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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

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MEMORANDUM

February 22, 2016

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Hearing on "The Fiscal Year 2017 HHS Budget"

On **Wednesday, February 24th, at 10:00 a.m., in Room 2123 of the Rayburn House Office Building**, the subcommittee will hold a hearing examining "The Fiscal Year 2017 HHS Budget." The sole witness will be the Honorable Sylvia Mathews Burwell, Secretary of the Department of Health and Human Services. Background information on a number of, but not all, proposals included in the budget appears below. For more specifics, please see the Fiscal Year 2017 Budget in Brief.

I. THE PRESIDENT'S BUDGET REQUEST FOR FISCAL YEAR 2017

The President's Fiscal Year (FY) 2017 Budget proposal is estimated to save $242 billion over ten years and provides $82.8 billion in discretionary funding for the Department of Health and Human Services. The budget makes robust investments in mental and behavioral health programs, scientific research, food safety, and emergency preparedness. It strengthens our health care system by promoting quality care and information sharing and providing additional incentives for states to expand Medicaid.

II. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

A. Medicare

The President's budget proposals would save the Medicare program $419.4 billion over ten years and extend the solvency of the Medicare Hospital Insurance Trust Fund by more than 15 years.

The budget builds on work done by Congress and the Administration on delivery system reform. It broadens the scope of Accountable Care Organizations (ACOs) to include beneficiary assignment by non-physician providers, Federally Qualified Health Centers, and Rural Health Clinics, all of which play a role in providing primary care for the Medicare population. The budget would also allow ACOs to incentivize beneficiaries for primary care visits. Together these policies would save $300 million over 10 years.

The President's FY 2017 Budget includes a number of proposals to better target payments to post-acute care providers, including moving post-acute provider payments to a bundled system and reducing certain market basket updates. In 2014, Congress passed the Improving Medicare Post-Acute Care Transformation Act of 2014 or IMPACT Act of 2014, which is intended to improve how post-acute care services are reported. The data gathered as a result of the IMPACT Act will help in these efforts. These proposals for bundled post-acute care would save $9.9 billion over ten years.

The budget would reinstate the 10 percent Medicare primary care bonus payment program beginning in 2017. The temporary program was included in the Affordable Care Act (ACA) to increase access to primary care for seniors. The budget proposes including the program in the physician fee schedule in a budget neutral manner.

Teaching hospitals receive Indirect Medical Education (IME) payments to help offset the costs of training residents that are not accounted for in traditional graduate medical education payments. The budget proposes reducing IME payments by 10 percent beginning in 2017 and giving the Secretary authority to use graduate medical education payments to encourage training of primary care doctors and promote high-quality, high-value health care. This proposal saves $17.8 billion over 10 years.

The budget eliminates Medicare beneficiary coinsurance for polyp removal performed during a colonoscopy. Screening colonoscopies are not subject to deductibles or coinsurance but may result in polyp removal, which can present a financial challenge to receiving this preventive service. This proposal would cost $2.4 billion over 10 years.

The budget includes $142 million to improve the processing of provider and beneficiary claim appeals, including $44 million in new initiatives to improve the efficiency of the Medicare appeals process.

B. Medicare Advantage

The President’s budget includes a new proposal for Medicare Advantage to establish a “competitively bid” Medicare Advantage benchmark, against which plans are paid. Under traditional Medicare, providers are paid for each item or service provided to a beneficiary. However, in Medicare Advantage, a capitated monthly payment is made to an MA plan regardless of how many or few services a beneficiary actually uses. Capitated payments to plans are determined, in part, on a benchmark, or maximum payment. Separate benchmarks are calculated for each county. Currently, the county benchmarks are set at a percentage of fee for service spending in each county. This policy would establish a competitively bid benchmark,

whereby an adjusted benchmark would be calculated based on the lesser of either the current law fee-for-service benchmark or the average Medicare Advantage plan bid. This proposal would save $77.2 billion over ten years. This is a new proposal and has not yet been examined for its program impact.

The budget also includes a proposal to expand telehealth in Medicare Advantage by eliminating otherwise applicable Part B face-to-face requirements. This proposal would save $160 million over ten years.

C. Medicare Part D

In Medicare Part D, the budget proposes to expand quality bonus payments for high-performing plans (no budget impact), close the prescription drug doughnut hole three years earlier for brand-name drugs ($10.2 billion in savings), and require mandatory reporting of other prescription drug coverage ($480 million in savings).

Additionally, a proposal is included to establish a so-called "Part D Lock-In Program" to prevent prescription drug abuse in Medicare Part D by targeting and tracking high-risk beneficiaries. This proposal was passed by the House as part of the 21st Century Cures legislation.

D. Affordable Care Act and Private Insurance

The President's Budget fully funds the ACA. It includes $659 million in funding for Marketplace operations, $744 million for consumer information and outreach, and $657 million for Information Technology costs.

The budget would also build on the ACA by developing uniform and transparent health care billing documents and eliminating surprise out-of-network charges at an in-network hospital. It also proposes clarifying the definition of "Indian" in the ACA, which will ensure that all American Indians and Alaska Natives will be treated equally with respect to the ACA's coverage provisions.

E. CMS Program Integrity

The President's Budget includes an additional $199 million in funding to enhance current program integrity measures and give HHS new tools to fight waste, fraud, and abuse in Medicare and Medicaid. These investments will yield $23.8 billion in savings over 10 years.

F. Dual-Eligible Enrollees

The budget includes four proposals that aim to improve care for dual-eligible enrollees. These proposals include streamlining and integrating the appeals process between Medicare and Medicaid for these enrollees, and improving alignment of the "asset" definitions for the Medicare savings program and Part D subsidy determinations so that beneficiaries are not subjected to two different, yet duplicative reviews. In addition, the budget also includes a

proposal that would allow for a coordinated state and federal review of marketing materials used by Special Needs Plans with this population, and would permanently authorize a current demonstration that ensures our lowest income beneficiaries have access to Part D drug coverage while their eligibility is being determined.

G. Medicaid

The budget includes a number of proposals to improve care for beneficiaries and strengthen the Medicaid program, many that build on or extend key provisions passed by the ACA.

The budget would extend the Children's Health Insurance Program (CHIP) for two years, and permanently extend the express lane eligibility program. It would also reinstate the "primary care bump," increasing federal financial support for primary care services up to Medicare levels for certain providers in Medicaid, and this year, it would add additional types of providers in Medicaid for which there is a shortage.

Additionally, the budget includes a Medicaid Expansion proposal to provide states that have not yet expanded their Medicaid programs with additional incentive to do so, providing three years of the full 100 percent federal match (authorized in the ACA for only expansion years 2014-2016).

The President's budget also includes a proposal to extend full tobacco cessation assistance (using both prescription drugs and counseling services) to all Medicaid beneficiaries, a high proportion of whom use tobacco.

The budget further includes proposals to equalize care for pregnant women in Medicaid, ensure continuous eligibility for Medicaid enrollees, and prioritize home and community based care. The President's budget also includes a proposal to extend the 100 percent federal match to all Indian health programs; currently, urban Indian health programs are excluded.

There is also a budget proposal for a comprehensive long term care pilot state plan option. The pilot program's focus would be on equalizing delivery of home and community based services with an institutional level of care. This program would continue for eight years, with Secretarial authority to expand it following its conclusion in year eight.

III. FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) is charged with ensuring the safety and effectiveness of medical products, the security of our nation's food supply, the safe use of cosmetics, and reductions in harm from the use of tobacco. The President has proposed $5.1 billion in funding for the FDA to fulfill these responsibilities, which is an increase of $358 million from the previous fiscal year.

A. Medical Products

The agency currently leads the world in approving novel new drugs. In 2015, FDA approved 56 novel drugs and biological products. Aimed at building upon this success, the President proposes $2.8 billion in resources for FDA, an increase of $116 million, in funding for FY 2017. This funding would ensure the safety of a global drug and device market, including foreign and domestic inspections, product surveillance, and reviewing product applications. This funding will also be critical in the fight against opioid abuse, enabling FDA to address opioid safety through post-market surveillance and providing guidance to industry on the development of abuse-deterrent properties. The budget includes $18 million to continue oversight of compounding pharmacies. Oversight of compounding pharmacies is critical to protecting against outbreaks resulting from contaminated products. It will also help to boost FDA's ability to inspect compounding pharmacies and outsourcing facilities to ensure the facilities are equipped to compound safely.

B. Next Generation Treatments

The President has also proposed additional funding for FDA to help encourage the development of the next generation of treatments and support the race to cure cancer. FDA would receive $4 million to help support precision FDA, a platform for public-private collaborations related to precision medicine, and $75 million to work with the NIH to improve access to clinical trials and data related to the development of cancer treatments.

C. Food Safety

FDA oversees about 80 percent of our food supply and has been empowered with additional authority to transition our food safety system to one that works to prevent outbreaks before they occur. Since passage of the Food Safety Modernization Act (FSMA), FDA has conducted over 7,000 inspections of high-risk food establishments and issued five final rules building the food safety framework. The President is proposing $1.5 billion in his FY2017 budget to support the implementation of FSMA, including implementation of the Foreign Supplier Verification Program and expanding foreign inspections. This is an important proposal because it includes user fees that will help provide FDA with a stable funding stream to support a robust food safety system. The President's budget also proposes to update the Nutrition Facts Label to better reflect new science and to help consumers make informed choices about the food they purchase.

D. Tobacco

Tobacco continues to be the leading cause of preventable death in the United States, resulting in more than 480,000 deaths each year. One key step in reversing this trend is to ensure that FDA is able to regulate the manufacturing, distribution, and marketing of all tobacco products, including e-cigarettes. Enforcement will also be critical towards preventing tobacco use amongst young adults, including initiating No-Tobacco Sale Orders against retailers who sell to minors as FDA did this past fall. The President's budget includes $596 million in user fees to

be dedicated towards product standards, nicotine regulatory policy, product reviews and safety controls, compliance and enforcement, and public education targeted to our youth.

E. Cosmetics

Once again the President's budget proposes a user fee program to support oversight of cosmetic products. Recent outbreaks related to women's hair and beauty products have resulted in an interest by some to give FDA more authorities to ensure the agency can guarantee the cosmetics Americans use every day are safe from harm. As a result, $20 million in user fees has been included to help meet this goal.

IV. SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

The President's budget proposes funding SAMHSA at $4.3 billion, an increase of $590 million over FY 2016-enacted levels. Mental health programs were increased by a total of $115 million and substance abuse treatment programs by a total of $469 million compared to FY2016-enacted levels. SAMHSA leads our public health efforts in mental health and substance abuse.

V. HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

The President's budget proposes funding HRSA at $10.7 billion, or $84 million above FY 2016-enacted level. The President's budget includes a two-year extension of ACA mandatory funding, proposing $3.6 billion in new mandatory funding, for health centers to support the delivery of cost-effective and high-quality primary care services. The budget proposes a total of $1.3 billion for HRSA workforce programs, including the National Health Service Corps (NHSC), graduate medical education, and workforce diversity efforts. The budget proposes to increase mandatory funding for the NHSC to $810 million in each of fiscal years 2018 through 2020, which would be an increase of $500 million each year in mandatory funding over FY 2016-enacted level.

The President's budget also proposes an increase of $7 million in funds for the administration of the 340B program, and a new user fee totaling $9 million to support the continual successful operation of the program. The budget also seeks rulemaking authority from Congress so that the federal government can better ensure the most effective use of this critical safety net program.

VI. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The President's budget proposes funding CDC at a program level of $11.9 billion, or $87 million above FY 2016-enacted level. The budget proposes $629 million to support CDC's National Center for Emerging and Zoonotic Infectious Diseases, an increase of $50 million over FY16-enacted levels. The budget proposes $218 million for implementing the National Action Plan for Combating Antibiotic-Resistant Bacteria through the CDC, which includes an increase of $40 million over FY 2016-enacted levels to support CDC's Antibiotic Resistance Initiative.

VII. NATIONAL INSTITUTES OF HEALTH (NIH)

The President's budget proposes funding NIH at a program level of $33.1 billion, or more than $800 million above the FY 2016-enacted level. The budget proposes $300 million, an increase of $100 million above FY16-enacted levels, for the Precision Medicine initiative. The budget proposes $195 million, an increase of $45 million above FY16-enacted levels, for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. The budget proposes $680 million to NIH for the recently announced Vice President's Cancer Moonshot initiative.

VIII. NEW POLICY INITIATIVES & PRIORITIES

A. Antibiotic-Resistant Bacteria

Among other initiatives, the President proposes investing $877 million for developing new drugs and diagnostics in the fight against, and the spread of antibiotic resistant pathogens. This amount would be an increase of $43 million for NIH, CDC, the Biomedical Advanced Research and Development Authority (BARDA), FDA, and AHRQ.

B. Drug Pricing Proposals

The President's budget includes a number of proposals meant to address recent drug price increases, including supporting rebates for low-income beneficiaries in Medicare and Medicaid, allowing the Secretary to negotiate prices for high-cost drugs and biologics, developing transparent reporting requirements related to the prices of prescription drugs, and encouraging competition among biologics earlier. Further discussion of these proposals is below.

i. Lowering Reimbursement for Medicare Part B Drugs. The budget proposes lowering reimbursement for Medicare Part B drugs from Average Sales Price (ASP) plus six percent to ASP plus three percent. If physician costs are greater than ASP plus three percent, a drug manufacturer would be required to provide the physician a rebate. Both the impact of the current Part B reimbursement methodology and this proposal should be carefully examined to determine what steps Congress should take to contain costs while ensuring beneficiaries have access to necessary treatments. This proposal saves $7.8 billion over ten years.

ii. Rebates for Prescription Drugs. As in past years, the budget includes a proposal to require Medicaid-like rebates for prescription drugs provided to dual-eligible beneficiaries. Prior to establishment of the Medicare Part D program, manufacturers paid Medicaid rebates for drugs provided to the dual eligible population. Those rebates no longer accrue to the federal government, as these beneficiaries now receive their drug coverage through the Part D program. This proposal allows Medicare to recoup the rebates for the population that Medicaid would have received and saves $121 billion in savings over ten years.

iii. Encourage Generic Utilization in Medicare Part D. The budget again includes a proposal to incentivize more use of generics by the Medicare Part D low-income population. Currently, copayments for brand and generic drugs are set by statute for the Medicare Part D LIS (low-income subsidy) population. This proposal would lower copayments for generic drugs, while simultaneously increasing brand copayments to twice the level under current law. This proposal would save $9.6 billion over ten years.

iv. Other Medicare Part D Proposals. The budget also includes several additional proposals to address drug pricing that do not have a budgetary impact. First, the budget would allow the Secretary to negotiate for high cost drugs and biologics in the Medicare Part D program. The budget would also increase Part D plan sponsors' risk for drug costs in the catastrophic phase of the Part D benefit; modifying the benefit structure in this way would provide a greater incentive for sponsors to manage drug costs, as currently, the federal government assumes virtually full risk for this part of the program. Finally, the budget would create a process in Part D, modeled after traditional Medicare, that would allow the Part D program to continually collect evidence and data to support the use of high cost drugs, allowing plans to use this evidence to improve negotiations with manufacturers.

v. Federal-State Medicaid Negotiation for High-Cost Drugs. The budget would create a federal-state Medicaid negotiating pool for high-cost drugs; this proposal would give states the support of CMS to negotiate supplemental rebates in situations where a drug threatens to overwhelm state Medicaid budgets because the Medicaid population is significantly impacted, as in the case of Hepatitis C drugs. This proposal is projected to save $5.8 billion over ten years, because the Medicaid drug rebate program provides support to the negotiation process.

vi. Modifies Medicaid Drug Rebate Program. The budget also includes a collection of targeted tweaks and revisions to the Medicaid drug rebate program such as excluding generic drugs from the calculations used to determine brand-name rebates. These changes would result in an additional $5.6 billion in savings over ten years.

C. Health Information Technology

The President's budget provides continued investment in our nation's health information systems. The budget would propose an overall increase of $22 million for the Office of the National Coordinator for Health Information Technology (ONC). Additionally, the budget proposes new authority for ONC to strengthen patient safety and quality of care by advancing nationwide interoperability, reliability, and usability of health information technology.

D. Mental Health Proposals

The President proposes a new two-year $500 million initiative, including $230 million in mandatory funds to increase access to mental health services. It includes $115 million in new mandatory funding in each of 2017 and 2018 for a new formula-SAMHSA grant program to assist states with evidence-based early intervention programs for individuals with serious mental illnesses. A proposal for a new $10 million SAMHSA Crisis Systems grant program to help states and communities build, fund, and sustain crisis response systems and a new $10 million SAMHSA grant program to increase the number of trained peer professionals in mental health and substance abuse were also proposed.

To address the increased prevalence of suicide, the President has proposed an increase of $28 million for suicide prevention over FY16-enacted levels, including $26 million for a new Zero Suicide grant program to reduce the number of suicides in America and $2 million to implement other recommendations of the National Strategy for Suicide Prevention. A new set-aside within the SAMHSA Children's Mental Health Services Program is also included to dedicate up to 10 percent of the $119 million in requested funding for this program to focus on youth and young adults who are at clinical high risk for developing a first episode of psychosis. The budget also proposes $50 million in new mandatory funding to HRSA, which includes funding programs to expand access to mental health services.

The Budget would also expand the Medicare and Medicaid Electronic Health Record Incentive Programs to include behavioral health providers, which aims to better integrate physical and behavioral health care.

The Budget proposes to lift the 190-day lifetime limit on inpatient psychiatric facilities for Medicare beneficiaries beginning in FY2017. It also contains three proposals in the Medicaid behavioral health space. First, there is a proposal that would allow states the option to offer home and community-based waiver services to children eligible for psychiatric residential treatment facilities (PRTFs). Without this statutory change, children in the Medicaid program cannot receive an institutional level of psychiatric care in the community setting. Second, the President's budget would again propose to lift the federal Medicaid exclusion of comprehensive children's coverage in Medicaid inpatient psychiatric care. Finally, the President's budget includes a new proposal to extend the Excellence in Mental Health Act demonstration project to an additional six states; as currently authorized, only eight states may be a part of the full demonstration, but 24 states were awarded planning grants. This policy would allow promising additional proposals to participate in the full demonstration.

E. Prescription Drug and Heroin Abuse

The President's budget proposes $1 billion across HHS over two years to improve access to treatment for opioid dependence. It also includes $559 million in new mandatory and discretionary funding increases for SAMHSA programs to expand the availability of naloxone and medication-assisted treatment as well as improve state planning and coordination efforts. For example, the budget proposes $460 million for each of FY 2017 and FY 2018 for a new State Targeted Response Cooperative Agreements program that aims to close the treatment gap

in substance use disorder treatment. Requested funding for these purposes constitutes an increase of $510 million above FY 2016-enacted levels.

The budget proposes $50 million in new mandatory funding to HRSA which includes funding for programs to expand access to treatment for prescription drug and heroin abuse and a new $10 million SAMHSA discretionary grant program to increase the number of trained peer professionals in mental health and substance abuse. The budget proposes $80 million for CDC's efforts to address the prescription drug and heroin abuse epidemic, which is an increase of $10 million over FY 2016-enacted levels. That increase would be used specifically to support the comprehensive translation and dissemination of CDC's Prescription Drug Overdose guidelines.

The President's budget proposal also includes a policy to track high prescribers and utilizers of prescription drugs in Medicaid. Under this policy, states would be required to monitor high risk billing activity to identify and remediate problematic prescribing and utilization patterns.

F. Puerto Rico

The President's budget makes investments and improvements to Puerto Rico's Medicaid program. Puerto Rico's Medicaid program is structured as a capped block grant. The cap along with recent increases in Puerto Rico's economic needs and fiscal challenges has made it more difficult for Puerto Rico to respond as fully as it should.

In particular, the budget would lift the federal cap on Medicaid funding, and expand eligibility for beneficiaries across the board to 100 percent of the federal poverty level. This proposal would also increase the federal matching rate for Puerto Rico, and provides incentives to modernize the program.

The President's budget would allow the Secretary to use a proxy for Supplemental Security Income (SSI) when determining Medicare Disproportionate Share (DSH) payments to Puerto Rico hospitals. Because Puerto Rico residents are not eligible for SSI, Puerto Rico's hospitals have been at a disadvantage for DSH payment calculations. This legislation would cost $70 million over ten years.

IX. WITNESSES

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services