



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Funding Highlights:

- The mission of the Department of Health and Human Services (HHS) is to protect and strengthen the health and well-being of Americans through effective health and human services for the American people and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.
- The Budget addresses the Nation's critical public health needs through investments that combat the opioid epidemic and support mental health services, increase efforts to eliminate infectious diseases, support high priority biomedical research, speed access to new innovative technology, and enhance emergency preparedness and health security. The Budget also offers strategies to reduce drug-related costs, improve the health of older Americans, and strengthen work requirements to promote self-sufficiency.
- The Budget also invests in child care to support America's working families, and promotes work among able-bodied adults receiving assistance.
- The 2020 Budget requests \$87.1 billion for HHS, a 12-percent decrease from the 2019 estimated level. The Budget proposes \$1,248.8 billion in net mandatory health savings, reducing longer-term deficits.

The President's 2020 Budget:

The Budget supports the mission of HHS while creating a streamlined Federal Government that promotes the most efficient and effective use of taxpayer dollars. The Budget invests in the highest priority public health needs of the Nation—combatting the opioid epidemic, supporting services for serious mental illness, and preparing for public health threats. The Budget launches an initiative to end HIV/AIDS in America, an ambitious, yet necessary effort to eliminate a disease that has plagued the Nation for more than three decades. In addition, the Budget takes bold steps to increase access and reduce drug costs for Americans, empowers consumers and States to regain control over health-care and increase affordability and consumer choice, and strengthens and protects the Medicare program for America's seniors.

Combats the Opioid Epidemic. In addition to progress already being made by the Administration, the Budget makes significant investments to combat the drug abuse and opioid epidemic, which claimed more than 70,000 lives in 2017. In the last year, the President released a new Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand, secured \$6 billion in new resources in the 2018 and 2019 to combat the epidemic, and signed the SUPPORT for Patients and Communities

Act, which enhances the Federal response to the opioid epidemic. The number of opioid prescriptions dispensed monthly has fallen by more than 20 percent since the beginning of 2017 and preliminary data from the Centers for Disease Control and Prevention (CDC) suggests that the number of drug overdose deaths are finally starting to level off or even decline.

The Budget sustains critical investments in surveillance, prevention, treatment, access to overdose reversal drugs, recovery support services, and research. For example, the Budget includes \$1.5 billion for State Opioid Response grants, which fund prevention, treatment, and recovery support services in all States and Territories. The Budget maintains more than \$1 billion in the National Institutes of Health (NIH) for opioid and pain research, including the continuation of the Helping to End Addiction Long-term Initiative that began in 2018.

The Budget includes \$221 million to expand the behavioral health workforce, including an additional \$4 million for a new effort authorized in the SUPPORT for Patients and Communities Act to increase the number of providers that are able to prescribe medication-assisted treatment. In addition, the Budget maintains \$120 million to support treatment and prevention of substance use disorder, including opioid abuse, in rural communities at the highest risk. The Budget also enables States to more easily provide one year of post-partum Medicaid coverage for women with a substance use disorder, to improve health outcomes for mothers and their infants.

The Budget provides \$476 million for CDC to continue current activities in support of all 50 States and Territories, as well as local jurisdictions, to track and prevent overdose deaths. CDC would prioritize expanding support to States and Territories to collect and report real-time overdose and robust overdose mortality data. The Budget also provides \$58 million for CDC to address the infectious disease consequences of the opioid epidemic. Approximately 95 percent of new Hepatitis C infections and one of every seven new HIV infections is due to injection drug use. CDC would focus on areas most at risk for outbreaks of HIV and hepatitis due to injection drug use.

Addresses Mental Health Needs. Mental illness, especially serious mental illness, takes a toll on individuals, families, and communities all across the United States. In 2017, only 7.5 million of the 11.2 million adults suffering from serious mental illness received mental health services in the past year. The Budget invests in activities that increase access to mental health services. The Budget includes \$723 million for the Community Mental Health Services Block Grant, which provides funding to every State to provide services to seriously mentally ill adults and children with serious emotional disturbances, and \$150 million for Certified Community Behavioral Health Centers, which provide comprehensive healthcare services, including 24-hour crisis response services to individuals with serious mental illness. The Budget also makes new targeted investments to help divert seriously mentally ill individuals away from the criminal justice system and into treatment, and to increase the access to evidence-based comprehensive services. In addition, the Budget contains important investments for children and young adults, including \$125 million for Children's Mental Health Services and \$133 million for school violence prevention. The Budget funds important suicide prevention activities, such as the suicide lifeline and activities to address the high suicide rates in middle-age and older adults.

Reforms Drug Pricing and Payment. The Administration's comprehensive drug pricing strategy addresses the problem of high drug prices, provides greater access to lifesaving medical products, and ensures that the United States remains the leader in biomedical innovation. Consistent with the Administration's *American Patients First Blueprint*, the Budget proposes strategies targeted at increasing competition, encouraging better negotiation, incentivizing lower list prices, and lowering out-of-pocket costs for beneficiaries.

- **Modernizes the Medicare Part D Prescription Drug Benefit**—In the past year, the Administration made great strides to better equip plans with the tools necessary to manage drug spending in the Part D program. The Budget builds on this progress by addressing the misaligned incentives of the Part D benefit structure. The proposed changes are designed to: encourage utilization of higher value drugs by eliminating cost-sharing for generic drugs for beneficiaries who receive the low-income subsidy; remove the competitive disadvantage placed on generic drugs that increases spending for both beneficiaries and the Government; and provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap.

"One of my greatest priorities is to reduce the price of prescription drugs. In many other countries, these drugs cost far less than what we pay in the United States. That is why I have directed my Administration to make fixing the injustice of high drug prices one of our top priorities. Prices will come down."

President Donald J. Trump
January 30, 2018

- **Reduces Costs for Part B Drugs**—The Budget addresses unnecessary barriers to free-market competition in Part B and proposes reforms to payment for Part B drugs, which heavily influences physician-prescribing behavior. Longstanding challenges in Part B include the lack of competition among drugs with similar health effects and limited tools to encourage lower drug prices. To address these challenges, the Budget includes proposals targeted at: removing the three-year payment protection of average sales price (ASP) plus six percent for certain new drugs provided in outpatient hospitals; deterring anti-competitive behavior from drug manufacturers that exploit aspects of the patent system to keep out competition; and moving coverage of some Part B drugs to Part D to reduce spending while protecting beneficiaries from increased out of pocket costs.

In addition, the Budget limits growth in Part B drug payment to an inflation benchmark and mandates manufacturers report ASP data for all Part B drugs to improve payment accuracy. The Budget also modifies hospitals' payment for drugs acquired through the 340B drug discount program by rewarding hospitals that provide charity care and reducing payments to hospitals that provide little to no charity care.

- **Increases Access to More Affordable Generics Through Greater Competition**—The Budget would include a number of proposals to speed development of generics and eliminate loopholes that have allowed drug companies to use the regulatory framework to hinder competition. The Budget would:
 - Reform the current 180-day exclusivity forfeiture provision for first generics so that first generics do not block subsequent generics from U.S. Food and Drug Administration (FDA) approval.
 - Clarify FDA's approach in determining whether a new drug is a new chemical entity to ensure that only truly innovative new drugs receive an additional five years of exclusivity.
 - Enhance FDA authority to address abuse of petition process so FDA has greater flexibility to summarily deny petitions when circumstances indicate that the primary purpose of the petition is to delay FDA approval.

- Enable FDA to tentatively approve a subsequent generic application, which would start the 180-day exclusivity clock, when a first to file generic application cannot be approved due to deficiencies.
- Improves Program Integrity—The Budget proposes to improve the integrity of the 340B program and ensure that benefits are used to help low-income and uninsured patients. This proposal includes broad regulatory authority for the 340B Drug Pricing Program to set enforceable standards of program participation and requires all covered entities to report on use of program savings.
- Lowers Costs and Increases Flexibility for Medicaid Prescription Drugs—The Budget proposes removing the cap on Medicaid manufacturer drug rebates, to ensure rebates reflect all price increases for a drug. In addition, the Budget includes new demonstration authority allowing States to test innovative approaches for Medicaid prescription drug coverage. Under the demonstration, participating States would test a closed formulary and negotiate prices directly with manufacturers. The Budget also prevents manufacturers from using authorized generics to lower their rebate obligations, and includes payment changes so State Medicaid programs do not overpay for generic drugs, saving money for States and taxpayers.

"[U]nder this Administration, we are putting American patients first...I've instructed Secretary Azar to begin moving forward on reforms that will bring soaring drug prices back down to earth."

President Donald J. Trump
May 11, 2018

Empowers States and Consumers to Reform Healthcare.

Under the Patient Protection and Affordable Care Act (PPACA) healthcare spending has increased significantly, particularly premiums for families without employer-sponsored coverage who don't qualify for Obamacare subsidies. To help expand families' health coverage options, the President signed into law the Tax Cut and Jobs Act, which eliminated Obamacare's individual mandate penalty, and took swift administrative actions that empower individuals to purchase health coverage that best suits their needs. Some new flexibilities already implemented include expanding access to Association Health Plans for employers and many self-employed individuals, extending the duration and renewability of Short-Term Limited Duration Insurance, and proposing to allow employers to offer health reimbursement arrangements to employees for purchasing individual market coverage.

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First, the Budget continues to support a two-part approach, starting with enactment of legislation modeled after the Graham-Cassidy-Heller-Johnson bill proposed in September 2017, followed by enactment of additional reforms to help set Government healthcare spending on a sustainable fiscal path that leads to higher value spending. Beginning in 2021, the Market-Based Health Care Grant Program, the Medicaid block grant, and the per capita cap program are set to grow at the Consumer Price Index. These programs would support States as they transition to more sustainable healthcare programs and encourage States to pursue innovative ideas that aim to curb costs moving forward. The Budget acknowledges the importance of ensuring protections for individuals with pre-existing conditions and States would be required to include such plans in their applications for these grants. Specifically, States would be required to allocate at least 10 percent of their grant funding to

be used to ensure protections for high-cost individuals, including those with pre-existing conditions. States would have the flexibility to design an approach that best allows States to meet this goal. The two-part approach would also provide relief for States and consumers from many of the PPACA's insurance rules and pricing restrictions that have resulted in a lack of affordable coverage options. This new flexibility would build on the Administration's regulatory actions and would empower more people to buy insurance plans that work for them, a substantial benefit to middle class families who do not receive coverage through the workplace or do not qualify for subsidies.

The Budget also proposes to give States additional flexibility over their Medicaid programs by transferring control of Medicaid transformation efforts locally where it belongs. The Administration recognizes that the only way to reform Medicaid and set it on a sound fiscal path is by putting States on equal footing with the Federal Government to implement comprehensive Medicaid financing reform through a per capita cap or block grant. A new Federal-State partnership is necessary to eliminate inefficient Medicaid spending, including repeal of the Medicaid expansion, and reducing financing gimmicks such as provider taxes. The Budget would empower States to design State-based solutions that prioritize Medicaid dollars for the most vulnerable and support innovation.

The Budget emboldens individuals to take charge of their healthcare needs and own their healthcare spending, while protecting them from large unexpected costs. Currently, too many Americans are gouged by unfair and often surprise bills for hospital care and for pharmaceutical drugs. The President is committed to addressing this issue and proposes that the Congress partner in these efforts to increase healthcare price transparency of providers, suppliers, and insurers, including curtailing surprise medical bills. This would not only help protect consumers from unexpected healthcare costs, but would also empower them to make more informed healthcare decisions. Such price transparency may lead to more robust competition between actors in the healthcare supply chain, ultimately lowering costs for patients and plan sponsors such as employers, associations, and unions. To further encourage increased consumer engagement, the Budget immediately requires all subsidized individuals that purchase health coverage on the Federal Exchange to contribute something to their healthcare coverage.

Health savings accounts (HSAs) are a tool to increase consumer engagement and lower healthcare spending without negatively affecting quality. The Budget includes a series of reforms to expand access to HSAs. Under tax provisions originally enacted in 2003, persons enrolled in certain high deductible health plans—which are generally referred to here as HSA-qualified plans—may contribute to savings accounts to pay for healthcare expenses on a tax-preferred basis. The Budget proposes that all plans with an actuarial value of up to 70 percent may be integrated with HSAs. This would enable consumers to utilize the benefits of HSAs with a larger number of innovative plan designs.

Together, these reforms and consumer protections aim to encourage innovation from States, help consumers with the costs of their healthcare, and focus Medicaid resources on the most vulnerable individuals, while continuing to protect those with high healthcare needs.

Modernizes Medicaid to Enhance State Flexibility. The Budget would empower States with additional tools to strengthen their Medicaid programs and empower States to further modernize Medicaid benefits and eligibility. The Budget would give States additional flexibility around benefits and cost-sharing, such as increasing copayments for non-emergency use of the emergency department to encourage appropriate use of healthcare resources, as well as allowing States to consider savings and other assets when determining Medicaid eligibility. In addition, the Budget would allow States to streamline appeals processes and delegate authority to another entity, to help eliminate duplicative appeals and reduce beneficiary confusion. The Budget would also bolster the safety net available to

States experiencing Children's Health Insurance Program (CHIP) funding shortfalls, while eliminating funding streams that do not support children's health.

Reduces Wasteful Medicaid Spending. The Budget takes numerous steps to reduce wasteful Medicaid spending. The Budget proposes eliminating loopholes that some States use to shift and increase costs to Federal taxpayers, and for the Centers for Medicare and Medicaid Services (CMS) to issue guidance ensuring that State Medicaid supplemental payments to hospitals and other providers are supported by robust and timely data. The Budget also proposes realigning the Federal matching payments for State Medicaid eligibility workers with other administrative costs, providing a fair balance between Federal and State resources for these activities. In addition, the Budget extends current law reductions in Medicaid disproportionate share hospital payments, and proposes to limit reimbursement to Government providers to no more than the cost of providing services to Medicaid beneficiaries.

Improves Program Integrity for Medicare, Medicaid, and CHIP. The Budget includes several legislative proposals and administrative actions to reduce monetary loss from improper payments and strengthen the integrity and sustainability of Medicare, Medicaid, and CHIP. Combined with additional funding investments in the Health Care Fraud and Abuse Control program, these policies provide CMS with additional resources and tools to combat waste, fraud, and abuse and to promote high-quality and efficient healthcare.

The Budget proposes to expand the Medicare program's authority to conduct prior authorization on items or services at high risk of fraud and abuse. The proposal helps ensure that the right payment goes to the right provider for appropriate services and saves taxpayer dollars from paying for Medicare services that are not medically necessary. The Budget also addresses healthcare overutilization and waste by expanding CMS's work in notifying providers that prescribe drugs or perform procedures in excess of their peers. In addition, the Budget proposes to strengthen Medicare Advantage program integrity by ensuring initial risk-adjustment payments are paid correctly and expanding risk-adjustment data validation audits.

Addressing vulnerabilities to Medicaid program integrity is a key priority for the Administration, and the Budget includes a number of proposals to ensure sound stewardship and oversight of Medicaid resources. For example, the Budget proposes to strengthen CMS's ability to partner with States to address improper payments and ensure Federal recovery of incorrect eligibility determinations, an area of concern identified by the HHS Office of Inspector General. In addition, the Budget allows States flexibility to more frequently assess beneficiary eligibility, ensuring resources are available for the millions of Americans who depend on Medicaid's safety net.

Strengthens and Protects the Medicare Program. The Budget proposes to reduce wasteful spending and incentivize efficiency and quality of healthcare in Medicare, extending the solvency of the program for America's seniors consistent with the President's promise to protect Medicare. The Budget brings transparency to several Medicare payments to hospitals, by financing payments not directly related to Medicare's health insurance role outside the Medicare Trust Fund and tying future growth to inflation growth; the Budget also reduces Medicare's spending on beneficiaries' unpaid cost sharing obligations, consistent with private sector business practices. In addition, the Budget proposes realigning incentives through site neutral payment reform to ensure accurate payments across different healthcare provider types are based on patient characteristics rather than site of care. By ensuring payments are accurately aligned with the costs of care and strengthening providers accountability to improve quality and health outcomes, the Budget protects seniors from excessive out-of-pocket costs and improves the standard of care they receive. The Budget also supports the Administration's commitment to reduce provider burden so providers can focus on patient care by

eliminating reporting burden and low-value metrics in performance-based payment for physicians, improving incentives for physicians to participate in advanced payment models that reward high-value healthcare delivery, and providing CMS with greater flexibility in beneficiary education and quality assurance.

The Budget demonstrates the Administration's commitment to ensuring Medicare beneficiaries have access to timely and appropriate care, by reprioritizing primary care through a budget neutral increase to payments for primary care providers. The Budget proposes to expand seniors' personal control and introduce more consumer power into the healthcare market by allowing Medicare beneficiaries to make tax-deductible contributions to HSAs associated with high deductible health plans offered by their employers or Medicare Advantage plan. The Budget would extend Medicare's solvency by roughly eight years.

Supports Access to Innovative New Medical Technology. Consistent with the Administration's commitment to addressing barriers to healthcare innovation, the Budget includes several administrative actions and a legislative proposal aimed at ensuring Medicare beneficiaries have access to critical and life-saving new cures and other technologies that improve beneficiary health outcomes. In particular, the policies would instill greater transparency and consistency in how Medicare covers and pays for innovative technology. The Budget also proposes to test new ways of covering and paying for certain devices. For Medicare beneficiaries with diabetes, to improve health outcomes and cost savings for both beneficiaries and the Government, the Budget proposes expanding coverage of disposable devices that substitute for a durable device for use in the management and treatment of diabetes.

Launches an Initiative to End the HIV Epidemic in America. For more than three decades, the Nation and the world have confronted the challenges posed by HIV and AIDS. More than 700,000 Americans have lost their lives to HIV since 1987. Each year, there are approximately 40,000 new HIV infections in the United States, the majority clustered in a limited number of counties. For the first time in modern history, America has the ability to end the epidemic, with the availability of biomedical interventions such as antiretroviral therapy and pre-exposure prophylaxis (PrEP). This initiative is the first step toward this goal.

The Administration is proposing a new multiyear initiative focused on accelerating progress to eliminate new HIV infections in America, with the goal of reducing new infections by 75 percent within five years, and by 90 percent within 10 years. The 2020 Budget provides a total of \$291 million to HHS for the Ending HIV Epidemic Initiative. Of this amount, the Budget provides \$140 million for CDC to reduce new HIV infections by working closely with State and local health departments on intensive testing and referral to care efforts in areas of the Nation that constitute the majority of new infections. The Budget also includes \$120 million for the Health Resources and Services Administration to deliver additional care and treatment for people living with HIV through the Ryan White HIV/AIDS Program and to supply testing, evaluation, prescription of PrEP, and associated medical costs for people who are at risk for HIV infections through the Health Centers program. In addition, the Budget prioritizes the reauthorization of the Ryan White program to ensure Federal funds are allocated to address the changing landscape of HIV across the United States. Reauthorization of the Ryan White Program should include data-driven programmatic changes as well as simplifying and standardizing certain requirements and definitions. These changes would ensure Federal funds may be allocated to populations experiencing high or increasing levels of HIV infections/diagnoses while continuing to support Americans already living with HIV across the Nation. The Indian Health Service would also receive funding to enhance HIV testing and linkages to care. In addition, the Initiative would leverage NIH current regional Centers for AIDS Research to refine implementation strategies to assure effectiveness of prevention and treatment.

Game-changing Progress on HIV Drugs

With advances in research and development, biomedical tools are now available to end the HIV epidemic in America. HIV antiretroviral therapy has progressed substantially from the drugs available in the 1990s. What were formerly multi-pill, high-toxicity regimens have progressed to more potent, one pill per day regimens with few side effects. In addition, there is now a groundbreaking single pill, pre-exposure prophylaxis (PrEP), which is proven to prevent HIV transmission. There are more than 1.2 million Americans at high risk for HIV for whom PrEP is indicated, yet only about 10 percent are currently on preventive therapy.

Reforms and Improves the U.S. Public Health Service Commissioned Corps (Corps). The Budget proposes to transform the Corps into a leaner and more efficient organization that would be better prepared to respond to public health emergencies and provide vital health services. The Budget significantly reduces the number of Corps officers working in non-mission critical positions and increases the number of officers working in mission critical positions. The Budget creates a Ready Reserve Corps similar to those used by other uniformed services to provide additional surge capacity during public health emergencies. The Budget also makes changes to the funding structure of the Corps' retirement pay and survivor's benefits to align with how the Government pays for almost all civilian and military retirement costs.

Prioritizes Critical Health Research. The Budget provides \$33 billion to improve public health by advancing knowledge of living systems to tackle major health challenges and improve diagnosis, prevention, and treatment of diseases and disorders. With this investment, NIH would continue to address the opioid

epidemic, make progress on developing a universal flu vaccine, and support the next generation of researchers. NIH has provided upfront funding for certain projects in recent years and would continue this approach in 2019 and 2020 to facilitate efficient management of NIH resources across multiple years. The Budget also supports cutting-edge intramural research by addressing the backlog of repair and improvement across NIH facilities. In addition, the Budget includes a new, dedicated effort to support research and develop new treatments for childhood cancer. Cancer is the leading cause of death from disease among children and adolescents in the United States. The basic biology of childhood cancers is not fully understood and differs from that of adult cancers. The Budget includes increased funding and an innovative initiative to enable the Nation's best researchers and doctors to learn from every child with cancer, providing the opportunity to comprehend finally the unique causes and the best cures for childhood cancer.

Strengthens Health Services for American Indians and Alaska Natives. The Budget expands access to direct health services for American Indians and Alaska Natives by funding the staffing and operations of new facilities and extending services to newly recognized Tribes. In addition, the Budget boosts recruitment and retention efforts for qualified health professionals by funding competitive employment packages for positions with high vacancies and building new staff quarters at remote sites. The Budget also begins a multiyear effort to modernize the Indian Health Service's electronic health record (EHR) system to promote interoperability between Federal health systems, as the Department of Veterans Affairs transitions to a new EHR system.

Enhances Emergency Preparedness and Health Security. Infectious disease outbreaks whether naturally occurring, such as an influenza pandemic, deliberate, or accidental, remain a serious threat to the U.S. homeland. HHS undertakes a variety of activities to prevent, mitigate, and respond to outbreaks and other public health threats. The Budget continues support for a variety of preparedness and response programs across HHS.

The Budget includes an increase of \$10 million for the Strategic National Stockpile, compared to 2019 enacted, to enhance medical preparedness for chemical, biological, radiological, and nuclear threats. The Budget supports priority HHS biodefense and emergency preparedness such as the Biomedical Advanced Research and Development Authority, BioShield, and pandemic influenza. This funding would enable HHS to continue to build on investments to protect the civilian population in the event of public health emergencies related to infectious disease outbreaks, and other man-made crises.

As newly evolved strains of drug-resistant influenza viruses emerge that pose a significant threat to public health, as seen with the 2017 H7N9 avian influenza outbreak in China, the Budget continues to build on previous investments in pandemic preparedness and response capacity. Through the Assistant Secretary for Preparedness and Response and the Office of Global Affairs, the Budget provides \$260 million to support investments in critical domestic influenza vaccine manufacturing facility infrastructure, continue the advanced research and development of improved vaccines, therapeutics, and rapid in-home diagnostics, and support international pandemic preparedness. The Budget also includes an increase of \$10 million for CDC's influenza activities compared to 2019 enacted to support vaccine effectiveness studies, help expand the production capacity of cell-grown vaccine candidates, and undertake other high priority flu activities in support of the Administration's efforts to modernize influenza vaccines. The Budget also includes \$50 million within CDC to build up the Infectious Diseases Rapid Response Reserve Fund. These funds provide needed flexibility for HHS agencies to quickly respond to emerging health threats as they arise.

The Budget includes \$100 million to support CDC's global health security activities, an increase of \$50 million compared to 2019 enacted. The Global Health Security Agenda is a multiyear global initiative to reduce infectious disease threats by strengthening the capacity of other countries to contain outbreaks at their source. Containing the spread of deadly infectious diseases through efficient biodefense capabilities is vital to protect the homeland and preserve U.S. national and economic security. CDC will implement a regional hub office model, allowing staff to more efficiently work in multiple countries in a region, as needed, to support health security priorities. CDC will primarily focus its activities on areas where it has seen the most success: lab and diagnostic capacity; surveillance systems; training of disease detectives; and establishing strong emergency operation centers.

Advances Medical Product Safety. The Budget provides \$6.1 billion in total resources for FDA, \$643 million more than the 2019 estimated level. The Budget includes \$55 million to strengthen FDA's activities in response to the Nation's opioid crisis, \$55 million to advance digital technology, \$13.5 million to ensure that compounded drugs are safe and effective, and \$20 million for a pilot program to develop and test technology that could detect pathogens in the blood supply.

Tackles the Epidemic of Youth E-Cigarette Use. The Budget includes a new user fee on e-cigarettes and other electronic nicotine delivery system products and proposes new FDA authority to collect user fees in support of its regulatory oversight of new tobacco and nicotine related products in the future as appropriate. The proposal would amend current law to add e-cigarette manufacturers and importers to a list of product categories subject to the user fee. The FDA's annual user fee cap of \$712 million would be increased by \$100 million and future collections of all tobacco related products would be indexed to inflation. This proposal would ensure that FDA has the resources to address today's alarming rise in youth e-cigarette use as well as new public health threats of tomorrow. New tobacco or nicotine products that are regulated by FDA should also pay a user fee, just as other tobacco related products that are subject to FDA's user fee.

Serves Older Americans. The Budget prioritizes funding for programs that address the needs of older Americans, many of whom require some level of assistance to continue living independently

or semi-independently within their communities. This funding provides critical help and support to seniors, providing direct services such as respite care, transportation assistance, and personal care services. These services also include \$907 million for senior nutrition programs. This funding is estimated to provide 221 million meals to more than 2.3 million older Americans nationwide.

Strengthens Work Requirements to Promote Self-Sufficiency. The Budget improves consistency between work requirements in federally funded public assistance programs, including Medicaid and Temporary Assistance for Needy Families (TANF), by requiring that able-bodied, working-age individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This would enhance service coordination for program participants, improve the financial well-being of those receiving assistance, and ensure federally funded public assistance programs are reserved for the most vulnerable populations.

Supports Children and Families in Achieving Their Potential. The Budget continues to invest in programs that help American families and children thrive. The Budget's investments in child care and early learning would help families access and afford the care they need while they work, go to school, or enroll in job training. The Budget maintains funding for Head Start and the Child Care and Development Block Grant at HHS. The Budget also proposes a \$1 billion one-time mandatory investment for States to build the supply of care and stimulate employer investment in child care.

The Budget also supports States in providing key services to children and youth by increasing State flexibilities and reducing administrative burdens in foster care. These child welfare reforms focus on preventing the need for foster care unless absolutely necessary to ensure families can remain intact. In addition, the Budget promotes evidence-building and innovation to strengthen America's safety net, proposes improvements to the TANF program, and supports efforts to get noncustodial parents to work. Together, these proposals reflect the Administration's commitment to helping low-income families end dependency on Government benefits and promote the principle that gainful employment is the best pathway to financial self-sufficiency and family well-being.

Expands Statutory Access to the National Directory of New Hires (NDNH) for Program Integrity and Evidence Building. The Budget includes a package of proposals to provide valuable employment and earnings data—NDNH—for program integrity and evidence building activities, while ensuring privacy and security safeguards. Program integrity proposals to strengthen eligibility verification and/or reduce improper payments include those at HHS's CMS, the Railroad Retirement Board, and the Department of the Treasury's Do Not Pay Business Center on behalf of agencies with statutory access to NDNH. Evidence-building proposals include providing access for statistical agencies and evaluation offices, as well as access for State agencies to administer child support, workforce, and vocational rehabilitation programs. The package is detailed in *Analytical Perspectives*, Chapter 6, "Building and Using Evidence to Improve Government."