

Deputy Secretary Hargan Written FY 2020 Budget Testimony

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. This work is organized into five strategic goals, and is unified by a vision of our healthcare, human services, and public health systems working better for the Americans we serve. By undertaking these efforts in partnerships with states, territories, tribal governments, local communities, and the private sector, we will succeed at putting Americans' health first.

This past year saw HHS, the Department of Labor, and the Department of Treasury open up new affordable health coverage options, at the same time the Affordable Care Act (ACA) exchanges were stabilized, with the national average benchmark premium on HealthCare.gov dropping for the first time ever. According to a report by the Council of Economic Advisers, actions taken by the Administration, along with the elimination of the individual mandate penalty, are estimated to provide a net benefit to Americans of \$453 billion over the next decade.

Congress worked with the Administration to deliver new resources for fighting the opioid crisis, allowing HHS to make more than \$2 billion in opioid-related grants to states, territories, tribes, and local communities in 2018. Prescriptions for medication-assisted treatment options and naloxone are up, while legal opioid prescribing is down. HHS also worked to bring down prescription drug prices, including by setting another record for most generic drug approvals by FDA in a fiscal year and working with Congress to ensure pharmacists can inform Americans about the lowest-cost prescription drug options.

The President's Fiscal Year (FY) 2020 Budget supports HHS's continued work on these important goals by prioritizing key investments that help advance the Administration's commitments to improve American health care, address the opioid crisis, lower the cost of drugs, and streamline federal programs, while reforming the Department's programs to better serve the American people.

The Budget proposes \$87.1 billion in discretionary budget authority and \$1.2 trillion in mandatory funding for HHS. It reflects HHS's commitment to making the federal government more efficient and effective by focusing spending in areas with the highest impact.

HHS's Fiscal Year 2020 Budget reflects decisions not just to be prudent with taxpayer dollars, but also to stay within the budget caps Congress created in the Budget Control Act. With the largest non-defense discretionary appropriation of any cabinet agency in 2019, HHS must make large reductions in spending in order to stay within Congress's caps, set a prudent fiscal course, and provide for other national priorities. This budget demonstrates that HHS can prioritize its important work within these constraints, and proposes measures to reform HHS programs while putting Americans' health first.

REFORM, STRENGTHEN, AND MODERNIZE THE NATION'S HEALTH CARE SYSTEM

Reforming the Individual Market for Insurance

The Budget proposes bold reforms to empower states and consumers to improve American healthcare. These reforms return the management of health care to the states, which are more capable of tailoring programs to their unique markets, increasing options for patients and providers, and promoting financial stability and responsibility, while protecting people with pre-existing conditions and high health care costs.

The Budget includes proposals to make it easier to open and use Health Savings Accounts and reform the medical liability system to allow providers to focus on patients instead of lawsuits.

Lowering the Cost of Prescription Drugs

Putting America's health first includes improving access to safe, effective, and affordable prescription drugs. The Budget proposes to expand the Administration's work to lower prescription drug prices and reduce beneficiary out-of-pocket costs. The Administration has proposed and, in many cases, made significant strides to implement bold regulatory reforms to increase competition, improve negotiation, create incentives to lower list prices, reduce out-of-pocket costs, improve transparency, and address foreign free-riding. Congress has already taken bipartisan action to end pharmacy gag clauses, so patients can work with pharmacists to lower their out-of-pocket costs. The Budget proposes to:

- Stop regulatory tactics used by brand manufacturers to impede generic competition;
- Ensure federal and state programs get their fair share of rebates, and enact penalties to prevent the growth of prescription drug prices beyond inflation;
- Improve the Medicare Part D program to lower seniors' out-of-pocket costs, create an out-of-pocket cap for the first time, and end the incentives that reward list price increases;
- Improve transparency and accuracy of payments under Medicare Part B, including imposing payment penalties to discourage pay-for-delay agreements; and
- Build on America's successful generic market with a robust biosimilars agenda, by improving the efficient approval of safe and effective biosimilars, ending anti-competitive practices that delay or restrict biosimilar market entry, and harnessing payment and cost-sharing incentives to increase biosimilar adoption.

Reforming Medicare and Medicaid

Medicare and Medicaid represent important promises made to older and vulnerable Americans, promises that President Trump and his administration take seriously. The Budget supports reforms to make these programs work better for the people they serve and deliver better value for the investments we make. This includes a plan to modernize Medicare Part D to lower drug costs for the Medicare program and for Medicare beneficiaries, as well as proposals to drive Medicare toward a value-based payment system that puts patients in control. The Budget also provides additional flexibility to states for their Medicaid program, putting Medicaid on a path to fiscal stability by restructuring its financing, reducing waste, and focusing the program on the low-income populations Medicaid was originally intended to serve: the elderly, people with disabilities, children, and pregnant women.

Paying for Value

The Administration is focused on ensuring federal health programs produce better care at the lowest possible cost for the American people. We believe that consumers, working with providers, are in the best position to determine value. The Budget supports an expansion of

value-based payments in Medicare with this strategy in mind. That expansion, along with implementation of a package of other reforms, will improve quality, promote competition, reduce the federal burden on providers and patients, and focus payments on value instead of volume or site of service. Two of these reforms are: (1) a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers; and (2) a consolidated hospital quality program in Medicare to reduce duplicative requirements and create a focus on driving improvements in patients' health outcomes. Advancing value in Medicare along with the other reforms in the Budget will extend the life of the Medicare Trust Fund by eight years, while also helping to drive value and innovation throughout America's entire health system. Furthermore, in December the administration released a report entitled *Reforming America's Healthcare System Through Choice and Competition*, which contains a series of recommendations to improve the health care system by better engaging consumers and unleashing competition across providers.

PROTECT THE HEALTH OF AMERICANS WHERE THEY LIVE, LEARN, WORK, AND PLAY

Combating the Opioid Crisis

The Administration has made historic investments to address opioid misuse, abuse, and overdose, but significant work must still be done to fully turn the tide of this public health crisis. The Budget supports HHS's five-part strategy to:

- Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Better target the availability of overdose-reversing drugs;
- Strengthen our understanding of the crisis through better public health data and reporting;
- Provide support for cutting edge research on pain and addiction; and
- Improve pain management practices.

The Budget provides \$4.8 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all opioid activities at the same funding level as FY 2019, including the successful State Opioid Response Program and grants, which had a special focus on increasing access to medication-assisted treatment—the gold standard for treating opioid addiction. At this level, the Budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance use disorder treatment curricula.

In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance use disorder, including opioid use disorder, through the Rural Communities Opioid Response Program, the National Health Service Corps, behavioral health workforce programs, and the Health Centers Program.

Medicare and Medicaid policies and funding will also play a critical role in combating the opioid crisis. The Budget proposes allowing states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. The Budget also proposes to set minimum standards for Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between

the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The Ending HIV Epidemic Initiative

Recent advances in HIV prevention and treatment create the opportunity to not only control the spread of HIV, but to end this epidemic in America. By accelerating proven public health strategies, HHS will aim to reduce new infections by 90 percent within ten years, ending the epidemic in America. The Budget invests \$291 million in FY 2020 for the first phase of this initiative, which will target areas with the highest infection rates with the goal of reducing the number of new diagnoses by 75 percent in five years.

This effort focuses on investing in existing, proven activities and strategies and putting new public health resources on the ground. The initiative includes a new \$140 million investment in the Centers for Disease Control and Prevention (CDC) to test and diagnose new cases, rapidly link newly infected individuals to treatment, connect at-risk individuals to Pre-exposure prophylaxis (PrEP), expand HIV surveillance, and directly support states and localities in the fight against HIV.

Clients receiving medical care through the Ryan White HIV/AIDS Program (RWHAP) were virally suppressed at a record level of 85.9 percent in 2017. The Budget includes \$70 million in new funds for RWHAP within HRSA to increase direct health care and support services, further increasing viral suppression among patients in the target areas. The Budget includes \$50 million in HRSA for expanded PrEP services, outreach, and care coordination in community health centers. Additionally, the Budget also prioritizes the reauthorization of RWHAP to ensure federal funds are allocated to address the changing landscape of HIV across the United States.

For the Indian Health Service (IHS), the Budget includes \$25 million in new funds to screen for HIV and prevent and treat Hepatitis C, a significant burden among persons living with HIV/AIDS. The Budget also includes \$6 million for the National Institutes of Health's regional Centers for AIDS Research to refine implementation strategies to assure effectiveness of prevention and treatment interventions.

In addition to this effort, the Budget funds other activities that address HIV/AIDS including \$54 million for the Minority HIV/AIDS Fund within the Office of the Secretary and \$116 million for the Minority AIDS program in SAMHSA. These funds allow HHS to target funding to minority communities and individuals disproportionately impacted by HIV infection.

Prioritizing Biodefense and Preparedness

The Administration prioritizes the nation's safety, including its ability to respond to acts of bioterrorism, natural disasters, and emerging infectious diseases. HHS is at the forefront of the nation's defense against public health threats. The Budget provides approximately \$2.7 billion to the Public Health and Social Services Emergency Fund within the Office of the Secretary to strengthen HHS's biodefense and emergency preparedness capacity. The Budget also proposes a new transfer authority that will allow HHS to enhance its ability to respond more quickly to public health threats. Additionally, the Budget supports the government-wide implementation of the President's National Biodefense Strategy.

The Budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The Budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to state and local governments, protecting America against threats such as anthrax, botulism, Ebola, and chemical, radiological, and nuclear agents.

STRENGTHEN THE ECONOMIC AND SOCIAL WELL-BEING OF AMERICANS ACROSS THE LIFESPAN

Promoting Upward Mobility

The Budget promotes independence and personal responsibility, supporting the proven notion that work empowers parents and lifts families out of poverty. To ensure Temporary Assistance for Needy Families (TANF) enables participants to work, the Budget includes a proposal to ensure states will invest in creating opportunities for low-income families, and to simplify and improve the work participation rate states must meet under TANF. The Budget also proposes to create Opportunity and Economic Mobility Demonstrations, allowing states to streamline certain welfare programs and tailor them to meet the specific needs of their populations.

The Budget supports Medicaid reforms to empower individuals to reach self-sufficiency and financial independence, including a proposal to permit states to include asset tests in identifying an individual's economic need, allowing more targeted determinations than are possible with the use of a Modified Adjusted Gross Income standard alone.

Improving Outcomes in Child Welfare

The Budget supports implementation of the Family First Prevention Services Act of 2018 and includes policies to further improve child welfare outcomes and prevent child maltreatment. The Budget also expands the Regional Partnership Grants program, which addresses the considerable impact of substance use, including opioids use, on child welfare.

Strengthening the Indian Health Service

Reflecting HHS's commitment to the health and well-being of American Indians and Alaska Natives, the Budget provides \$5.9 billion for IHS, which is an additional \$392 million above the FY 2019 Continuing Resolution. The increase supports direct health care services across Indian Country, including hospitals and health clinics, Purchased/Referred Care, dental health, mental health and alcohol and substance abuse services. The Budget invests in new programs to improve patient care, quality, and oversight. The Budget fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, ensuring tribes have the necessary resources to successfully manage self-governance programs.

FOSTER SOUND, SUSTAINED ADVANCES IN THE SCIENCES

Promoting Research and Prevention

NIH is the leading biomedical research agency in the world, and its funding supports scientific breakthroughs that save lives. The Budget supports strategic investments in biomedical research and activities with significant national impact.

NIH launched the Helping to End Addiction Long-term (HEAL) initiative in April 2018 to advance research on pain and addiction. Toward this goal, NIH announced funding opportunities for the historic HEALing Communities Study, which will select several communities to measure the impact of investing in the integration of evidence-based prevention, treatment, and recovery across multiple health and justice settings. The Budget provides \$500 million to continue the HEAL initiative in FY 2020.

The Budget supports a targeted investment in the National Cancer Institute to accelerate pediatric cancer research. Cancer is the leading cause of death from disease among children in the United States. Approximately 16,000 children are diagnosed with cancer in the United States each year. While progress in treating some childhood cancers has been made, the science and treatment of childhood cancers remains challenging. Through this initiative, NIH will enhance drug discovery, better understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer research. This initiative will develop safer and more effective treatments, and provide a path for changing the course of cancer in children.

The new National Institute for Research on Safety and Quality (NIRSQ) proposed in the Budget will continue key research activities currently led by the Agency for Healthcare Research and Quality. These activities will support researchers by developing the knowledge, tools, and data needed to improve the health care system.

Addressing Emerging Public Health Challenges

CDC is the nation's leading public health agency, and the Budget supports its work putting science into action.

Approximately 700 women die each year in the United States as a result of pregnancy or delivery complications or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Findings from Maternal Mortality Review Committees indicate that more than half of these deaths are preventable. The Budget supports data analysis on maternal deaths and efforts to identify prevention opportunities.

The United States must address emerging public health threats, both at home and abroad, to protect the health of its citizens. The Budget invests \$10 million to support CDC's response to Acute Flaccid Myelitis (AFM), a rare but serious condition that affects the nervous system and weakens muscles and reflexes. With this funding, CDC will work closely with national experts, healthcare providers, and state and local health departments to thoroughly investigate AFM.

The Budget also provides \$100 million for CDC's global health security activities. Moving forward, CDC will implement a regional hub office model and primarily focus their global health security capacity building activities on areas where they have seen the most success: lab and diagnostic capacity, surveillance systems, training of disease detectives, and establishing strong emergency operation centers. In addition, CDC will continue on-going efforts to identify health emergencies, track dangerous diseases, and rapidly respond to outbreaks and other public health threats around the world, including continuing work on Ebola response.

The Budget also strengthens the health security of our nation by continuing CDC's support to state and local government partners in implementing programs, establishing guidelines, and conducting research to tackle public health challenges and build preparedness.

Innovations in the Food and Drug Administration

FDA plays a major role in protecting public health by assuring the safety of the nation's food supply and regulating medical products and tobacco. The Budget provides \$6.1 billion for FDA, which is an additional \$643 million above the FY 2019 Continuing Resolution. The Budget includes resources to promote competition and foster innovation, such as modernizing generic drug review and creating a new medical data enterprise. The Budget advances digital health technology to reduce the time and cost of market entry, supports FDA opioid activities at international mail facilities to increase inspections of suspicious packages, strengthens the outsourcing facility sector to ensure quality compounded drugs, and pilots a pathogen inactivation technology to ensure the blood supply continues to be safe. FDA will continue to modernize the food safety system in FY 2020.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

Almost one quarter of total federal outlays are made by HHS. The Department employs more than 78,000 permanent and temporary employees and administers more grant dollars than all other federal agencies combined. Efficiencies in HHS management have a tremendous impact on federal spending as a whole.

Advancing Fiscal Stewardship

HHS recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

In an effort to operate Medicare and Medicaid efficiently and effectively, both to rein in wasteful spending and to better serve beneficiaries, HHS is implementing actions such as enhanced provider screening, prior authorization, and sophisticated predictive analytics technology, to reduce improper payments in Medicare and Medicaid without increasing burden on providers or delaying Americans' access to care or to critical medications. HHS continues to work with law enforcement partners to target fraud and abuse in health care, and the Budget increases investment in health care fraud and abuse activities. The Budget includes a series of proposals to strengthen Medicare and Medicaid oversight, including increasing prior authorization, enhancing Part D plans' ability to address fraud, and strengthening the Department's ability to recoup overpayments made to states on behalf of ineligible Medicaid beneficiaries.

Implementing ReImagine HHS

HHS eagerly took up the call in the Administration's Government-wide Reform Plan to more efficiently and effectively serve the American people. HHS developed a plan –"ReImagine HHS"– organized around a number of initiatives.

ReImagine HHS is identifying a variety of ways to reduce federal spending and improve the functioning of HHS's programs through more efficient operations. For example, the Buy Smarter initiative streamlines HHS's procurement process by using new and emerging technologies.

Conclusion

Americans deserve health care, human services, and public health programs that work for them and make good use of taxpayer dollars. The men and women of HHS are committed, innovative, hardworking public servants who work each day to improve the lives of all Americans. President Trump's FY 2020 Budget will help advance us toward that goal, accomplish the Department's vital mission, and put Americans' health first.