communities?

Answer. This proposal preserves beneficiary access while promoting payment efficiency. CMS does not expect any significant adverse impact on rural access to care as a result of these proposals. These proposals represent targeted reductions in cost-based reimbursement only to those CAHs that are not the sole providers in their communities. These proposals were crafted with the needs of rural areas in mind. Specifically, these proposals ensure that the basic cost-based reimbursement structure for CAHs is preserved, and that only hospitals that are the sole source of emergency and basic inpatient care for their communities maintain CAH status. Current CAHs that do not meet the distance criteria could convert to a Medicare-participating

pating hospital and be paid under the same system as other Medicare-participating hospitals.

RURAL HEALTHCARE WORKFORCE

Question. Madam Secretary, approximately 16 percent of Americans live in rural communities, yet only 9 percent of the Nation's physicians practice in rural areas. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress redistributed 3,000 residency slots among the Nation's hospitals in an effort to train more residents to practice in primary care and in rural areas. However, the National Institute on Minority Health and Health Disparities released a report in January that stated this effort did not meet its objective. Out of the 304 hospitals receiving additional positions, only 12 were rural, and they received fewer than 3 percent of all positions redistributed. What is your response to this conclusion of this report and how is the Department working to address the shortfall of physicians serving in our rural communities?

Answer. We recognize the need to invest in the workforce to improve the healthcare system, particularly in rural and underserved communities facing shortages. CMS understands that ensuring an adequate supply of physicians is crucial to the success of the Affordable Care Act. New payment reforms, like Accountable Care Organizations and other models to promote coordination can play a role in addressing a shortage of physicians by encouraging a team approach to medicine. By using the skills of other practitioners, like nurse practitioners and pharmacists, this approach allows physicians to more efficiently use their time. A number of provisions in the Affordable Care Act are designed to strengthen the healthcare workforce, such as Medicare payment bonuses for primary care providers and providers in underserved areas and investments in health professional training programs to increase supply. In addition, the Health Care Innovation Awards are also testing ideas to strengthen the primary care workforce. For example, in Michigan, the Michigan Public Health Institute received an award to integrate community health workers into primary care teams in order to coach patients on self-management and encourage regular primary care visits.

Section 422 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Secretary to develop and implement a process to redistribute resident slots from hospitals that were not fully utilizing those slots to hospitals that needed the resident slots in order to expand or create new programs or pay for the residents already in existence above their historical funding cap. The movement of slots from hospitals where they were not utilized to hospitals that can fill the positions has resulted in Medicare funding additional positions—approximately 2,600 indirect medical education slots and 3,060 direct medical education slots. The redistribution process allowed the creation of 73 new residency programs in rural areas and in areas with fewer than 1 million people.

Section 5503 of the Affordable Care Act also required a redistribution of resident slots from hospitals that were not fully utilizing the slots. This section required that not less than 75 percent of the redistributed slots must be in a primary care or general surgery residency. The Affordable Care Act set priorities for certain areas, including whether the resident-to-population ratio is low, the ratio of the population living in a health professional shortage area to the total population of the State is high, and hospitals located in a rural area. In 2011, CMS redistributed approximately 620 indirect medical education slots and 720 direct medical education slots to 58 hospitals. As per the statutory priorities, a portion of the redistributed slots went to rural hospitals and hospitals in States where there is a high proportion of the population living in a health professional shortage area.

CMS is working closely with its partner agencies across HHS, including the Health Resources and Services Administration (HRSA), to ensure an adequate pipeline of primary care providers is supported. We recognize that a range of responses is needed to address workforce shortages in various geographic areas and among primary care physicians. We will continue to carefully monitor access to ensure our policies continue to lower costs while maintaining access to quality services. I look forward to working with you to address this issue.

FACE-TO-FACE PHYSICIAN ENCOUNTER MEDICARE HOME HEALTH

Question. The Affordable Care Act added a new face-to-face physician encounter requirement for Medicare home health services. As this rule's documentation requirements have evolved, further administrative burdens have been imposed on physicians, increasing operations costs for home health agencies. Has the Department reviewed any of the administrative requirements around this face-to-face requirement to determine efficiencies within this process?

Answer. Yes. The Affordable Care Act did add a requirement that, prior to certifying a patient's eligibility for home health, the certifying physician (or non-physician practitioner) must have a face-to-face visit and must document the encounter. CMS does not require a specific form, or format, for the documentation of this face-to-face encounter. CMS allows the face-to-face encounter to be documented as part of the certification or as a signed addendum to the certification. This approval allows flexibility for the clinical findings from the encounter to be dictated by the physician to one of his or her support personnel, or to allow the documentation to be generated by the physician's electronic medical record software.

Certifying physicians also have the option of using existing documentation, such as a discharge summary or referral or an acute/post-acute physician's documentation of a face-to-face encounter that occurred in the acute/post-acute care facility, as his or her face-to-face encounter documentation. Such documentation is acceptable as long as those documents meet all the requirements for the face-to-face documentation, and the certifying physician signs that documentation provided to him/her. This approval demonstrates that the certifying physician is using that discharge summary, referral, or acute/post-acute care physician's documentation as his or her documentation of the face-to-face encounter.

Question. For example, would having a single form allowing physicians to document the face-to-face encounter on the plan of care documentation be a feasible option?

Answer. Yes. CMS understands that some physicians use a single form for both the certification of eligibility and the plan of care. CMS does not require a specific form, or format, for the documentation of the face-to-face encounter. Documenting the face-to-face encounter can be part of the certifying physician's certification of a patient's eligibility for home health services. Whether the face-to-face encounter documentation is on the certification form itself or is an addendum to it, it must be separate and distinct. So long as the following content requirements are met, such documentation would meet the face-to-face documentation requirements: (1) titled as the face-to-face encounter; (2) the patient's name; (3) date of the encounter; (4) how the patient's clinical condition as seen during the encounter supports homebound status and the need for skilled services; (5) the certifying physician's signature (original signature, a faxed copy, copy of original document with signature or electronic signature—but not stamped signature); and (6) the date of the certifying physician's signature.

PEDIATRIC DENTAL BENEFIT

Question. Madam Secretary, it has been brought to my attention that the Department is treating medical plans and stand-alone dental plans differently inside and outside of the health insurance exchanges. Specifically, it is my understanding that inside the exchange there is no requirement for an individual or small group to purchase pediatric dental coverage and medical carriers have the option of offering medical-only plans. However, outside the exchange, in the private market, all individuals, including adults without dependents, must purchase pediatric dental coverage and it must be provided by their medical carrier unless the medical carrier receives "reasonable assurance" that the individual has purchased coverage from an "exchange-certified stand-alone dental plan." A main principle in the President's remarks during healthcare reform debate was that if an individual liked the coverage he or she had, he or she could keep it. How is that principle being followed when over 45,000 children who have stand-alone dental coverage in Kansas today may not have that option in 2014 when health insurance exchanges are operational?

Answer. Several provisions of the Affordable Care Act affect the coverage of pediatric dental essential benefits. Section 1302 of the Affordable Care Act generally requires issuers in the individual and small group markets inside and outside the marketplaces to offer all essential health benefits. Essential health benefits requirements apply to health insurance issuers, which must offer certain benefits—they are not requirements for individuals or families to obtain coverage for a particular benefit. Section 1302(d)(4)(F) of the Affordable Care Act, however, expressly permits issuers to omit pediatric dental coverage from a plan offered in the marketplace if there is a stand-alone dental plan offering the pediatric dental essential benefit in that marketplace. This authority does not apply outside the marketplace. Thus, the different issuer requirements in the Affordable Care Act lead to different consumer experiences inside and outside of the marketplace.

In the essential health benefits final rule, CMS specified that an issuer outside the marketplace would not be found to be noncompliant with the requirement to offer essential health benefits even if the issuer did not itself offer pediatric dental benefits as long as the issuer is reasonably assured that the applicant has obtained

the pediatric dental essential health benefit through a marketplace-certified stand-alone dental plan.

Question. Furthermore, why are adults without dependents required to purchase pediatric dental in the private market while adults purchasing through the exchanges have no such requirement?

Answer. As discussed in the previous question and explained in further detail the Essential Health Benefits Final Rule at 78 FR 12853, the Affordable Care Act does not require adults purchasing policies subject to the essential health benefit (EHB) requirements outside the marketplace to purchase pediatric dental coverage. Rather, because essential health benefits requirements are requirements on what issuers must offer, the rule provided that issuers offering coverage in the individual and small group markets outside the marketplace must be reasonably assured that an individual has purchased a marketplace-certified pediatric dental plan in order to offer a health plan that does not include the pediatric dental essential health benefits.

The Affordable Care Act does not provide for the exclusion of a pediatric dental EHB outside of the Marketplace as it does in section 1302(b)(4)(F) of the Affordable Care Act for QHPs. Therefore, individuals enrolling in health insurance coverage not offered through the marketplace must be offered the full ten EHB categories, including the pediatric dental benefit. However, in cases in which an individual has purchased stand-alone pediatric dental coverage offered by a marketplace-certified stand-alone dental plan outside the marketplace, that individual would already be covered by the same pediatric dental benefit that is a part of EHB. When an issuer is reasonably assured that an individual has obtained such coverage through a marketplace-certified stand-alone dental plan offered outside the marketplace, the issuer would not be found non-compliant with EHB requirements if the issuer offers that individual a policy that, when combined with the marketplace-certified stand-alone dental plan, ensures full coverage of EHB.

MEDICARE PART D EFFICIENCY

Question. In its final call letter for calendar year 2014, CMS expresses concerns with mail order pharmacy automatic refill programs. This call letter states that Medicare Part D sponsors should require their network pharmacies, retail and mail, to obtain beneficiary consent to deliver a prescription, new or refill, prior to each delivery. Additionally, CMS recommends that plan sponsors require network pharmacies to implement this consent requirement for the remainder of 2013. In particular, CMS acknowledges medication waste in these auto-ship programs: “Shipment of unwanted medications is not only wasteful, but also a source of significant beneficiary aggravation and a financial imposition that can negatively affect enrollee satisfaction with the plan. Supporting this idea, we received a number of comments that indicate beneficiaries return large quantities of unneeded medications to community pharmacies for take-back programs because they were unable to stop auto-ship refill programs.” Additionally, CMS is concerned with Part D plans offering incentives for mail order of 30-day medication supplies. The call letter contains the following sentence: “Finally, we are concerned that the practice of plans offering powerful incentives such as \$0 or other very low cost sharing for 30-day supplies at mail-service, without offering the same cost sharing at their retail network, is driving purchasing behavior for beneficiaries for whom mail-service may not be a good option.” Are HHS and CMS studying the cost impact to the Medicare Part D program related to such mail order pharmacy automatic refill programs?

Answer. Mail order programs are an important and convenient way for Medicare beneficiaries to receive maintenance medications; that being said, CMS has determined the “beneficiary consent” requirement is a simple step to ensure the medication is needed before incurring any expense or waste. As CMS has indicated in 2014 Call Letter, there are concerns with the cost impact of some mail order practices on the Part D program, beneficiaries, and the pharmacy industry. Although CMS is unable to differentiate prescription refills that were generated by a mail order auto-fill program from other mail order refills directly initiated by a beneficiary, CMS will continue to review mail order practices to ensure these practices conform to the requirements to not increase costs to the program.

Question. If so, could you please detail the issues and results of this analysis? Also, could you detail the improvements that CMS recommends to address these issues?

Answer. CMS is continuing to look at available data and work with various stakeholders to ensure mail order is used in both an effective and efficient manner. Reducing both cost and waste continues to be a significant policy goal for CMS and for the Part D program. While mail order can help achieve these goals, CMS wants

to ensure that incentives are aligned to benefit the Part D program and the beneficiaries it serves. As noted in the previous question, the 2014 Call Letter requires that beneficiaries provide consent before prescriptions are delivered to them. CMS believes this significant will help reduce unnecessary cost and waste to beneficiaries and the Part D program.

Question. CMS notes its final call letter for calendar year 2014 that it is scrutinizing costs related to Medicare Part D plans with preferred networks, “comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks.” CMS goes on to state the following: “We are concerned because our initial results suggest that aggregate unit costs weighted by utilization (for the top 25 brand and top 25 generic drugs) may be higher in preferred networks than in non-preferred networks in some plans. Combined with lower cost sharing, we believe these higher unit costs may violate the requirement not to increase payments to such plans.” To address this concern, CMS suggests the following: “We strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor’s preferred network is the best way to encourage price competition and lower costs in the Part D program. Doing so would also likely mitigate some beneficiary disruption and travel costs, especially in rural areas.” Could you please provide an update of CMS’s efforts to address this cost concern?

Answer. CMS is continuing to investigate policy options to both ensure that preferred pharmacy costs do not increase payments to Part D sponsors and to encourage price competition and lower costs by increasing pharmacy participation in preferred pharmacy networks.

MEDICARE BENEFICIARY ACCESS TO MEDICAL SUPPLIES

Question. I understand that certain pharmacies will be prohibited beginning July 1, 2013 from providing home delivery of diabetic testing supplies (DTS) to homebound Medicare beneficiaries as well as beneficiaries in long-term care and assisted living facilities. Is this prohibition a decision that CMS made pursuant to its regulatory authority?

Answer. In the November 2, 2010 final rule, “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011” (CMS–1503–FC), at section 414.402, CMS codified the definitions of mail order item and non-mail order item. Mail order item means any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary’s home, regardless of the method of delivery, and non-mail order item means any item (for example, diabetic testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront. As discussed in the preamble of this rule, CMS concluded it was necessary to revise the definition of mail order to make a clear distinction between mail order and non-mail order. CMS received several comments on the proposed rule advocating that local deliveries be excluded from the definition of mail order item. CMS considered these comments carefully; however, CMS concluded that such an exception is not warranted because contract suppliers will be required to deliver these items to any beneficiary regardless of where they live. In addition, local pharmacies may continue to provide these items to their walk-in customers.

Question. If implemented, I am concerned this policy will cause disruption in the care provided to some of the frailest of Medicare patients. Many Medicare Part B beneficiaries, who are in need of DTS, are homebound and may not have a caregiver available to pick up DTS from the local pharmacy. In addition, many beneficiaries in long-term care and assisted living simply cannot make a trip to the local pharmacy, and many cannot navigate the complexities of ordering supplies via the mail. Community pharmacies in Kansas and across the country play an important role in delivering DTS to patients in their homes. For example, in the community setting, a survey found that 91 percent of all pharmacies make some form of home delivery of DTS in a given month. The survey also found that 45 percent of all small community pharmacies deliver diabetes testing supplies to assisted living facilities. Could you tell me what particular pharmacies are subject to this new prohibition?

Answer. All pharmacies are subject to the new definitions of “mail order” and “non-mail order”.

Question. A recent report conducted by the Office of Inspector General found that certain mail order suppliers were home delivering DTS to a wide geographic area while billing at the higher retail rate. Are you concerned that this new CMS home delivery prohibition will disproportionately impact rural Medicare beneficiaries and the community pharmacies that serve them when it appears CMS intended this policy to address the mail-order suppliers that were home-delivering DTS for higher rates?

Answer. CMS does not have any concerns that this policy will disproportionately impact rural beneficiaries as they will have the same access to mail-order contract suppliers as all other beneficiaries, and may continue to obtain these items at their local pharmacy on a walk-in basis.

QUESTIONS SUBMITTED BY SENATOR RICHARD C. SHELBY

CENTER FOR MEDICARE AND MEDICAID SERVICES HEALTH INSURANCE EXCHANGES

Question. The fiscal year 2013 budget requested approximately \$1 billion to implement health insurance exchanges. However, after transfers from the Prevention and Public Health Fund, the Secretary's transfer authority, the Implementation Fund, and the Non-Recurring Expense Fund combined with \$315 million from the Center for Medicare and Medicaid Services' (CMS) base operations, insurance exchanges will receive approximately \$1.57 billion in fiscal year 2013. Madam Secretary, why did you allocate significantly more funds than requested in the fiscal year 2013 budget for health insurance exchanges?

Answer. The current operating plan level for fiscal year 2013 represents updated estimates and our work to best meet these needs through the resources available to the Department.

Question. The Affordable Care Act authorization provided "such sums as necessary" to implement State-based health insurance exchanges. However, it is my understanding that this unlimited authority cannot be used to fund the 33 States that did not choose to setup a State-based exchange. How much funding is necessary to implement the federally run exchanges in States that did not setup their own exchange?

Answer. The fiscal year 2014 President's budget requests \$1.5 billion for costs related to marketplaces including operations of a federally facilitated marketplace in each State that will not have its own marketplace by January 1, 2014, oversight of State-based and Partnership Marketplaces, and to carry out the Secretary's duties on behalf of all marketplaces, such as operation of a data services hub.

Question. How much of the fiscal year 2014 CMS discretionary request is required for the activities related to implementing the federally run exchange in the States that are not setting up a State-based exchange?

Answer. The fiscal year 2014 request of \$1.5 billion reflects funding needed to operate the federally facilitated marketplace (FFM) for activities such as certification of qualified health plans, consumer outreach and education, eligibility, and the operations of the Small Business Health Option Program. In addition, the budget includes funding for CMS's marketplace responsibilities outside of the FFM, including the data services hub, State Marketplace oversight, and payment management functions.

PREVENTION AND PUBLIC HEALTH FUND

Question. The Prevention and Public Health Fund (Prevention Fund) was authorized under the Affordable Care Act to fund prevention, wellness, and public health activities. Since the Prevention Funds' establishment, I have raised concerns that this has been a \$1 billion slush fund for the Administration to use for any purpose. In fiscal year 2013, the Administration used the Prevention Fund as an offset within its budget request. Last week, the Department announced it would use \$453.8 million from the Prevention Fund to implement health insurance exchanges. Madam Secretary, I have questions about how last week's decision adversely affects public health funding at the Centers for Disease Control and public health workforce development at the Health Resources and Services Administration. Because the Administration has used the Prevention Fund to supplant budget authority throughout the Department, programs that now rely on Prevention Fund dollars to remain level-funded will be reduced. Madam Secretary, the fiscal year 2014 budget again supplants budget authority throughout the Department. As we develop a fiscal year 2014 Labor/HHS Appropriations bill, how can we be sure that you would allocate funding as reflected in the request since your proposal in fiscal year 2013 is so drastically different than how funding was actually distributed?

Answer. The Prevention Fund allocation is developed following the annual Federal budget process. HHS considers comments, stakeholder input, and current priorities in developing a yearly strategy for these resources. This year presented circumstances which resulted in HHS revising the initial allocation developed for fiscal year 2013. The fiscal year 2013 President's budget presented a planned allocation for the resources totaling \$1.25 billion. After the budget was released, the Middle Class Tax Relief and Job Creation Act of 2012 reduced this funding to \$1 billion.

The Prevention Fund was then further reduced by \$51 million in sequestration reductions. As a result of these changes in law and because the fiscal year 2013 appropriation did not provide the resources requested by the Administration for implementation of the health insurance marketplace to fully enable individuals to access affordable healthcare, the Department is leveraging and reallocating existing resources from multiple sources to provide short term and immediate funding for these efforts. In recognition that some key prevention and public health activities should be continued at resource levels higher than can be provided through the Prevention Fund alone in fiscal year 2013, HHS is providing additional base resources for specific programs within CDC and SAMHSA through the use of transfer authority within the Department.

Question. The fiscal year 2014 budget continues to supplant budget authority. For example, a long-standing program at the Health Resources and Services Administration, Poison Control Centers, is proposed to be entirely funded out of the Prevention Fund. Why does the fiscal year 2014 request continue to supplant budget authority?

Answer. The Prevention Fund allocation is determined as part of the annual budget process. In this tight fiscal environment, HHS had to make difficult decisions within the discretionary budget to prioritize funding for programs that are critical to advance the Department's mission while also reducing cost to meet our overall fiscal goals. The budget presents total program levels, including the Prevention Fund, at levels that support the policies presented by the Administration. In order to sustain funding for programs HHS considers key to promoting prevention and improving public health outcomes, Prevention Fund resources were used to support some activities in which funding could not be maintained through base resources alone.

CENTERS FOR DISEASE CONTROL AND PREVENTION PREPAREDNESS

Question. The budget request reduces funding for public health preparedness and response by \$47.5 million. These reductions could impede communities' ability to distribute vaccines, test for biological and chemical agents, and coordinate disaster response. Why is preparedness not a priority for this Administration?

Answer. Preparedness remains a top priority for the Administration, and Centers for Disease Control and Prevention (CDC) seeks to balance public health preparedness and capabilities to address existing health threats. State and local governments have leveraged over a decade of Federal grants to build emergency preparedness capabilities, and the fiscal year 2014 budget builds upon those investments by better targeting ongoing funding and reducing administrative burden to grantees.

For example, CDC supports State and local health departments through the Public Health Emergency Preparedness Cooperative Agreement (PHEP). Massachusetts used PHEP funding to enhance its emergency preparedness and response capabilities, including redundant communication systems and planning initiatives, such as trainings, drills, and exercises. These preparedness and response capabilities were tested during the April 15th Boston Marathon bombing. Within 10 minutes of the explosions and throughout the event, the Health and Homeland Alert Network provided emergent information quickly and consistently to all hospitals in the Commonwealth. Massachusetts activated its Emergency Operations Center, tested fatality and volunteer management procedures, and effectively used WebEOC (crisis information management system) to manage and track the response. This improved health security is a direct result of PHEP investments and capability improvement efforts across the Nation.

The PHEP also supports the laboratory response network, which is an integrated network of State and local public health, Federal, military, and international laboratories that can respond quickly to bioterrorism, chemical terrorism and other public health emergencies.

STRATEGIC NATIONAL STOCKPILE

Question. The Strategic National Stockpile (SNS), a program within the Centers for Disease Control (CDC), is the national repository of life-saving medical countermeasures that will be essential in the event of a large-scale public health emergency. The SNS manages the procurement, storage, and transportation of medical supplies, and monitors the shelf-life of pharmaceuticals to ensure that they are kept within U.S. Food and Drug Administration limits. The SNS is a vital part of the medical countermeasure enterprise along with the Project BioShield's Special Reserve Fund and the Biomedical Advanced Research and Development Authority (BARDA). How does the CDC plan to work with BARDA to maintain the products secured through Project BioShield and the Special Reserve Fund over the last 10

years, including planning for and coordinating budget needs over the next 5 years to replenish expired countermeasures and ensure procurement of new products as they become ready for licensure and the SNS?

Answer. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is responsible for defining and prioritizing requirements for public health emergency Medical Countermeasures (MCMs) and establishing deployment and use strategies for SNS products. Furthermore, the PHEMCE formulates and maintains an intra-agency 5-year budget plan that takes into consideration requirements and lifecycle costs of SNS products throughout HHS. Timely procurement of new and replacement MCMs is necessary to achieve established PHEMCE goals and protect the public from health security threats. CDC coordinates with PHEMCE to prioritize and identify which expiring products need to be replaced to maintain current capabilities with available funding.

CHILDREN'S HOSPITAL GRADUATE MEDICAL EDUCATION

Question. The Children's Hospitals Graduate Medical Education Program supports the training of residents and fellows and increases the supply of primary care and pediatric medical and surgical subspecialties. Nationwide, freestanding children's hospitals have trained 49 percent of all pediatric residents and 51 percent of all pediatric specialists. Research has indicated that there is a significant shortage of pediatric subspecialists, resulting in children with serious illnesses being forced to travel long distances, or experience long wait periods, to see a pediatric specialist. The President's budget proposes to decrease funding for training pediatric residency positions \$177 million below fiscal year 2012. Meanwhile, the budget proposes again to begin a new Pediatric Specialty Loan Repayment program to repay medical school loans. It seems illogical that we would allocate funding to repay loans of physicians but reduce the funding to train physicians. Why is training pediatric physicians not a priority for the Administration when there continues to be work shortages for pediatric physicians?

Answer. HRSA investments in the primary care workforce include general pediatrics through the National Health Service Corps, the Primary Care Residency Expansion initiative, the Primary Care Training and Enhancement Program, and the Teaching Health Center GME Program.

While the CHGME program has supported pediatric training at many facilities across the country, HRSA is working within the context of a budget that requires tough choices. A challenging budget environment required a closer examination of how resources are spent and difficult choices. The fiscal year 2014 President's budget provides \$88 million to fund the direct medical education portion of the CHGME payment. This funding supports expenses that directly support the residents and faculty so that training in pediatric care can continue, but does not provide funding for the indirect graduate medical education costs.

The proposal in the President's budget to reduce Medicare Graduate Medical Education payments is narrowly targeted and unlikely to adversely affect patient access to care. It is important to note that this proposal would not reduce the number of graduate medical education slots supported by Medicare, nor would it reduce the payments CMS makes to support the direct costs of graduate medical education, such as residents' salary and benefits. Rather, the proposal is limited to indirect graduate medical education (IME) payments, which support the higher costs associated with providing patient care in a teaching hospital. Independent analyses by MedPAC have concluded that IME payments are significantly higher than is empirically justified—the proposed 10 percent reduction to IME in the President's budget would only partially correct this discrepancy.

Note that in addition to the reduction to IME, the President's budget proposal would also allow the Secretary to set new standards for teaching hospitals to encourage primary care and high-quality care delivery. These requirements will help ensure that the teaching hospitals train a medical workforce that can fully meet patients' needs in the years and decades to come.

AREA HEALTH EDUCATION CENTERS

Question. The Area Health Education Centers (AHEC) program has a 40-year record of success. Last year, AHECs trained over 476,000 healthcare professionals and 26.4 percent of those were physicians. AHECs work collaboratively with 120 medical schools and 600 nursing/allied health schools to improve the health of rural and underserved communities. Given AHECs critical role in developing and retaining a healthcare workforce to work with rural and underserved individuals and communities throughout the Nation, why is the AHEC program not a higher priority for the Department?

Answer. The fiscal year 2014 President's budget prioritizes allocating Federal resources to training programs that directly increase the number of primary care providers. Given the lean fiscal climate, HRSA had to make difficult choices regarding program funding levels. While HRSA has made longstanding investments in these activities to enhance health professions training since 1972, they do not directly increase the supply of providers. Given that most AHEC programs have been in place for many years and have State and local support, it is anticipated that the AHEC Program grantees will continue much of their efforts relying on these other funding sources.

HEAD START

Question. The budget proposes a \$1.43 billion increase for a new Early Head Start/Child Care Partnership Initiative. According to the budget request, the program's goal is to expand access to 110,000 infants and toddlers nationwide. I believe it is critical that these children not only have access to Federal care programs, but that these programs are high-quality early learning development programs that do not create duplication within early child care programs. How do we ensure that this program does not duplicate current services provided through the Early Head Start program?

Answer. Currently fewer than 5 percent of infants and toddlers living below the poverty line receive Early Head Start services. As part of President Obama's Early Education Plan, we would expand high-quality early learning to over 100,000 infants and toddlers through the Early Head Start/Child Care Partnerships. These partnerships will build on the strengths of Early Head Start and child care. Instead of duplicating efforts, HHS will purposefully use the existing infrastructure of child care centers and homes in partnership with Early Head Start to improve access and quality so that more of our Nation's most vulnerable infants and toddlers will receive the high quality, comprehensive full day full year services they need.

TOLL-FREE DEPARTMENT OF HEALTH AND HUMAN SERVICES HOTLINES

Question. Can you please list, by agency, the hotlines currently funded by the Department of Health and Human Services with the amount funded in fiscal year 2012 and the funding request for fiscal year 2014?

Answer. The Department of Health and Human Services is charged with protecting the health of all Americans and providing essential human services, and a big part of achieving our mission is making sure that information on HHS program services is readily available to the public. One of the most effective ways of making that information available is through the use of hotlines. The HHS Information and Hotline Directory, located at www.hhs.gov/about/referlst.html, lists more than 100 of the Department's hotlines, including the National Suicide Prevention Lifeline (1-800-273-TALK), the Medicare Help Line (1-800-MEDICARE), the Health Care Fraud Hotline (1-800-HHS-TIPS), and the Alzheimer's disease Education and Referral Center (1-800-438-4380). Spending on individual hotlines is embedded in Agency operating budgets, and is not tracked as a separate category.

COMPETITIVE VERSUS FORMULA FUNDING

Question. We need to ensure that our entire Nation, not just population-rich, urban areas, is reaping the benefits of Federal healthcare programs. There are numerous consolidations and reductions in the budget that eliminate formula funded grants which will result in the redirection of critical Federal funds from smaller, rural States to urban areas. In addition, the majority of new programs proposed within the Department would be distributed on a competitive basis. Madam Secretary, how do we make certain that programs that are deemed competitive actually allow all States to compete on a level playing field?

Answer. The Department of Health and Human Services places high premium on the integrity of its grants application and award process. The process is founded on the requirements for grant application and award as reflected in the Federal Grant and Cooperative Agreement Act of 1977, regulations, OMB's Uniform Administrative Requirements for Grants and Cooperative Agreements and HHS's own grants policies. The process is objective, transparent, and designed to foster a fair, "level playing field" for competition.

HHS generally classifies its financial assistance programs in two major categories of grants—competitive and formula. Formula grants are noncompetitive programs stemming from congressional authorizing legislation that directs HHS to make awards to recipients (usually States) who meet specific eligibility criteria based on a predetermined formula. HHS is required to make these awards if the recipient (usually a State) submits an acceptable plan or an application that meets statutory

and regulatory eligibility, and compliance requirements for the program. Competitive grants are awarded on a competitive basis, during which HHS exercises judgment in selecting the recipient and determining the amount of the award. Competitive grants may be further categorized by purpose—such as grants for research, training, services, and construction. Awards are made following a fair and transparent competitive process. While competitive grantees are typically States and tribes, a wide array of applicants are eligible to apply, including: States, local governments, private for profit and nonprofit organizations, universities, and hospitals.

HHS regulations and policies outline the key steps HHS Operating Divisions must take to ensure all eligible applicants have: The ability to find funding opportunities, understand the objective criteria under which their application is judged, and undergo an unbiased objective review based on the technical merits of their proposal. The competitive process for competitive grants begins with a widespread and nationwide funding opportunity announcement or a formal call for applications via the Grants.gov Web site, Catalog of Federal Domestic Assistance Web site, the HHS Forecast Web site, and other sources. The announcement gives ample time for applicants to complete and submit their application, thus, maximizing the number of applicants who will respond. It is a carefully crafted technical document which describes all components of a complete application as well as criteria for reviewing scoring each application. As needed, HHS provides technical assistance to applicants to ensure a full understanding of the application process, as well as the programmatic requirements associated with implementing the grant.

Once the applications are received by HHS, they are screened for completeness before being subjected to an objective review process. The objective review process involves a thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit. The review is performed by experts and is essential to ensuring selection of applications that best meet the needs of the program consistent with the established criteria in funding opportunity announcement. It provides assurance to applicants and the public that the evaluation and selection process was impartial and fair, thus leveling the playing field for all who submitted applications. Scored applications are rank ordered and presented to the approving official, who in turn will select the award-winning applications. HHS's describes its grant application, review and award process in its Grants Policy Statement and in its NIH Grants Policy Statement, both of which are available to the public via the Internet.

NATIONAL INSTITUTES OF HEALTH—BRAIN INITIATIVE

Question. The National Institutes of Health (NIH) is collaborating with both Federal partners and private institutions on a new initiative to map the human brain. This is a very exciting proposal that could revolutionize the field of neuroscience and advance therapies for numerous diseases, including Alzheimer's and Parkinson's. While I understand that the specifics of this proposal are still being developed, there was very limited information provided in the budget justification outlining future costs for this proposal. In fiscal year 2014, the NIH proposes \$40 million for the initiative, but there was no information on potential future costs or timeframe. Can you provide details on what the 10-year budget picture may entail, both for the initiative overall, and NIH's share?

Answer. It will be imperative that cost estimates be strongly informed by a rigorous scientific planning process. To achieve these aims, NIH has charged a high level advisory group with developing such a plan, which is to include timetables, milestones, and cost estimates. As part of this process, members will consult the scientific community, patient advocates, and the general public to ensure that this plan is informed by stakeholder input. Final recommendations are anticipated in the summer of 2014. This plan will be publicly available and widely shared with the both the public and with BRAIN Initiative partners.

Question. As the lead institution, do you foresee NIH's funding role being increased in future years?

Answer. Yes. It is anticipated that as the BRAIN Initiative gains momentum, additional funds will be needed to support promising areas of research. The pace at which NIH's role might grow in future years will depend on the relative competing priorities and the overall availability of funds at that time.

SUPPORT CLINICAL TRIAL

Question. The University of Alabama at Birmingham (UAB) recently received a letter from the Office for Human Research Protections (OHRP) about the SUPPORT clinical trial, a research study of premature infants and supplemental oxygen. In the

letter, OHRP determined that UAB should have informed parents of an increased risk of death of their infant by participating in the study.

Could you please provide the specific scientific data that existed at the start of the study that shows this increased risk?

Answer. At the time the SUPPORT study began, substantial information was available on possible risks of increased mortality at lower oxygen levels. In 2003, an international group of over 30 experts began a collaboration around improving the understanding of neonatal oxygenation through well-designed clinical trials. One output of this nascent collaboration was a 2003 commentary in *Pediatrics* (Cole et al., Resolving Our Uncertainty About Oxygen Therapy, *Pediatrics* 2003;112:1415), which discussed many aspects of what such studies should involve. They noted, for example, that a large sample would be needed to “exclude smaller, important differences in outcomes such as mortality and disability to address real concerns about the safety of lower oxygen tensions.” This information, and other similar concerns, is more fully described in the letter dated June 4, 2013, from OHRP to the University of Alabama, which can be found on OHRP’s web site at http://www.hhs.gov/ohrp/detrm_lettrs/YR13/jun13a.pdf.

Question. If no such data existed, could you please explain why it would be scientifically credible or ethical to explain unknown risks of a study?

Answer. At the time the SUPPORT study began, substantial information was available on possible risks of increased mortality at lower oxygen levels.

Question. What is the process for appealing the findings of OHRP? Is there a mechanism for having an independent review of OHRP actions especially when they are so universally called into question as in this case? (Please see, for example, editorials and correspondence in the *New England Journal of Medicine* and *The Hastings Center Bioethics Forum*.)

Answer. OHRP’s compliance oversight procedures state that an institution or complainant may request that the Director of OHRP reconsider any determinations resulting from a for-cause compliance oversight evaluation, <http://www.hhs.gov/ohrp/compliance/evaluation/index.html>. OHRP has no recollection of any such requests for reconsideration from an institution against which OHRP made a determination of noncompliance. Historically, OHRP has received such requests only from complainants concerned that OHRP did not agree with their allegations of noncompliance. If such complainants are unsatisfied with the response of the OHRP Director, OHRP informs them that they may communicate with the Principal Deputy Assistant Secretary for Health and the Assistant Secretary for Health and ask them to review the matter.

MEDICAL COUNTERMEASURES

Question. Madam Secretary, given that there is little to no commercial market for lifesaving medical countermeasures, it is imperative that the government invest in the research, development, and procurement of these lifesaving products. What progress has the Department made over the past decade in terms of medical countermeasure procurement?

Answer. Originally, Project BioShield’s funding of \$5.6 billion was expected to be a sufficient incentive to bring large, fully integrated pharmaceutical companies into the biodefense market space. Unfortunately, a limitation on these funds was that, with minor exceptions, they could not be used to pay MCM vendors until a product was delivered to the SNS, thereby placing the majority of risk on the private sector. Over the past 9 years, HHS has developed additional tools to foster its relationship with these partners to address this concern. This development has included the establishment of BARDA, the provision of ARD funding, and the expansion of authorities under Project BioShield—most notably the introduction of milestone payments in contracts.

Due to the work of the past nine plus years, the Special Reserve Fund has resulted in HHS’s creation of a robust development pipeline containing more than 80 medical countermeasure candidates for chemical, biological, radiological, and nuclear threats. This development has resulted in the delivery of 11 new medical countermeasures (MCMs) to the Strategic National Stockpile (accessible by Emergency Usage Authorization) and the FDA licensure of two of these MCMs.

More recently, per recommendations from the Secretary’s Review of the Public Health Emergency Medical Counter Measure Enterprise (PHEMCE) following the 2009 H1N1 pandemic, came the establishment of Centers of Innovation for the Advanced Development and Manufacturing (CIADM). These public-private partnerships allow BARDA to pair large established pharmaceutical companies with smaller firms. These pairings mitigate the scientific and manufacturing risks associated with MCM development by providing the necessary expertise to bring promising

technologies to the marketplace. Additionally, the PHEMCE Review recommended the establishment of a MCM Strategic Investor, an independent nonprofit entity, which uses HHS funding to support capital investments in private companies with promising technologies. By providing critical capital in exchange for a strategic role in the management of these small firms, HHS is able to mitigate the financial and management risk that some small firms face, thereby increasing the probability of successful technologies and products.

Since the development and procurement of MCMs is an inherently risky endeavor, BARDA remains focused on keeping sufficient incentives in place for its industry partners. This effort includes an HHS intra-agency multiyear budgeting practice driven by the long-lead time necessary for MCM development and acquisition. Large pharmaceutical companies are now joining the biodefense MCM sector, using long-range budget planning routinely as a good business management practice. Venture capital investors, which fund many small biotech companies in the biodefense sector, may choose to support biotech companies in a different sector that has a better benefit-to-risk profile than biodefense. These circumstances support the critical need to ensure a long-term funding commitment is maintained with annual appropriations in the future. Maintaining the progress that has been achieved in the recent years requires Congress's continued support for these future activities.

Question. How will this progress be affected by proposed funding cuts in fiscal year 2014?

Answer. The fiscal year 2014 President's budget requests funding for BARDA across three categories: Advanced Research and Development (ARD), Pandemic Influenza and Project BioShield. Based on MCM development and procurement across multiple years and relevant PHEMCE priorities, BARDA determined that \$250 million was needed for procurements in fiscal year 2014. This funding request will support the replenishment of modified vaccinia Ankara (MVA) vaccine (smallpox), vendor-managed inventory (VMI) costs for an antineutropenia cytokine acquisition to treat acute radiation syndrome, and a new BioShield award for artificial skin to treat thermal burn patients. The fiscal year 2014 President's budget also explicitly commits to a renewed multiyear funding commitment supporting the procurement of MCMs via Project BioShield for the Strategic National Stockpile (SNS). BARDA expects that at least 12 new MCMs in the present advanced development pipeline will mature sufficiently from fiscal year 2014–2018 for consideration of procurement under Project BioShield. Moving forward, BARDA will continue to support the development and procurement of new MCMs, substantially improving the Nation's preparedness.

For future funding of BioShield, the fiscal year 2014 President's budget requests \$250 million available until expended. HHS requests no-year funding to maximize the flexibility and provide stability to align with the original BioShield appropriation.

Question. How will the proposed reduction in funding to Project BioShield Special Reserve Fund and the Biomedical Advanced Research and Development Authority (BARDA) affect the Nation's preparedness?

Answer. The fiscal year 2014 President's budget requests funding for BARDA across three categories: Advanced Research and Development (ARD), Pandemic Influenza and Project BioShield. Based on MCM development and procurement across multiple years and relevant PHEMCE priorities, BARDA determined that \$250 million was needed for procurements in fiscal year 2014. This funding request will support the replenishment of modified vaccinia Ankara (MVA) vaccine (smallpox), vendor-managed inventory (VMI) costs for an anti-neutropenia cytokine acquisition to treat acute radiation syndrome, and a new BioShield award for artificial skin to treat thermal burn patients. The fiscal year 2014 President's budget also explicitly commits to a renewed multiyear funding commitment supporting the procurement of MCMs via Project BioShield for the Strategic National Stockpile (SNS). BARDA expects that at least 12 new MCMs in the present advanced development pipeline will mature sufficiently from fiscal year 2014–2018 for consideration of procurement under Project BioShield. Moving forward, BARDA will continue to support the development and procurement of new MCMs, substantially improving the Nation's preparedness.

For future funding of BioShield, the fiscal year 2014 President's budget requests \$250 million available until expended. HHS requests no-year funding to maximize the flexibility and provide stability to align with the original BioShield appropriation.

Question. It is my understanding that the \$250 million request for the BioShield Special Reserve Fund was based on BARDA's assessment of which products will be ready for procurement in 2014. To better understand this, please provide details on the Department's 5-year biodefense spend plan—including the National Institute of

Allergy and Infectious Diseases, BARDA's advanced development program, Special Reserve Fund procurements and the Strategic National Stockpile's maintenance.

Answer. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) requires HHS to produce a multiyear budget for medical countermeasure programs across the Department. Agencies within HHS are currently collaborating to compile and submit budget data for investments for fiscal years 2013–2018 consistent with this requirement.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES—WORKFORCE INVESTMENT ACT
COLLABORATION

Question. In 2012, the Government Accountability Office released a report that stated, “HHS is collaborating with Labor to conduct an evaluation to better understand policies, practices, and service delivery strategies that lead to better alignment of the Workforce Investment Act (WIA) and Temporary Assistance for Needy Families (TANF).” Can you update the Subcommittee on the findings so far and when you expect the report to be released? In particular, please cite examples of State and local practices that may be models for other areas to follow and how WIA–TANF duplication can be reduced?

Answer. The ACF project underway to analyze coordination between Temporary Assistance to Needy Families (TANF) programs and services funded by the Workforce Investment Act (WIA) is a descriptive, qualitative study of the practices in place in 11 sites in 8 States that were identified as having a moderate to high degree of coordination between TANF and WIA programs. Based on a preliminary analysis, the study has begun to identify practices that are in use to varying degrees across the sites. The practices are suggestive of strategies that may increase coordination and reduce the duplication of services between the TANF and WIA programs. However, given the scope of the study the findings cannot be conclusive about which practices lead to the best results. Data from field observations are still being analyzed. ACF expects to release a report in early 2014.

The following are practices that appear to promote coordination of common services across the two programs:

- Possible benefits of co-location of TANF and WIA services: Shared physical space with a common entry may support communication and shared knowledge across staff as well as integration of job search, job readiness, and job development services.
- Possible benefits when the same entity is both the one-stop operator and the TANF employment services provider: Coordination between the TANF and WIA programs was supported in existing environments of service coordination, specifically where WIA and Wagner-Peyser employment services are already integrated within a one-stop.
- Administrative and staffing practices: Integrating management structures over both programs within the one-stop and aligning job classifications and pay scales across the two programs may improve coordination. In addition, a couple of sites use specialized positions—such as a TANF mentor—at the local level to support knowledge across programs.
- Many of the sites either conducted a systematic series of trainings during the transition to integrate services or conduct ongoing cross-training of all staff to build rapport across staff and lessen anxiety of the organizational changes. Embedded within this training is a shared focus on employment across the two programs.
- Sites have also adopted shared procedures and tools. For example, some sites used prerequisites for training and the selection of training and education programs from eligible provider lists created in the WIA program to guide training for TANF recipients. Sites also link and use common data across the programs.
- Specific to the delivery of services common to customers across both programs, sites have created shared responsibility for core services in one-stops. In a few sites, both WIA and TANF staff help with entry processes, staffing resource rooms, and facilitating job readiness workshops. Some sites have gone farther to integrate staff functions such as career counseling and job development and placement to serve customers across the two programs.

QUESTIONS SUBMITTED BY SENATOR LAMAR ALEXANDER

PATIENT PROTECTION AND AFFORDABLE CARE ACT

Question. Have you done any analysis to determine the cumulative impact upon premiums of all the new mandates, taxes, and fees being imposed upon health plans

operating in the new health insurance exchanges? If so, please provide the total cost. If not, please explain why.

Answer. We do not have an aggregate estimate of the impact on premiums at this time. It will be up to issuers to determine how to set their premiums. We expect that the marketplace will be competitive, and we will evaluate premium information once we receive the qualified health plan certification packages from issuers.

Question. Please detail your legal authority to use Prevention and Public Health funds to pay for implementation of the new health law, including the new navigator grant program and implementation of the health insurance exchanges.

Answer. The purpose of the Prevention and Public Health Fund is to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector healthcare costs. In fiscal year 2013 CMS will invest resources from the Prevention Fund to assist Americans in gaining affordable healthcare coverage which aligns with the purpose of the Prevention Fund which may be used for prevention, wellness, and public health activities. Specific activities will include consumer engagement and education, eligibility support including support for appeals, assistance with enrollment, and the Navigator program to help individuals understand options available and enroll in health insurance. Implementing the health insurance marketplace is the Administration's top public health activity which has a large potential to improve prevention in the next year by enabling individuals to enroll in coverage through private health insurance and have greater access to primary and preventive care. Increasing access to care and in particular preventive services is a component of our national efforts to restrain the cost of healthcare and ensure more Americans can lead healthy lives, which is a key intent of the Prevention Fund.

Question. In your agency's recent budget, the outlays for the Federal Pre-existing Condition Insurance Program are projected to be greater than the amount of money left in the fund. Please detail how your agency will fill this shortfall so that those enrolled do not lose access to insurance before 2014.

Answer. CMS has been monitoring PCIP enrollment and spending closely and has made necessary adjustments to the program to ensure responsible management of the one-time appropriation of \$5 billion. To date, CMS has made program modifications to control spending, including a change in provider networks used by the federally-operated PCIP, reducing both its negotiated and out-of-network payment rate for providers; negotiation of additional discounts on reimbursement rates with targeted hospitals that were treating a disproportionate number of PCIP enrollees; a change in coverage of specialty drugs to require dispensing by only those pharmacies and providers that were most cost effective; and a consolidation of three benefit plan options into one, increasing the maximum out-of-pocket limit from \$4,000 to \$6,250 for in-network services.

CMS published an interim final rule that sets the facility and provider payments rates in the federally operated PCIP for most claims at 100 percent of Medicare rates and prohibits balance billing from facilities and providers who accept claims payments from the federally operated PCIP to protect PCIP enrollees from high out-of-pocket costs, effective June 15, 2013. CMS also finalized a revised contract terms with the State-operated PCIP to work within a fixed contract amount for the remaining months of the program. CMS is making these changes to maintain coverage for the over 100,000 members with pre-existing conditions through December 31, 2013 when people enrolled in PCIP can obtain coverage from a qualified health plan offered through the health insurance marketplaces beginning on January 1, 2014.

Question. When are insurance plans due to the Health Insurance Oversight System (HIOS)? And when are rate increases made public?

Answer. HIOS began accepting submissions on April 1, 2013 and plans to continue accepting submissions until April 30, 2013. On October 1, 2013, individuals and families will be able to log on to Healthcare.gov to request an eligibility determination and view a variety of plans available to them and see premium quotes for their unique situation based on their preferences. Premiums charged to consumers will vary for a variety of reasons including the type of plan chosen (individual or family), the level of coverage chosen (i.e. silver, gold), any premium tax credits that the consumer may be eligible for and any other allowable rating factor such as age, geography, and smoking status.

Question. For States in which the Federal Government is responsible for plan management, when will the rates submitted be made public? And what will the health insurance plans in those States look like?

Answer. On October 1, 2013, individuals and families in federally facilitated Marketplace States will be able to log on to Healthcare.gov to request an eligibility determination and view a variety of plans available to them and see premium quotes for their unique situation based on their preferences. Premiums charged to con-

sumers will vary for a variety of reasons including the type of plan chosen (individual or family), the level of coverage chosen (i.e. silver, gold), any premium tax credits that the consumer may be eligible for and any other allowable rating factor such as age, geography and smoking status. Plans offered through the federally facilitated marketplaces will provide essential health benefits, will meet specified levels of coverage (e.g. bronze, silver, gold, platinum and catastrophic), and provide protection from high out of pocket costs through the limitations on out of pocket expenses. While all plans will provide these basic benefits and protections, issuers were given flexibility to design quality plans and we will know more about the exact plan offerings once the federally facilitated marketplace completes certification of plans later this year.

Question. Will you accept public comments on qualified health plans? If so, how long will the comment period be open? If not, please explain why.

Answer. While the certification of QHPs is not open to public comment due to proprietary and market constraints, the regulations that defined the criteria for QHPs were open to public comment for 108 days and received over 2,000 comments. All certified QHPs will provide essential health benefits, follow established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts), and meet other requirements as detailed in the marketplace establishment regulation.

MEDICARE DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING

Question. In the fiscal year 2014 budget request, you estimate that the Medicare Durable Medical Equipment (DME) Competitive Bidding program is expected to save the government \$25.8 billion over 10 years and to save beneficiaries \$17.2 billion over 10 years. This savings may not be realized if there are problems with implementing the program, as appears to be the case with the State of Tennessee. Medicare awarded contracts to DME suppliers not licensed in Tennessee to serve Medicare beneficiaries in Tennessee, despite a clear requirement in the CMS "Request for Bids" that, "every supplier location is responsible for having all applicable license(s) for each state in which it provides services."

When preparing for the Medicare Durable Medical Equipment Competitive Bidding Program Round 2 bidding, did the National Supplier Clearinghouse provide incorrect information to CMS regarding the Tennessee license requirements for durable medical equipment suppliers when CMS?

Answer. In preparing for Round 2 and the national mail-order competition, the National Supplier Clearinghouse (NSC) conducted an intensive and exhaustive process to verify licensure requirements nationwide and works regularly with the States to maintain the latest requirements and interpretations. State requirements can be complex and subject to change or re-interpretation, so this task can be challenging. The NSC also provided an upgraded licensure guide on its Web site to assist suppliers in determining applicable State licensure requirements. The NSC's licensure database reflected accurate but incomplete information for Tennessee during the time of bidding.

Question. What procedures did CMS, or the National Supplier Clearinghouse, use to verify that suppliers bidding for contracts to supply Medicare beneficiaries in the State of Tennessee were licensed by the State to do business in Tennessee?

Answer. Each supplier is responsible for obtaining the correct licensure and providing licensure documentation to the NSC. CMS conducts an in-depth review of each bidder to determine its licensure status. This process involves checking bidder enrollment records and, if necessary, seeking additional information from bidders and verifying information directly with the State.

Question. If the National Supplier Clearinghouse provided incorrect information regarding Tennessee requirements, are there any penalties CMS can impose? If so, will CMS enforce those penalties?

Answer. As stated earlier, State licensure can be complex and subject to change or re-interpretation. The NSC works diligently to maintain a guide of the most complete and current State licensure requirements through activities such as quarterly outreach to State licensing agencies. CMS will remain mindful of the importance of accuracy and completeness as well as the challenging nature of this work in evaluating the NSC's performance.

Question. To submit a Round 2 bid, was it a requirement to have a State license in the State in which the company submitted a bid to supply products?

Answer. The request for bids requires bidders to meet all State licensure requirements for the applicable product categories and for every State in a competitive bidding area. However, each supplier location is not required to have licenses for every State in the competitive bidding area as long as each State has a bidding location

licensed for the product category. Suppliers are evaluated based on State licensure requirements in place at the time of bidding.

Question. How many Medicare competitive bid contract winners for the State of Tennessee are actually not licensed by the State? Please itemize by company and which contracts they won by CBA and product category.

Answer. CMS is in the process of evaluating the situation and does not have a final count of suppliers at this time. Once CMS completes the investigation, CMS will take corrective action as appropriate, including potentially voiding the contracts.

Question. Will there be enough licensed companies able to serve Medicare beneficiaries when Medicare switches to competitive bid winners on July 1 if the unlicensed companies decline to get a license?

Answer. Yes. Even assuming corrective action is taken on all the suppliers CMS is currently investigating, given the large number of remaining suppliers, plus grandfathered suppliers, CMS is confident that beneficiaries will continue to have access to a wide variety of quality items and services in the State. In addition, CMS may consider making new awards to qualified and licensed suppliers in the future. CMS will continue to examine this issue and closely monitor the situation in the State.

Question. What is your plan of action to address this State license issue and ensure Medicare beneficiaries in Tennessee are able to get durable medical supplies when the competitive bidding program is enforced starting July 1?

Answer. Even assuming corrective action is taken on all the suppliers CMS is currently investigating, given the large number of remaining suppliers, plus grandfathered suppliers, CMS is confident that beneficiaries will continue to have access to a wide variety of quality items and services in the State on July 1. In addition, CMS may consider making new awards to qualified and licensed suppliers in the future. CMS will continue to examine this issue and closely monitor the situation in the State.

Question. If there are not enough companies licensed by July 1 to fulfill demand, how long will it take to assign new companies contracts to fulfill need? How will you determine who wins that business?

Answer. CMS will award additional contracts if necessary using the process established through regulations. This process requires offering contracts to qualified suppliers with bids above the winning range starting with the supplier that had the lowest composite bid above the pivotal bid for the applicable product category.

Question. What burden are you placing on the State of Tennessee to rely on them to go through the licensing process for multiple suppliers on a rushed timeframe to make the July 1 deadline?

Answer. CMS has been in communication with the State of Tennessee regarding this issue to ensure that CMS and the contract suppliers are responsive to Tennessee's licensure requirements. Suppliers are responsible for obtaining the appropriate State licenses and CMS is investigating suppliers that may not have had the correct State license in Tennessee to determine if corrective action is necessary.

Question. Are companies that bid without a license subject to penalties or other consequences?

Answer. If a contract supplier does not have all applicable State licenses, CMS may take one of many corrective actions, including voiding their contract. Each supplier is responsible for obtaining the appropriate State license.

Question. Are there any other States with contract winners that do not have a State license? Please list out the States and the number of winners not licensed by the State. Please itemize by company and which contracts they won by CBA and product category.

Answer. State licensure requirements change periodically and can sometimes be re-interpreted by the State. CMS will investigate any issues raised regarding contract suppliers that may not have the correct licensure.

Question. Suppliers properly licensed by the State of Tennessee may have faced unfair competition from unlicensed businesses that were awarded contracts. Please explain why you think the competition for Tennessee was fair and reasonable in light of this mistake.

Answer. All bidders were required to meet supplier standards, financial standards, quality standards, accreditation requirements, bona fide bid requirements, and other rules. CMS is investigating suppliers in Tennessee that may not have the appropriate license and, if needed, may consider offering additional contracts to suppliers who hold the appropriate State licenses.

SUBCOMMITTEE RECESS

Senator MORAN. And at this time, we will conclude the hearing of this Labor-HHS Subcommittee of the Senate Appropriations Committee.

The record will stay open for 7 days for other statements or questions for the record.

Thank you very much. Thank you, Senator Merkley.

[Whereupon, at 12:05 p.m., Wednesday, April 24, the subcommittee was recessed, to reconvene subject to the call of the Chair.]