

Sec. Azar Written Budget Testimony

The President's Fiscal Year (FY) 2021 Budget (Budget) is built around a vision for HHS and a vision for American healthcare. We are building toward a future where HHS's programs work better for the people we serve; where America's healthcare system is affordable, personalized, and puts patients in control; and where our human services programs put people at the center.

The Budget reflects the Administration's commitments to delivering on this vision and other important themes of HHS's work: advancing a patient-centered healthcare system, protecting the lives of the American people, promoting independence, and making HHS the healthiest organization it can be.

Over the past year, under President Trump's leadership, the men and women of HHS have delivered remarkable results. Beginning in 2018 and through 2019, the number of drug overdose deaths in America began to decline for the first time in nearly two decades, thanks to huge expansions, assisted by HHS, in access to evidence-based addiction treatment. The Food and Drug Administration (FDA) approved a record number of generic drugs and biosimilars in FY 2019. We launched new payment models in Medicare that pay for health and outcomes, rather than sickness and procedures. We finalized a requirement, effective January 2021, that hospitals provide patients with useful price information, and proposed measures to give patients control over their own health data through interoperability. We launched President Trump's initiative to end the HIV epidemic in America within ten years, and worked with Congress to secure funding for it. The Department played a vital role in responding to an Ebola outbreak in the eastern Democratic Republic of the Congo and the humanitarian crisis in Latin America. We took unprecedented steps to expand access to treatment for Americans with serious mental illness and worked to help seniors remain in their homes. The latest data from the Administration for Children and Families shows a record number of adoptions with child-welfare-agency involvement, and reductions in the number of children entering foster care. The Budget proposes to continue work on these priorities, while also identifying new areas for action, such as maternal and rural health.

The Budget proposes \$94.5 billion in discretionary budget authority and \$1.3 trillion in mandatory funding. Within our discretionary programs, it prioritizes funding for programs that have demonstrated effectiveness, proposes to end programs that have not, and focuses on direct services provided to the American people. On mandatory spending, the Budget proposes commonsense reforms that will pave a path to fiscal sustainability and make these important programs work better for the people they serve.

FACILITATE PATIENT-CENTERED CARE

Providing Price and Quality Transparency

President Trump's Executive Order on *Improving Price and Quality Transparency in American Healthcare to Put Patients First* directs HHS to make healthcare prices transparent, laying the foundation for a patient-driven and value-based health system. HHS has acted swiftly to require hospitals to publish the prices they negotiate with insurers and is working to do the same for issuers, so patients can understand their own out-of-pocket costs. CMS has also required Part D

prescription drug plans to develop tools that allow beneficiaries to determine plan benefits and formularies.

The Executive Order calls for the development of a Health Quality Roadmap that aligns and improves reporting on data and quality measures across Medicare, Medicaid, the Children's Health Insurance Program, and other Federal health programs. The Roadmap will include a strategy for establishing, adopting, and publishing common quality measures; aligning hospital inpatient and hospital outpatient measures; and eliminating low-value or counterproductive measures.

HHS legislative proposals increase price and quality transparency in Medicare. For instance, the Budget would eliminate coinsurance or copayments for a screening colonoscopy when a polyp is found, saving lives and supporting the President's policy to reduce out-of-pocket costs for this common procedure.

The Budget also invests funding in programs that promote transparency. The Budget requests \$51 million for the Office of the National Coordinator for Health IT, which includes funding to develop, promote, and adopt common standards to integrate health information and product transparency while protecting privacy. In addition, the new National Institute for Research on Safety and Quality within the National Institutes of Health (NIH) supports the Administration's efforts to move healthcare organizations from volume to value by focusing on improving outcomes, reducing cost, and expanding choices for consumers. Research investments will focus on developing knowledge, tools, and data needed to improve the healthcare system.

Lowering the Cost of Prescription Drugs

The United States is first in the world in biopharmaceutical investment and innovation. But too often, this system has not put American patients first. We have access to the greatest medicines in the world, but access is meaningless without affordability. The Budget supports quick Congressional action to pass comprehensive legislation to address these flaws in our current drug pricing system and provide needed relief to the American people.

The Budget delivers on President Trump's promise to bring down the high cost of drugs and reduce out-of-pocket costs for American consumers by pursuing policies that align with the four pillars of the President's *American Patients First Blueprint*: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

The Budget includes an allowance for bipartisan drug pricing proposals. The Administration supports legislative efforts to improve the Medicare Part D benefit by establishing an out-of-pocket maximum and reducing out-of-pocket costs for seniors. The Administration also supports changes to bring lower cost generic and biosimilar drugs to patients. These efforts would increase competition, reduce drug prices, and lower out of pocket costs for patients at the pharmacy counter.

The Budget includes an allowance for savings of \$135 billion over ten years to support the President's commitment to lower the cost of prescription drugs.

Protecting and Improving Medicare for our Nation's Seniors

Over 60 million American seniors are in the Medicare program, and they are overwhelmingly satisfied with the care they receive through traditional Medicare and Medicare Advantage. The President is continuing to strengthen and improve these programs.

The Budget continues to implement the President's Executive Order on *Protecting and Improving Medicare for Our Nation's Seniors*, building on those aspects of the program that work well, while also introducing market-based approaches to Medicare reimbursement. The Administration seeks to protect and reform Medicare with proposals that strengthen fiscal sustainability and deliver value to patients. To drive reform, the Centers for Medicare & Medicaid Services (CMS) is modernizing the Medicare Advantage program, unleashing innovation, expanding telehealth options, and driving competition to improve quality among private Medicare health and drug plans. The Administration is expanding flexibility for these Medicare Advantage plans to maximize choices for seniors, and taking action to ensure fee-for-service Medicare is not promoted over Medicare Advantage.

President's Health Reform Vision Allowance

While Americans have the best healthcare options in the world, rising healthcare costs continue to be a top financial concern for many Americans. President Trump's Health Reform Vision will protect the most vulnerable, especially those with pre-existing conditions, and provide the affordability, choice, and control Americans want and the high-quality care that all Americans deserve.

The President's Health Reform Vision would build on efforts outlined in the Executive Order, *"Improving Price and Quality Transparency in American Healthcare To Put Patients First"* to provide greater transparency of healthcare costs and enshrine the right of a patient to know the cost of care before it is delivered. It focuses on lowering the price of medicine, ending surprise medical bills, breaking down barriers to choice and competition, and reducing unnecessary regulatory burdens. The Health Reform Vision will also prioritize Federal resources for the most vulnerable and provide assistance for low-income individuals. Medicaid reform will restore balance, flexibility, integrity, and accountability to the state-federal partnership. Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working-age adults over the truly vulnerable.

The Budget includes savings of \$844 billion over ten years for the President's Health Reform Vision Allowance.

Paying for Outcomes

The Administration is committed to advancing a personalized and affordable healthcare system that puts the patient at the center by ensuring Federal health programs produce quality outcomes and results at the lowest possible cost.

In part, this will be achieved by our continued focus on paying for outcomes rather than procedures. For instance, the Budget seeks to improve Medicare primary care services by ensuring payments more accurately reflect clinician time, resources, and outcomes. The Budget also implements a value-based purchasing program for hospital outpatient departments,

ambulatory surgical centers, and post-acute care facilities, offering incentives to improve quality and health outcomes. Finally, the Budget proposes a set of reforms that improve the physician experience and participation in the Quality Payment Program by eliminating reporting burdens for clinicians participating in the Merit-Based Incentive Payment System, CMS's largest value-based care payment program.

The Administration issued proposed rules to modernize key regulations that advance the movement to value-based care and paying for outcomes. Specifically, the Administration proposed reforms to the Anti-Kickback Statute, the Physician Self-Referral regulations (Stark Law), and 42 CFR Part 2. These proposed rules are part of HHS's Regulatory Sprint to Coordinated Care, which aims to reduce regulatory barriers and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. These proposed rules reduce unnecessary regulatory burden on physicians and other healthcare providers while reinforcing their statutory intents of protecting patients from unnecessary services, and limiting fraud waste and abuse. This includes adding flexibilities with respect to outcomes-based payments and part-time arrangements. These rules would allow physicians and other healthcare providers and suppliers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs.

The CMS Center for Medicare and Medicaid Innovation (Innovation Center) launched a number of innovative payment and service delivery models to test ideas to shift our healthcare system toward payment for outcomes and health rather than sickness and procedures. This effort includes Direct Contracting and Primary Care First, a new suite of payment model options that will transform primary care to deliver better value for patients throughout the healthcare system. In addition, the Emergency Triage, Treat, and Transport Model provides greater flexibility to ambulance care teams to address emergency healthcare needs of Medicare beneficiaries following a 911 call, rather than delivering them to the hospital or emergency department for an unnecessary and expensive visit.

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

In 2018, drug overdose deaths declined for the first time since 1990. A reduction in deaths from prescription opioid painkillers is almost entirely responsible for this decline. To maintain and build on this progress, HHS continues to advance the department's five-point 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 requests \$5.2 billion to address the opioid overdose epidemic and methamphetamine use, including \$169 million in new resources. Funding expands State Opioid Response grants in the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide treatment, recovery support services, and relapse prevention. The Budget provides funding to

the Health Resources and Services Administration (HRSA) for Addiction Medicine Fellowships to support approximately 60 fellows annually in underserved, community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services.

While opioids have been at the forefront of the drug landscape, the crisis continues to evolve and many public health experts believe we are entering into the fourth wave of the crisis, which is underscored by increases in overdose deaths involving cocaine and methamphetamine.

HHS is leveraging current efforts to address the opioid epidemic to combat the rising mortality and morbidity associated with methamphetamines and other stimulants. To allow flexibility to most effectively combat substance use in whatever form it takes, SAMHSA's State Opioid Response grant program has the flexibility to also address stimulants. HHS would direct \$50 million within NIH for research to develop medication-assisted treatment and evidence-based psychosocial treatment for methamphetamines and other stimulants.

Ending the HIV Epidemic: A Plan for America

In the 2019 State of the Union, President Trump announced a bold new initiative to reduce new HIV infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 400,000 HIV infections in that time period. This initiative focuses on four key strategies:

- Diagnose all individuals with HIV as early as possible after infection;
- Treat the infection rapidly and effectively after diagnosis, achieving sustained viral suppression;
- Protect individuals at risk for HIV using proven prevention approaches; and
- Respond rapidly to detect and respond to growing HIV clusters and prevent new HIV infections.

The Budget invests \$716 million in dedicated funding for the second year of the *Ending the HIV Epidemic: A Plan for America* initiative, an increase of \$450 million from FY 2020. This funding expands activities in the 57 target jurisdictions to increase HIV testing and access to prevention and treatment services.

With \$371 million, the Centers for Disease Control and Prevention (CDC) transitions from planning to implementation and intensifies work begun in FY 2020 in the 57 target jurisdictions. CDC grants to affected communities will drive additional testing with the goal in the second year of doubling the number of new HIV diagnoses rapidly treated with antiretroviral therapy to maintain health and prevent additional HIV transmissions. Funded jurisdictions will use pharmacy data, telehealth, mobile testing, and new science-based networks to ensure individuals enter and adhere to care.

With \$302 million, HRSA expands HIV prevention services to all community health centers in the targeted initiative areas and serves 28,000 additional HIV positive people through the Ryan White Program. HHS also requests \$27 million for the Indian Health Service (IHS) to enhance HIV testing and linkages to care for American Indians and Alaska Natives.

NIH directs \$16 million to leverage pilot data from 17 Centers for AIDS Research to design and evaluate effective, sustainable systems to implement HIV prevention and treatment interventions and rapidly implement strategies at scale that will be most effective.

These investments build on ongoing HIV activities supported across the Department and an announcement in 2019 to make pre-exposure prophylaxis medication available free of charge for up to 200,000 uninsured individuals each year for up to 11 years. The donation by Gilead Sciences, in partnership with HHS, will help reduce the risk of HIV infections, particularly for individuals that may be at the highest risk.

Improving Maternal Health

Approximately 700 women die each year in the United States from pregnancy-related complications and more than 60 percent of these deaths are preventable. In fact, women in the United States have higher rates of maternal mortality and morbidity than in any other industrialized nation – and the rates are rising. In addition to rising mortality rates, severe maternal morbidity affects more than 50,000 women and adds significant costs to the healthcare system.

Cardiovascular disease is now the leading cause of death in pregnancy and the postpartum period, constituting nearly 30 percent of pregnancy-related deaths. Chronic hypertension – which is diagnosed or present before pregnancy or before 20 weeks gestation – may result in significant maternal, fetal, and neonatal morbidity and mortality. The rate of chronic hypertension increased by 67 percent from 2000 to 2009, with the largest increase (87 percent) among African American women. CDC points to hypertensive disorders, cerebrovascular accidents, and other cardiovascular conditions as some of the leading causes of maternal deaths, all potentially preventable conditions. It is imperative to identify risk factors prior to pregnancy in order to prevent poor pregnancy and postpartum outcomes.

HHS's *Improving Maternal Health in America* initiative is addressing this significant public health problem. This initiative focuses on four strategic goals:

- Achieve healthy outcomes for all women of reproductive age by improving prevention and treatment;
- Achieve healthy pregnancies and births by prioritizing quality improvement;
- Achieve healthy futures by optimizing postpartum health; and
- Improve data and bolster research to inform future interventions.

The Budget provides a total of \$116 million for this initiative across the National Institute for Research on Safety and Quality (NIRSQ), CDC, HRSA, and IHS. This includes \$7 million for NIRSQ to improve service data, advance data evaluation, and expand medical expenditure surveys to ensure policy makers have timely and accurate data. The Budget also invests \$24 million in CDC to expand the Maternal Mortality Review Committees to all 50 states and D.C. to ensure every case of pregnancy-related death is examined. The Budget provides \$80 million in HRSA to improve the quality of maternal health services, expand access to care, and reduce disparities in care. The Budget invests \$5 million in IHS to help improve health outcomes by standardizing care, increasing cultural awareness, and improving care for pregnant women.

Advancing American Kidney Health

Today's status quo in kidney care carries a tremendous financial cost. In 2016, Medicare fee-for-service spent approximately \$114 billion to cover people with kidney disease, representing more than one in five dollars spent by the traditional Medicare program. In July 2019, the President signed an Executive Order launching an initiative to transform care for the estimated 37 million Americans with kidney disease. The *Advancing American Kidney Health* initiative tackles the challenges people living with kidney disease face across the stages of kidney disease, while also improving the lives of patients, their caregivers, and family members.

The Budget includes \$39 million across multiple HHS agencies and requests new legislative authority in support of the initiative's three goals:

- Reduce the number of Americans developing End-Stage Renal Disease (ESRD) by 25 percent by 2030.
- Have 80 percent of new ESRD patients in 2025 receive dialysis at home or a transplant.
- Double the number of kidneys available for transplant by 2030.

This funding also supports transplantation activities for other organs.

To achieve these goals, HHS is scaling programs nationwide to optimize screening for kidney disease and educate patients on care options. HHS is also supporting innovation and groundbreaking research to inform the next generation of targeted therapies and accelerate development of innovative products such as an artificial kidney. New and pioneering payment models are also being developed to increase both value and quality of care for the patient.

The Budget also targets new funding towards HRSA's Organ Transplantation Program to remove financial disincentives for living organ donors. The Budget invests \$31 million in HRSA for the Organ Transplantation program, including \$18.3 million for the Organ Procurement Transplantation Network, Scientific Registry of Transplant Recipients, and public and professional education efforts to increase public awareness about the need for organ donation. In addition, the proposed rule to increase accountability and availability of the organ supply – announced in December 2019 – would improve the donation and transplantation rate measures, incentivize Organ Procurement Organizations (OPOs) to ensure all viable organs are transplanted, and hold OPOs to greater oversight, transparency, and accountability while driving higher OPO performance.

HHS is working to accelerate innovation in the prevention, diagnosis, and treatment of kidney disease through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between HHS and the American Society of Nephrology. The HHS Office of the Chief Technology Officer will continue the KidneyX competition in FY 2021 by challenging individuals, teams, and companies to build and test prototype solutions, or components of solutions, that can replicate normal kidney functions or improve dialysis access.

The Budget proposes to establish a new program within the Office of the Assistant Secretary for Preparedness and Response (ASPR) that will advance kidney health. The Preparedness and Response Innovation program will support advanced research and development, prototyping and

procurement of revolutionary health security products, technologies and other innovations. The program's first project will focus on portable dialysis equipment for emergency response. This will ensure that individuals with kidney failure have access to dialysis during a disaster.

The Budget also advances legislative proposals to revolutionize the way patients with chronic kidney disease and kidney failure are diagnosed, treated, and supported. This effort includes extensions of both the NIH Special Diabetes Program and IHS Special Diabetes Program for Indians to address chronic conditions, such as diabetes, that can lead to kidney disease.

For patients who lose Medicare coverage at 36 months post-transplant and who do not have another source of healthcare coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without these drugs, the patient's body rejects the transplant, reverts to kidney failure, and requires dialysis. To prevent transplant rejection and reversion to dialysis, the Budget proposes to establish a new federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage. The Budget also proposes to increase competition among, and oversight over, Organ Procurement Organizations to improve performance and increase the supply of organs for transplant. In addition, the Budget advances new innovative kidney care payment models to encourage home dialysis, increase access to kidney transplants, and incentivize clinicians to better manage care for patients with kidney disease.

Transforming Rural Health

There are 57 million Americans living in rural communities. Rural Americans face many unique health challenges, including hospitals that are closing or in danger of closing; difficulty recruiting and retaining physicians, nurses, and other providers; and increased likelihood of dying from many leading causes of avoidable death such as cancer and heart disease.

HHS's *4-Point Strategy to Transform Rural Health* builds on current HHS initiatives in the following areas:

- Build a Sustainable Health Model for Rural Communities;
- Leverage Technology and Innovation;
- Focus on Preventing Disease and Mortality; and
- Increase Rural Access to Healthcare.

The Budget supports rural communities through programs such as the Rural Communities Opioids Response Program and the Telehealth Network Grant Program at HRSA, which supports substance use prevention, treatment, and recovery services, and promotes telehealth technologies for healthcare delivery in rural communities. Project AWARE (Advancing Wellness and Resiliency in Education) will increase mental health awareness training in rural communities. In response to American Indian and Alaska Native communities' demand for telebehavioral services, IHS expands the Telebehavioral Health Center of Excellence with funding for new space, updated equipment, and additional behavioral health providers.

Telehealth services strive to make rural health programs more effective, increase the quality of healthcare, and improve health outcomes. The Budget seeks to remove barriers to telehealth services in rural and underserved areas through a proposal to expand telehealth services in

Medicare fee-for-service advanced payments models with more than nominal financial risk. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access. The proposal expands the telehealth benefit in Medicare Fee-for-Service and provides authority for Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth services. It also permits IHS and tribal facilities to be originating and distant site providers, even if the facility does not meet the requirements for being located in certain rural or shortage areas, and allows for coverage across state lines. The Budget also proposes to modernize payments to Rural Health Clinics to ensure equitable payment for these health clinics and help rural communities maintain access to these crucial services. Finally, the Budget proposes to allow Critical Access Hospitals to voluntarily convert to an emergency hospital that does not maintain inpatient beds.

Addressing Tick-borne Diseases

Tick-borne diseases, of which Lyme Disease is the most common, account for 80 percent of all reported vector-borne disease cases each year and represent an important emerging public health threat in the United States. With 59,349 reported cases in 2017, the annual number of reported cases has more than tripled over the last 20 years; due to under-reporting, this number substantially under-represents actual disease occurrence. The geographic ranges of ticks are also expanding, which leads to increased risk for human exposure to the bites of infected ticks. Most humans are infected through bites from very small young ticks, hosted by deer or mice.

To address critical gaps in knowledge, diagnostics, and preventive measures for tick-borne diseases, HHS is proposing an action plan that will prioritize and advance the most promising candidates and technologies for diagnosing and preventing Lyme and other tick-borne diseases. This plan, led by the Office of the Assistant Secretary for Health in partnership with NIH, CDC, and FDA, will address four primary areas: innovations in diagnosis and advanced detection, developing vaccine-based prevention, ensuring robust domestic surveillance of vector borne diseases, and providing additional knowledge to advance the best treatment and prevention options. These efforts will improve outcomes for those affected by Lyme Disease symptoms. This plan builds on the Kay Hagan Tick Act, enacted through the Consolidated Appropriations Act for 2020, to improve research, prevention, diagnostics, and treatment for tick-borne diseases.

The Budget requests \$189 million, an increase of \$58 million, to address tick-borne diseases. This amount includes \$115 million for NIH to expand its research on of tick-borne disease, including in the prevention, diagnosis, and treatment; and \$66 million for CDC to address vector-borne diseases, focusing on tick-borne diseases, including tick surveillance, insecticide resistance activities, and development of improved diagnostics. FDA will ensure the safety and efficacy of products developed to prevent, diagnose, and treat vector-borne diseases.

Focusing on Influenza

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands die from influenza every year. In September 2019, the President signed Executive Order 13887, *Modernizing Influenza Vaccines in the United States to*

Promote National Security and Public Health. The Executive Order recognized influenza as a public health threat and national security priority, and directed HHS to prepare and protect the nation.

The Budget invests \$998 million to continue on-going influenza activities as well as targeted increases to support this directive. This amount includes \$306 million for ASPR to modernize influenza vaccine manufacturing infrastructure and advance medical countermeasure research and development. Activities include additional clinical studies on licensure of pre-pandemic recombinant-based influenza vaccine and the advanced development of novel diagnostics, respiratory protective devices, and alternative vaccine delivery technology. The Budget also funds the Office of Global Affairs to support US leadership of international efforts on pandemic influenza preparedness.

The Budget requests \$216 million for CDC's Influenza program, an increase of \$40 million. CDC will expand influenza vaccine effectiveness monitoring systems and develop and characterize candidate vaccine viruses for vaccine manufacturers, and efforts to improve the evidence-base on non-egg-based vaccines. CDC will support whole genome characterization of more than 10,000 influenza viruses. All of these activities help build domestic capacity. CDC will also increase influenza vaccine use by removing barriers to vaccination and enhance communication to healthcare providers about the performance of influenza vaccines.

The Executive Order also calls for the development of novel technologies to speed seed vaccine development, targeted development of vaccines that protect against multiple types of virus for multiple years, and to improve adjuvants. In support of this goal, the Budget includes \$49 million for FDA to support regulatory science research and clinical assessments to promote development and access to safe and effective influenza vaccines, and \$423 million for NIH to accelerate influenza research, including universal flu vaccine development.

Emergency Preparedness

HHS plays a key role in supporting domestic and international preparedness and response to ensure our nation's safety. The Budget invests \$2.6 billion in ASPR to expand efforts to prevent, prepare for, respond to, and recover from, the adverse health effects of public health emergencies. This amount includes \$562 million for the Biomedical Advanced Research and Development Authority to maintain a robust pipeline of innovative medical countermeasures that mitigate health effects of infectious diseases and chemical, biological, radiological, and nuclear agents. It also includes \$535 million for Project BioShield to support procurement of medical countermeasures against these threats, and \$705 million for the Strategic National Stockpile to sustain and increase inventory of high-priority countermeasures such as antibiotics to treat anthrax exposure and vaccine to prevent smallpox. These investments will help HHS advance progress towards national preparedness goals.

NIH supports a robust research portfolio to develop vaccines and therapeutics that enable rapid response to public health threats including emerging microbial threats, such as extensively drug-resistant tuberculosis, emerging viral strains such as Zika, and viral hemorrhagic fevers such as Ebola. The Budget continues investments in NIH in scientific research on these new threats, and

invests \$120 million in FDA to facilitate medical countermeasure development and availability to respond in the event of a microbial or other public health threat.

Strengthening the Indian Health Service

The Administration is committed to improving the health and well-being of American Indians and Alaska Natives. This population continues to experience significant health disparities, and the Budget includes key investments to ensure quality of care. The Budget invests \$6.2 billion in IHS, which includes \$125 million for electronic health record modernization, provides funding to support IHS Services, Ending the HIV Epidemic, and Maternal Health, and includes \$125 million for high-priority healthcare facilities construction projects. The Budget proposes a new, indefinite discretionary appropriation and reforms for IHS to address Indian Self-Determination and Education Assistance Act section 105(l) lease costs.

Reforming Oversight of Tobacco Products

The Budget proposes to move the Center for Tobacco Products out of FDA and create a new agency within HHS to focus on tobacco regulation. A new agency with a mission focused on tobacco and its impact on public health would have greater capacity to respond rapidly to the growing complexity of new tobacco products. Additionally, this reorganization will allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our nation's drug, food, and medical products supply.

Providing Shelter and Services for Unaccompanied Alien Children

The Administration for Children and Families (ACF) provides shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other Federal Government department or agency. The number of unaccompanied alien children requiring care is inherently unpredictable. In FY 2019, ACF cared for 69,488 children, the highest number in the program's history. To ensure adequate shelter capacity and care in FY 2021, the Budget requests a total of \$2 billion in discretionary funds to support capacity of 16,000 licensed permanent beds, depending on operational needs, and includes a mandatory contingency fund to provide up to \$2 billion in additional resources if needed.

PROMOTE INDEPENDENCE

Promoting Upward Mobility

In the human services work at HHS, the overarching goal is to promote personal responsibility, independence, and self-sufficiency—to help Americans lead flourishing, fulfilling, independent lives. HHS programs for low-income Americans achieve this goal by supporting work, marriage, and family life. HHS seeks to better align our social safety net programs with the booming economy, and focus on work as the means to lift families out of poverty.

Many Americans are joining the workforce as the Administration's policies continue to strengthen the economy and produce historically low unemployment rates. The Administration supports working families by investing in child care, an important work support that helps families achieve independence and self-sufficiency. The Administration is working to implement policies that increase access to high-quality, affordable child care.

The Budget proposes to improve the Temporary Assistance for Needy Families (TANF) program by restoring its focus on employment and work preparation, and by targeting funds to low-income families. The proposal fundamentally changes the way the program measures success by moving to measures that focus on employment outcomes, phasing out the ineffective work participation rate. In addition, the Budget establishes Opportunity and Economic Mobility Demonstrations that allow for the streamlining of funding from multiple safety net programs to deliver coordinated and effective services. The Budget also seeks to improve consistency between work requirements in TANF and Medicaid by requiring that able-bodied individuals participate in work activities at least 20 hours per week in order to receive welfare benefits.

Supporting Child Care

Child care is an investment in both present and future generations of the workforce. However, it is also one of the biggest expenses for families and can be a barrier to work. Funding plays a critical role in helping families achieve self-sufficiency by providing parents access to a range of child care options. In FY 2018, the most recent year for which preliminary data are available, over 1.3 million children from about 813,000 low-income families received a monthly child care subsidy from the Child Care and Development Fund. The Budget provides \$5.8 billion for the Child Care and Development Block Grant and \$4.2 billion in mandatory child care funding for a total investment of \$10.0 billion in child care. The mandatory funding includes a one-time \$1 billion fund for competitive grants to states to increase child care services for underserved populations and stimulate employer investment in child care. The Budget will serve 1.9 million children.

Promoting Adoption

Adoption gives children stability and love during their childhood, and also a safe and stable environment in which to grow into responsible adults who flourish. Approximately 20,000 youth exit or “age out” of foster care each year without the safety net of a forever family, and their outcomes are often concerning. A longitudinal study found that only 58 percent graduated from high school, and only half found employment by age 24. More than a third of youth in one study had experienced homelessness at least once by age 26. Children and young adults in foster care cannot be expected to achieve the independence they need to thrive and flourish on their own—but finding them a loving forever family could change all that.

According to ACF, the number of children adopted with help from public child welfare agencies rose from 59,000 in FY 2017 to more than 63,000 in FY 2018. To sustain this momentum, ACF has launched a Call to Action for states and other stakeholders, which aims to develop and sustain key partnerships across public and private groups, including faith-based groups, with the goal of reducing the number of children in foster care and increasing the number of children who find a forever family, through adoption or otherwise.

The Adoption Assistance and Guardianship Assistance programs will provide \$4.1 billion in FY 2021 in mandatory funding to provide monthly support payments to families adopting sibling

groups or other children with special needs. Under existing law, Adoption Assistance funding will keep pace with the number of qualifying children adopted each year.

HHS promotes adoption through administrative actions and funding incentives to promote adoption, and to identify and address barriers to adoption. Initiatives include family-finding programs, focusing on identifying the barriers that exist in the recruitment and development of foster and adoptive families, and the development and dissemination of court-related practice improvements addressing barriers to timely adoptions.

Supporting Families and Preventing the Need for Foster Care

Helping families receive the care and services they need before the involvement of a child welfare agency can help prevent a child from entering foster care. The Administration has focused on primary prevention, as well as adoption, and we are starting to see better results. HHS is implementing the Family First Prevention Services Act (Family First Act), which supports services to prevent child maltreatment and the need for foster care. This groundbreaking new legislation provides the opportunity for substantial improvements in outcomes for children and families. The Budget proposes to streamline the process for evaluating evidence-based prevention services programs under the Family First Act to give states and tribes access to more programs that help prevent the need for foster care and assist kinship caregivers.

The Budget invests \$510 million for discretionary child welfare activities in ACF, including services that allow children to remain safely with their families and education and training vouchers for youth aging out of foster care. In collaboration with CMS, the Budget proposes that Qualified Residential Treatment Programs (QRTPs) be exempted from the institution for mental diseases (IMD) payment exclusion allowing children in foster care to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD.

The Budget provides \$197 million to ACF for child abuse prevention grants. These grants support increased use of evidence-based prevention programs, allowing states to explore new research opportunities and to adapt more rigorous evaluations of existing programs; demonstration projects to test the effectiveness of partnerships that strengthen family capacity and prevent child abuse through the co-location of services; and state plans for safe care of infants affected by substance use disorders.

The Budget also proposes to expand the Regional Partnership Grant program by \$40 million each year, which will increase funding for grants that help courts, child welfare agencies, and other government and community entities work together and improve practices to address the impact of substance abuse, including opioids, on child welfare. The Budget proposes an increase of \$30 million each year for the Court Improvement Program to help courts improve practices and comply with new mandates in the Family First Act.

Strengthening Efforts to Treat Serious Mental Illness and Serious Emotional Disturbances

In 2018, more than 11 million adults in the U.S. were living with a serious mental illness. More than 7 million children and youth experienced a serious emotional disturbance. They faced a greater risk of suicide and life expectancy 10 years shorter than the general population.

The Budget provides \$1.1 billion to SAMHSA for serious mental illness and serious emotional disturbances, which includes funding to support Assertive Community Treatment for Individuals with Serious Mental Illness, Community Mental Health Services Block Grant, and Children's Mental Health Services. These programs provide comprehensive and coordinated mental health services for some of the nation's most vulnerable populations and increases access to mental health services in schools. The Budget will also provide targeted flexibility for states to provide inpatient mental health services to Medicaid beneficiaries with serious mental illness.

The Budget also invests in programs that address the nation's alarming rates of suicide. Suicide is the 10th leading cause of death in the United States – responsible for more than 47,000 deaths in 2017 – and suicide rates have increased steadily for individuals of all ages. The Budget provides \$93 million for suicide prevention activities, including additional funding to expand Zero Suicide initiatives to focus on adult suicide prevention and allow communities and states to tailor strategies to prevent suicide in their local jurisdictions.

Supporting Independence for Older Adults and People with Disabilities

The Administration prioritizes community living for older adults and people with disabilities to ensure that they can maintain independence and live fully integrated in their communities. The Budget invests \$1.5 billion in the Administration for Community Living for critical direct services that enable seniors and people with disabilities to live independently, such as senior meals, in-home chore assistance, independent living skills training, employment training, and information and referral services. These programs empower older adults and people with disabilities to live independently and make critical choices about their own lives.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

HHS is responsible for more than one-quarter of total federal outlays. The Department administers more grant dollars than all other federal agencies combined. HHS is committed to responsible stewardship of taxpayer dollars, and the Budget continues to support key reforms that improve the efficiency of Departmental operations.

Advancing Fiscal Stewardship

The Administration 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.

As the Department overseeing Medicare and Medicaid, HHS is committed to exercising proper oversight of these programs to protect the millions of impacted beneficiaries and the taxpayers in general. In accordance with the direction in the Executive Order on *Improving and Protecting*

Medicare, HHS is investing in the newest technological advancements, such as Artificial Intelligence, to enhance our ability to detect and prevent fraud, waste, and abuse.

The Department is committed to reducing improper payments in Medicare, Medicaid, and Children’s Health Insurance Program (CHIP). HHS continues to enhance existing program integrity tools to address improper payments and prevent fraud, including provider screening, prior authorization, and auditing providers and plans. New methods and technologies will allow HHS oversight to reduce improper payments and adapt to the changes in healthcare as we shift from a fee-for-service to a value-based healthcare payment system.

The Budget advances new legislative and administrative proposals to strengthen the Department’s ability to address weaknesses in Medicaid beneficiary eligibility determination processes, while providing tools to facilitate the recovery of overpayments made by states. HHS also continues to support updates to Medicaid information systems that offer critical support to program integrity efforts, including the Transformed Medicaid Statistical Information System (T-MSIS) and a new Medicaid drug rebate system. In addition, HHS includes proposals that enhance oversight of Medicare Advantage and Part D plans, increase the period of enhanced oversight on new providers, and expand Medicare fee-for-service prior authorization.

Implementing ReImagine HHS

HHS supports the President’s Management Agenda through *ReImagine HHS*, the Department’s robust reform and transformation effort, organized around core goals to streamline processes, reduce burden, and realize cost savings. The effort takes an enterprise approach, affecting activities across the Department. For example, the Buy Smarter initiative plans to use new and emerging technologies to leverage the enormous purchasing power of HHS and streamline the end-to-end procurement process. The Maximize Talent initiative addresses modern-day human capital management and human resources operational challenges, resulting in key achievements: HHS’s simplified recruitment process resulted in a significant increase in the number of new hires on-boarded since implementation, and HHS was rated the “Best Place to Work in the Federal Government” out of all executive departments in 2019. As part of the Bring Common Sense to Food Regulation initiative, FDA is working to increase collaboration between food regulatory programs to minimize dual jurisdiction and improve state product safety. As a result, 48 states and territories participate in the Produce Safety Implementation Cooperative Agreement Program, which increased state large farm inspections over 400 percent in FY 2019.

ReImagine HHS efforts are also making HHS more innovative and responsive. Under the Optimizing Regional Performance initiative, HHS developed a Regional Facilities Utilization Model with \$150 million in potential savings and a footprint reduction of more than 62 percent within ten years. For the first time since 1974, HHS completed a comprehensive assessment of regions to better align with Administration priorities and improve HHS’s ability to serve Americans across the country. In addition, under the Optimize Coordination Across HHS initiative, HHS configured a new cloud environment for an administrative data hub to provide dashboarding capabilities for Operating Divisions, bringing together human resources, travel, and facilities data to inform better decision-making across the enterprise.

In FY 2021, all *ReImagine HHS* projects will reside in their permanent offices within HHS. This ensures that their work can sustainably continue going forward.

Grants Management

HHS continues to drive change for grants management government-wide. Leveraging the efforts and success of the HHS ReImagine Grants Management initiative. The Office of Management and Budget pre-designated HHS as the Grants Quality Services Management Office (QSMO) to create and manage a marketplace of solutions for grants management; govern its long-term sustainability; institute a customer engagement model; and drive the implementation of standards and solutions to modernize grants management processes and systems. Guided by a government-wide governance board, QSMOs are tasked with offering solutions that, over time, will improve quality of service and customer satisfaction; modernize and automate processes and supporting technology; standardize processes and data; and achieve efficiencies in government-wide operations and maintenance.

In FY 2018, the government awarded over \$750 billion in grants to approximately 40,000 recipients across more than 1,500 programs.

Full designation as the Grants QSMO is contingent upon approval of a 5-Year Implementation Plan and budget estimate in alignment with the published QSMO Long-term Designation Criteria. HHS is developing a vision and strategy to inform the Grants QSMO 5-Year Implementation Plan, with significant engagement with stakeholders to ensure the Grants QSMO can meet their diverse needs.

Regulatory Reduction

HHS is committed to streamlining the regulatory process and evaluating necessary steps to eliminate or change regulations that impose unnecessary burden. Burdensome regulations can drive up costs of healthcare, while poorly designed regulations can come between doctors and patients, reducing the quality of care and the essential trust to that relationship. From FY 2017 to FY 2019, HHS succeeded in cutting the economic burden of its regulations by \$25.7 billion through 46 deregulatory actions. HHS had the largest deregulatory impact of any Cabinet agency during this time period.

HHS is using the power of new cognitive technologies for greater operational effectiveness and research insights, including regulatory reduction. HHS used an Artificial Intelligence-driven regulation analysis tool and expert insight to analyze the Code of Federal Regulations, seeking potential opportunities to modernize regulations. HHS since launched a Department-wide Regulatory Clean-Up Initiative to implement changes based on these findings, by reviewing and – where a change is warranted – addressing incorrect citations and eliminating the submission of triplicate or quadruplicate of the same citation.

HHS is working to implement the provisions of the Executive Order on *Promoting the Rule of Law through Improved Agency Guidance Documents*. This Executive Order will accomplish important policy goals that will improve HHS guidance practices in the long term. Prior to the issuance of this Executive Order, several Federal agencies issued internal memoranda regarding the appropriate use of guidance. The Executive Order requires agencies to now go a step further

and codify certain good guidance practices and policies into Federal regulations. By August 27, 2020, each agency must finalize regulations to set forth processes and procedures for issuing guidance documents. In addition, by February 28, 2020, Federal agencies must establish a single, searchable database on its website that contains, or links to, all of the agency's guidance documents currently in effect. Any guidance document not included in the guidance website is deemed rescinded. HHS is committed to meeting the President's timelines.