DEPARTMENT OF HEALTH AND HUMAN SERVICES
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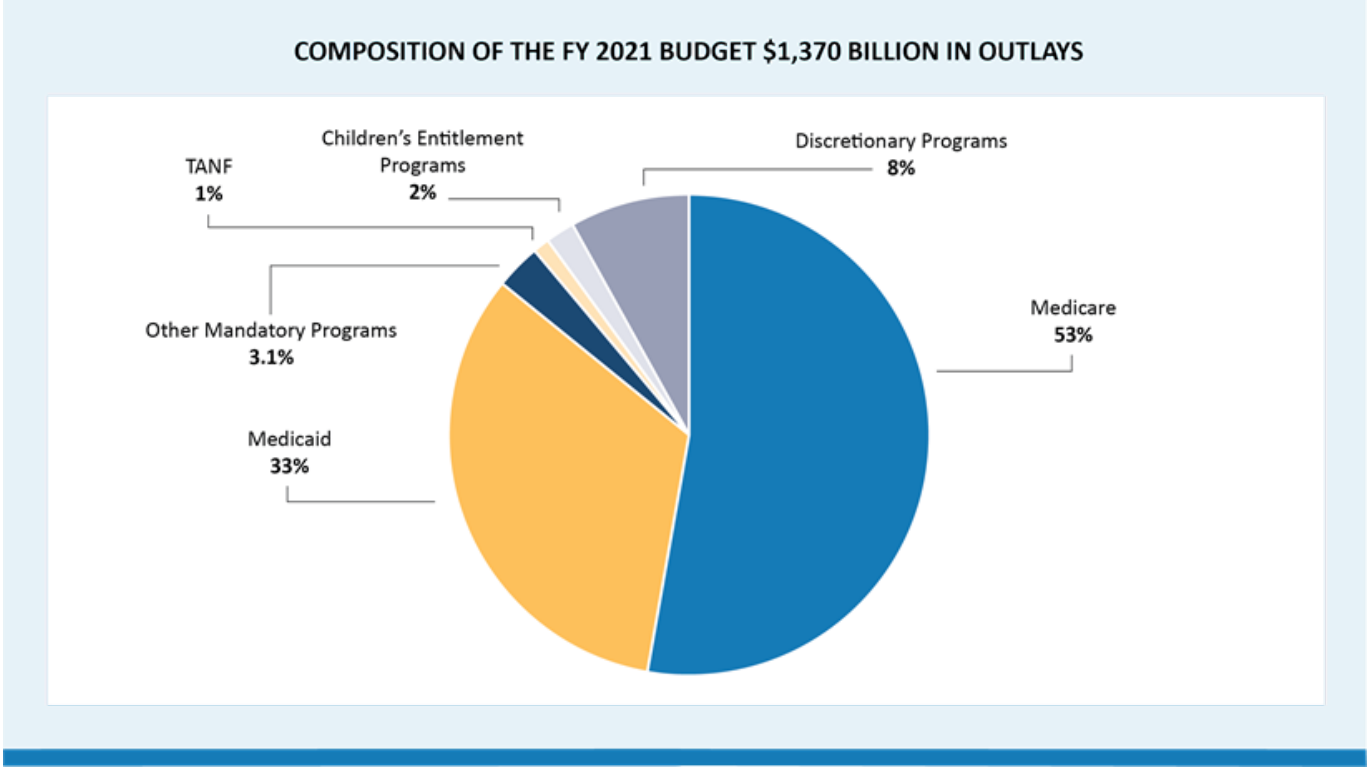
PUTTING AMERICA'S HEALTH FIRST
FY 2021 President's Budget for HHS

dollars in millions	2019	2020	2021
Budget Authority /1	1,284,349	1,368,202	1,427,609
Total Outlays	1,214,172	1,322,396	1,370,489

1/ The Budget Authority levels presented here are based on the Appendix, and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.



General Notes

Numbers in this document may not add to the totals due to rounding. Budget data in this book are presented "comparably" to the FY 2021 Budget, since the location of programs may have changed in prior years or be proposed for change in FY 2021. This approach allows increases and decreases in this book to reflect true funding changes. The FY 2020 and FY 2021 mandatory figures reflect current law and mandatory proposals reflected in the Budget.

PUTTING AMERICA'S HEALTH FIRST

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. We fulfill that mission by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

The President's Fiscal Year (FY) 2021 Budget (Budget) reflects the Administration's commitments to advance a patient-centered healthcare system, protect the lives of the American people, promote independence, and streamline federal programs.

The Budget proposes $94.5 billion in discretionary budget authority and $1.3 trillion in mandatory funding. These strategic investments ensure the Department's programs work well for the people they serve, and take crucial steps towards a future where these programs enhance and protect the health and well-being of every American.

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 their prices 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 PRESIDENT'S EXECUTIVE ORDER ON MEDICARE WILL:

Open up new options for plans within Medicare Advantage and test out new benefits

Accelerate Medicare's ability to pay for the latest medical technology

Pay doctors for the time they spend with patients, rather than procedures or paperwork

Cut waste, fraud, and abuse in Medicare that undermines the program

Help healthcare professionals like nurses practice to the top of their license

The budget contains 50 proposals – 42 legislative and 8 administrative – that respond to the Executive Order's directives.

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, including $169 million in new resources. Funding expands State Opioid Response grants in the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide direct 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 psychostimulants, particularly 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 abuse 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

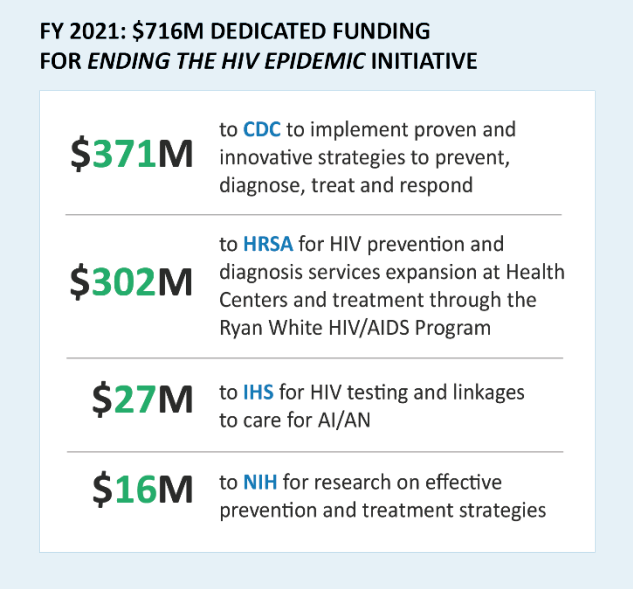
In the 2019 State of the Union, President Trump announced a bold new initiative to reduce new HIV infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 400,000 HIV infections in that time period. This initiative focuses on four key strategies:

- 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 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.

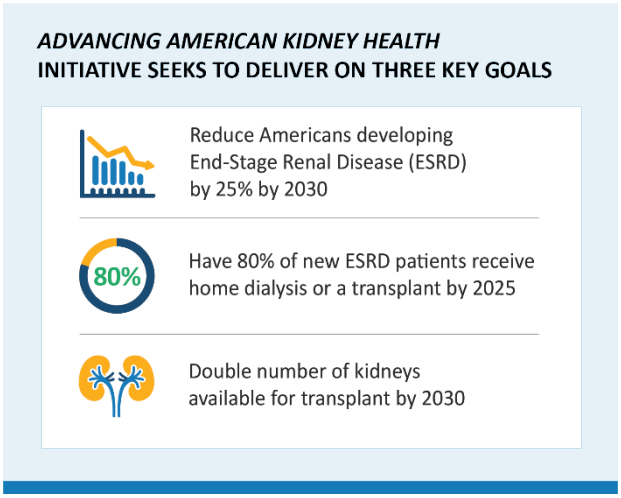
Advancing American Kidney Health

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 and the Telehealth Network Grant Program at HRSA, which supports substance abuse prevention, treatment, and recovery services in high-risk rural communities, and promotes telehealth technologies for healthcare delivery. 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 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, Federally Qualified Health Centers, as well as IHS and tribal facilities to be distant site providers for Medicare telehealth 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 the Food and Drug Administration (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 expand and 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 for IHS to address growing 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 law enforcement authorities. 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 all 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.

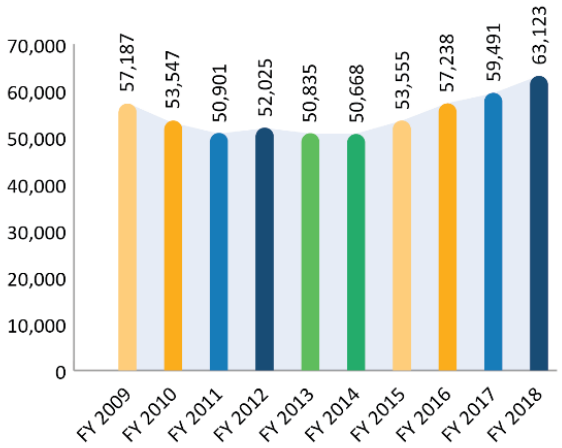
Supporting Child Care

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.

NUMBER OF CHILDREN ADOPTED WITH PUBLIC CHILD WELFARE AGENCY INVOLVEMENT



Source: U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth and Families, Children's Bureau, and Adoption and Foster Care Analysis and Reporting System (AFCARS)

According to ACF, the number of children adopted with help from public 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 and 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; state plans for safe care of infants affected by substance use disorders; and increased use of evidence-based prevention programs in local communities.

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. OMB 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.

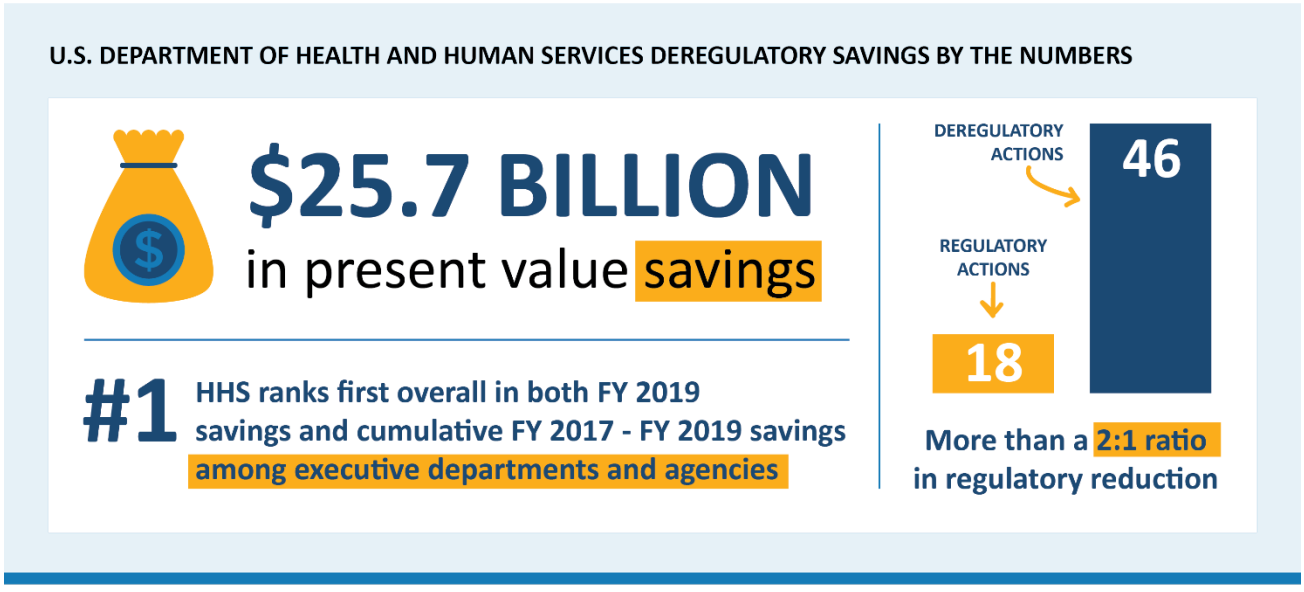
In FY 2018, the government awarded over $750 billion in grants to approximately 40,000 recipients across more than 1,500 programs.

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.

HHS BUDGET BY OPERATING DIVISION /1

dollars in millions	2019	2020	2021
Food and Drug Administration /3			
Budget Authority	3,147	3,267	3,293
Outlays	2,831	3,366	3,552
Health Resources and Services Administration			
Budget Authority	12,000	12,149	11,444
Outlays	11,575	11,791	11,951
Indian Health Service			
Budget Authority	5,939	6,241	6,391
Outlays	5,455	6,530	6,479
Centers for Disease Control and Prevention			
Budget Authority	7,878	8,366	7,134
Outlays	7,736	7,790	8,174
National Institutes of Health /2,3			
Budget Authority	38,090	40,523	37,905
Outlays	34,914	37,567	39,807
Substance Abuse and Mental Health Services Administration			
Budget Authority	5,700	5,748	5,598
Outlays	4,328	6,391	5,984
Agency for Healthcare Research and Quality /2			
Program Level	454	445	0
Budget Authority	337	338	0
Outlays	322	240	303
Centers for Medicare & Medicaid Services /4			
Budget Authority	1,144,763	1,224,467	1,297,294
Outlays	1,085,909	1,181,924	1,232,275
Administration for Children and Families			
Budget Authority	61,735	61,213	54,976
Outlays	55,969	59,561	57,489
Administration for Community Living			
Budget Authority	2,139	2,218	2,097
Outlays	2,023	2,511	2,153
Departmental Management /5			
Budget Authority	508	480	347
Outlays	332	919	645

HHS BUDGET BY OPERATING DIVISION

dollars in millions	2019	2020	2021
Non-Recurring Expense Fund			
Budget Authority	-400	-350	-500
Outlays	235	661	-185
Office of Medicare Hearings and Appeals			
Budget Authority	182	182	199
Outlays	182	248	199
Office of the National Coordinator			
Budget Authority	60	60	51
Outlays	55	92	53
Office for Civil Rights			
Budget Authority	39	39	30
Outlays	28	54	38
Office of Inspector General			
Budget Authority	93	87	91
Outlays	92	119	91
Public Health and Social Services Emergency Fund			
Budget Authority	2,625	3,272	2,641
Outlays	2,571	3,058	3,332
Program Support Center (Retirement Pay, Medical Benefits, Misc. Trust Funds)			
Budget Authority	725	738	756
Outlays	823	407	284
Offsetting Collections and Allowances/6			
Budget Authority	-1,038	-668	-2,000
Outlays	-1,038	-668	-2,000
Other Collections			
Budget Authority	-173	-168	-138
Outlays	-170	-165	-135
Total, Health and Human Services			
Budget Authority	**1,284,349**	**1,368,202**	**1,427,609**
Outlays	**1,214,172**	**1,322,396**	**1,370,489**

1/ The Budget Authority levels presented here are based on the Appendix and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.

2/ The 2021 Budget includes $257 million to consolidate the Agency for Healthcare Research and Quality's activities within the National Institutes of Health. Includes transfer from the Patient-Centered Outcomes Research Trust Fund.

3/ FDA and NIH BA include the full allocations provided in 21st Century Cures Act.

4/ Budget Authority includes non-CMS Budget Authority for Hospital Insurance and Supplementary Medical Insurance for the Social Security Administration and the Medicare Payment Advisory Commission.

5/ Includes the Pregnancy Assistance Fund, the Health Insurance Reform Implementation Fund, and transfers from the Patient-Centered Outcomes Research Trust Fund; and payments to the State Response to the Opioid Abuse Crisis Account.

6/Includes savings of $1.4 billion in FY 2021 attributable to the President's Drug Pricing Allowance.

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

dollars in millions	2019	2020	2021	2021 +/-2020
Discretionary Programs (Budget Authority):				
Food and Drug Administration /3,6	3,149	3,265	3,290	+25
Program Level	*5,723*	*5,940*	*6,205*	*+265*
Health Resources and Services Administration	6,912	7,047	6,305	-742
Program Level	*11,773*	*11,909*	*11,204*	*-705*
Indian Health Service	5,804	6,047	6,233	+185
Program Level	*7,156*	*7,399*	*7,661*	*+262*
Centers for Disease Control and Prevention	6,544	6,917	5,627	-1,289
Program Level	*12,099*	*12,787*	*12,612*	*-175*
National Institutes of Health /2,3,5	37,887	40,304	37,704	-2,600
Program Level	*39,184*	*41,685*	*38,694*	*-2,991*
Substance Abuse and Mental Health Services Administration	5,688	5,737	5,598	-139
Program Level	*5,835*	*5,884*	*5,742*	*-141*
Agency for Healthcare Research and Quality /2	338	338	0	-338
Program Level	*454*	*445*	*0*	*-445*
Centers for Medicare & Medicaid Services	3,966	3,975	3,694	-281
Program Level	*6,584*	*6,390*	*6,211*	*-179*
Administration for Children and Families	26,389	24,444	20,198	-4,245
Program Level	*26,389*	*24,444*	*20,198*	*-4,245*
Administration for Community Living	2,162	2,223	2,108	-115
Program Level	*2,245*	*2,306*	*2,164*	*-143*
Office of the Secretary:				
General Departmental Management	484	480	347	-133
Program Level /4	*573*	*544*	*436*	*-109*
1/ The FY 2019 column reflects the actual levels (post transfer, disaster supplemental and others).				
2/ The 2021 Budget includes $257 million to consolidate the Agency for Healthcare Research and Quality's activities within the National Institutes of Health.				
3/ FDA and NIH BA include the full allocations provided in the 2st Century Cures Act.				
4/ GDM PL does not include estimated reimbursable BA for HCFAC or MACRA PTAC, unless otherwise indicated.				

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

dollars in millions	2019/8	2020	2021	2021 +/-2020
Medicare Hearings and Appeals	182	192	196	+5
Program Level /6	182	192	199	+7
Office of the National Coordinator	60	60	51	-10
Program Level	*60*	*60*	*51*	*-10*
Office for Civil Rights	39	39	30	-9
Program Level	46	53	57	+4
Office of Inspector General /7	87	87	90	+4
Program Level	*381*	*392*	*419*	*+28*
Public Health and Social Services Emergency Fund	2,625	2,737	2,641	-96
Program Level	*2,641*	*2,737*	*2,641*	*-96*
Discretionary HCFAC	765	786	813	+27
Accrual for Commissioned Corps Health Benefits	29	29	31	+2
Total, Discretionary Budget Authority	**103,116**	**104,706**	**94,957**	**-9,749**
NEF Cancellation and Rescissions	-400	-350	-500	-150
Discretionary Budget Authority	**102,716**	**104,356**	**94,457**	**-9,899**
Less One-Time Rescissions	*-7,670*	*-9,263*	*-8,790*	*+473*
Revised, Discretionary Budget Authority	**95,046**	**95,093**	**85,667**	**-9,426**
Discretionary Outlays	**94,992**	**102,337**	**104,342**	**+2,005**
5/ NIH BA reflects a $5 million directed transfer to OIG.				
6/ Includes funding for Office of Medicare Appeals and Departmental Appeals Board for FY 2020 and FY 2021.				
7/ FY 2020 Enacted includes $1.5 million (rounded in the table display as $2 million), for the Food and Drug Administration Transfer and $5 million for the NIH Transfer in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill.				
8/ FY 2019 Final does not include supplemental appropriations ($6 million).				

COMPOSITION OF THE HHS BUDGET
MANDATORY PROGRAMS

	2019	2020	2021	2021 +/-2020
Mandatory Programs (Outlays):/1				
Medicare	643,905	696,507	728,236	+31,729
Medicaid	409,421	447,241	448,145	+904
Temporary Assistance for Needy Families /2	16,096	16,714	15,715	-999
Foster Care and Adoption Assistance	8,599	9,389	9,955	+566
Children's Health Insurance Program /3	17,692	17,964	15,778	-2,186
Child Support Enforcement	4,117	4,324	4,370	+46
Child Care Entitlement	3,244	2,961	3,231	+270
Social Services Block Grant	1,646	1,715	352	-1,363
Other Mandatory Programs /4	15,498	23,912	40,965	+17.053
Offsetting Collections	-1,038	-668	-600	+68
Subtotal, Mandatory Outlays	1,119,180	1,220,059	1,266,147	+46,088
Total, HHS Outlays	**1,214,172**	**1,322,396**	**1,370,489**	**+48,093**

1/ Totals may not add due to rounding.

2/ Includes outlays for the TANF, and the TANF Contingency Fund.

3/ Includes outlays for the Child Enrollment Contingency Fund.

4/ Includes savings of $1.4 billion in FY 2021 attributable to the President's Drug Pricing Allowance.

Food and Drug Administration

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
FDA Programs /2				
Foods	1,078	1,100	1,128	+28
Human Drugs	1,882	1,973	2,022	+49
Biologics	402	419	425	+6
Animal Drugs and Feeds	225	239	239	+0
Medical Devices	577	600	639	+39
National Center for Toxicological Research	67	67	66	-0
Tobacco Products	667	662	763	+101
Headquarters and Office of the Commissioner	310	318	326	+8
White Oak Operations	51	54	63	+9
GSA Rental Payment	239	241	237	-4
Other Rent and Rent Related Activities	124	133	151	+18
Subtotal, Salaries and Expenses	**5,619**	**5,805**	**6,060**	**+255**
Export Certification Fund	5	5	9	+4
Color Certification Fund	10	10	10	+0
Priority Review Voucher Fees /3	8	13	13	+0
Buildings and Facilities	12	32	14	-18
21st Century Cures Act	70	75	70	-5
Over-the Counter Monograph	-	-	28	+28
Total, Program Level	**5,723**	**5,940**	**6,205**	**+265**
Current Law User Fees				
Prescription Drug	1,010	1,075	1,119	+52
Medical Device	205	220	239	+15
Generic Drug	502	513	526	+10
Biosimilars	39	42	43	+1
Animal Drug	30	31	31	+0
Animal Generic Drug	18	20	21	+0
Family Smoking Prevention and Tobacco Control Act	712	712	712	-
Food Reinspection	6	7	7	+0
Food Recall	1	1	1	+0
Mammography Quality Standards Act	21	18	19	+1
Export Certification	5	5	5	-
Color Certification Fund	10	10	10	+0
Priority Review Voucher Fees /3	8	13	13	+0
Voluntary Qualified Importer Program	5	5	6	+0
Third Party Auditor Program	1	1	1	+0
Outsourcing Facility	2	2	2	+0
Subtotal, Current Law User Fees	**2,574**	**2,675**	**2,754**	**+80**
Proposed Law User Fees				
Export Certification	--	--	4	+4

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
Food Product Innovation Fee	--	--	28	+28
Over-the Counter Monograph	--	--	28	+28
Increase to the Tobacco User Fee	--	--	100	+100
Subtotal, Proposed Law User Fees	**--**	**--**	**161**	**+161**
Less Total, User Fees	**2,574**	**2,675**	**2,915**	**+241**
Total Discretionary Budget Authority	**3,149**	**3,265**	**3,290**	**+25**
Full-Time Equivalents	17,603	17,691	17,967	+173

1/ Reflects FY 2019 Final funding level, post required and permissive transfers and rescissions.
2/ Does not reflect Budget proposal to reorganize the Center for Tobacco Products.
3/ Includes priority review voucher fees for rare pediatric diseases, tropical diseases, and medical countermeasures.

The Food and Drug Administration protects the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. FDA also advances the public health by helping to efficiently advance innovations that make medicines more effective, safer, and affordable; and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. Furthermore, FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA strengthens the nation's counterterrorism capability by ensuring the security of the food supply and fostering development of medical products to respond to deliberate and naturally occurring public health threats.

The Food and Drug Administration (FDA) protects and advances public health by protecting the nation's food supply and ensuring safe and effective drugs are available in the United States. FDA carries out these responsibilities through an array of activities ranging from preventing drug shortages, to inspecting imported food products, to fostering development of drugs and devices to respond to public health threats. FDA is responsible for oversight of more than $2.6 trillion in food, medicines, devices, and other consumer products. FDA-regulated products account for 20 percent of every dollar spent by U.S. consumers.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $6.2 billion for FDA. This total includes $3.3 billion in discretionary budget authority and $2.9 billion in user fees. The Budget:

- Invests in artificial intelligence and other emerging technologies to transform food and device safety, as well as support industry adoption of artificial intelligence technology in medical devices;
- Provides resources for regulatory work related to cannabis and cannabis derivatives, including carrying out additional policy development and research, to protect the public health and improve regulatory pathways for lawful marketing;
- Addresses critical building repairs and improvements needed to ensure FDA can efficiently carry out its responsibilities; and
- Advances the modernization of the influenza vaccine to keep Americans safer from seasonal and pandemic influenza.

ADVANCING ACCESS TO SAFE AND EFFECTIVE MEDICAL PRODUCTS

FDA oversees the safety, effectiveness, availability, and quality of an extensive range of regulated products available to Americans, including prescription and over-the-counter drugs; biologics including vaccines, blood products, and gene therapies; animal drugs; and medical devices ranging from bandages to laser surgical equipment and radiation emitting products. FDA ensures that regulated products are marketed according to federal standards and that products available to the public are safe, especially as new clinical information emerges.

In FY 2021, the Budget requests $3.8 billion for medical product safety investments. This total includes $1.8 billion in budget authority and $2.0 billion in user fees. The Budget advances FDA's highest priority activities to ensure the safety and effectiveness of medical products for the American public, such as modernizing the manufacturing process for influenza vaccines to reduce production times.

FDA Accomplishments

In calendar year (CY) 2019, FDA had several notable innovations that will result in meaningful, life-saving differences for patients. In October 2019, FDA approved a new breakthrough therapy for cystic fibrosis, making a novel treatment available to most cystic fibrosis patients including adolescents who previously had no options, and giving others access to an additional effective therapy. FDA approved the first drug for postpartum depression, providing an important new treatment option. The FDA Oncology Center of Excellence announced a new pilot program to assist oncology healthcare professionals in gaining access to unapproved therapies, with the goal of making it easier for cancer patients, their families, and healthcare professionals to access investigational therapies.

In CY 2019, FDA approved 10 biosimilars, marking a record for the number of biosimilar approvals. Overall, there are 26 approved biosimilars. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

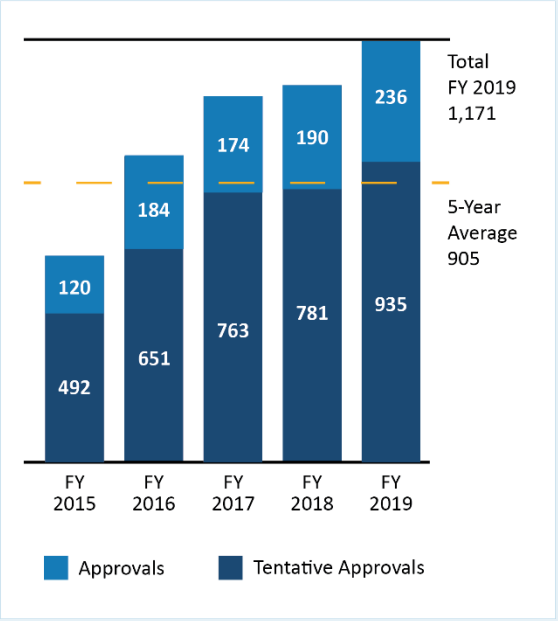
FDA has approved biosimilars to treat a range of conditions, including chronic skin and bowel diseases (like psoriasis, irritable bowel syndrome, Crohn's disease, and colitis), arthritis, kidney conditions, and cancer. Biosimilars may provide patients with more access to important treatment options through competition in the healthcare market at a potentially lower cost.

Innovations in Human Drug and Device Review

New medical therapies can change and save lives, and advances in science and technology offer extraordinary opportunities to develop innovative medical products, better treatments, and better care. FDA ensures the science for evaluating the benefits and risk of these products keeps pace with development. For example, scientists in the Center for Biologics Evaluation and Research are developing in vitro tests and animal models to study new therapies and product testing methods, assays, and standards. By developing the tools needed to assess safety and efficacy, FDA can facilitate the development of new and promising biological products and technologies. This work supports regulated products by enabling the development of manufacturing methods and providing tools to assess product safety, efficacy, and manufacturing consistency.

GENERIC DRUGS MORE WIDELY AVAILABLE THAN EVER BEFORE

FDA sets a record for the greatest number of generics approved in a single fiscal year – a 91% increase since FY 2015



Supporting the Administration's Drug Pricing Initiative with Increased Competition

Since the Administration issued *American Patients First,* its blueprint to lower drug-pricing costs, FDA has promoted competition in drugs and biologics, advanced a strong framework for biosimilars, and modernized regulatory oversight of generic drugs. FDA does not set drug prices, but can help lower prices by bringing efficiencies to the drug development and review process and by promoting robust competition for established drugs. FDA-approved generic drugs now account for 90 percent of the prescriptions dispensed in the United States, and in 2018 competition from generic drugs saved the healthcare system an estimated $293 billion.

In FY 2019, the agency approved an all-time record 1,171 generic drugs, following previous records of 971 approvals in FY 2018 and 937 approvals in FY 2017. First generics approved in FY 2019 included drugs to treat emergency opioid overdose, pulmonary arterial hypertension, breast cancer, seizures, depression, and various infections. FDA is also increasing approvals of complex generic drugs, which are harder to copy and traditionally lack competition.

The Administration has and continues to support legislative efforts to make the path to generic and biosimilar development more transparent, efficient, and predictable so that Americans have better access to these medicines that are often more affordable. Overall, addressing regulatory barriers and challenges and closing potential loopholes that hinder development of generics, will promote more competition, and advance patient access to more affordable medicines.

Fighting the Opioids Epidemic

As part of the HHS opioids epidemic response, FDA considers all facets of the epidemic: opioid abuse, misuse, addiction, overdose, and death. FDA's approach focuses on decreasing exposure to prescription opioids to reduce rates of new addiction, supporting treatment of those with opioids use disorder, fostering development of new pain therapies, and strengthening enforcement to crack down on illegal sales of opioids.

FDA provides front line defense against illegal, illicit, unapproved, and counterfeit drugs including opioids from entering the United States through international mail. The Budget provides $45 million for opioid activities at international mail facilities to increase enforcement. This investment will enable FDA to inspect 100,000 packages per year, many containing multiple products. Enhanced presence and expanded package screenings are a key regulatory activity to help reduce illegal and dangerous substances entering through ports of entry. Funding also supports on-site laboratory operations at select locations, to increase package sampling and testing, and specialized criminal investigators to combat the entrance of these substances into the United States via international mail facilities.

Supporting Quality Compounded Drugs

FDA's compounding program protects patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully marketed compounded drugs for patients with a medical need. Poor compounding practices can result in serious drug quality problems, such as contamination or a drug that contains too much active ingredient, and lead to serious patient injury and death. FDA continues to find significant problems at many inspected outsourcing facilities. To address this, FDA engages in policy development, stakeholder outreach, and robust oversight and enforcement activity. The Budget provides an additional $4.5 million, $78 million total, to strengthen the compounding scientific framework, develop a list of bulk drug substances approved for compounding by industry, bolster regulatory compliance, and expand policy development. The Budget will enable FDA to evaluate the over 300 unique bulk drug substances nominated for inclusion on the list of substances approved for compounding by industry. With this funding increase, outsourcing facilities are better positioned to meet healthcare providers' and patients' needs for quality compounded drugs.

Modernizing Influenza Vaccines

The President's September 2019 Executive Order on *Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health* focuses on making the domestic influenza vaccine supply more robust, secure, and nimble to combat seasonal influenza epidemics and potential influenza pandemics. The Administration is committed to safeguarding public health by helping ensure Americans have access to effective influenza vaccines. CDC estimates that influenza has resulted in between 12,000 – 61,000 deaths annually since 2010.

The Budget provides $49 million, a $5 million increase above FY 2020, for FDA influenza preparedness activities. The Budget implements new manufacturing technologies and expands alternative domestic manufacturing methods to reduce production times and account for emerging influenza strains. For example, influenza vaccines are currently produced using more time-consuming, egg-based technology. More rapid non-egg-based production methods would give experts more time to select the most relevant strains.

Transform Medical Device Safety, Cybersecurity, Review, and Innovation

FDA is improving policies and processes to address scientific advances and enhance the safety of medical

devices. These improvements are critical to protect patients and foster innovation. The Budget includes an increase of $18 million, for a total of $47 million, to continue building a knowledge management system and portal for medical devices using modern, agile information technology systems. This investment would allow FDA to transform the agency's premarket review and postmarket surveillance programs, and shorten review cycles without compromising patient safety, quickly identify and address safety signals and cyber vulnerabilities, and spur the development of innovative, safer, more effective devices.

User Fees

User fees are an important resource that supplement, but do not replace, appropriated dollars. First enacted in the Prescription Drug User Fee Act in 1992, industry fees support FDA capacity to carry out its food and medical product safety responsibilities. The Budget reflects increases to all currently authorized medical product user fees by an additional $198 million. In addition, the Budget continues to include a legislative proposal to modernize the over-the-counter drug monograph system and establish a user fee for an estimated $28 million in FY 2021.

MODERNIZING THE FOOD SAFETY SYSTEM

Each year, about 48 million people in the United States get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. FDA is transforming the nation's food safety system by shifting the focus from response to prevention. The seven foundational regulations of the Food Safety Modernization Act reach their compliance dates over the next several years. These regulations ensure the safety of the food supply is a shared responsibility among many different partners in the global supply chain for both human and animal food. The regulations are designed to make clear specific actions at each of these points to prevent contamination. FDA will track the impact on the food safety system and refine implementation of the law.

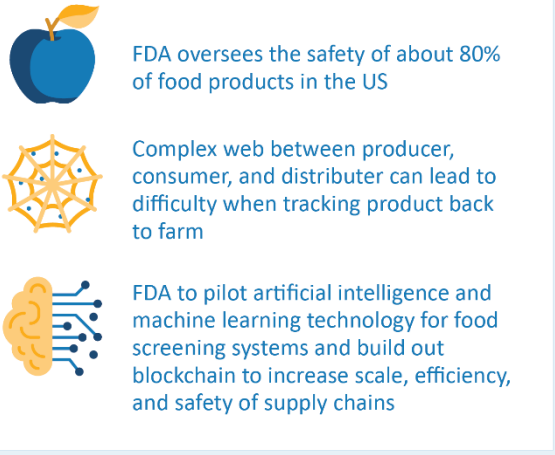
The Budget includes $1.5 billion for food safety across FDA, a $33 million increase above FY 2020. This total includes $1.4 billion in budget authority—a $5 million increase—and $28 million in user fees. These resources support centers across FDA to implement a preventive, not reactive, risk-based approach to food safety.

Smarter Food Safety

FDA is building on the Food Safety Modernization Act while advancing technology use such as block chain, sensor technology, and artificial intelligence. The Budget includes a $2 million increase for new technologies that make it easier to track-and-trace products through the supply chain, from the farm or manufacturer to the consumer. This investment will allow FDA to more quickly identify sources of outbreaks, get investigators to the outbreak site faster, and ultimately better understand the root cause of outbreaks and prevent future contamination.

TRACK AND TRACE

New era of smarter food safety modernizes how FDA protects consumers from foodborne illness



Signal Detection of Foodborne Illness

The Budget includes an increase of $1 million to improve signal detection of foodborne illness and strengthen FDA's response to human and animal food contamination. FDA will add additional capacity for evaluating and responding to foodborne outbreaks for human food.

Other Food Safety Activities

FDA continues to dedicate its food safety resources to priority food and feed safety activities, such as implementing its Nutrition Innovation Strategy to reduce preventable death and disease from poor nutrition. The strategy empowers consumers with information and facilitates industry innovation toward healthier foods that consumers want. For example, FDA is modernizing claims and labels to make identifying healthful food easier.

Other food safety activities include fostering industry innovation such as in the plant biotechnology field; and ensuring animal feed is safe, made under sanitary conditions, and properly labeled. FDA continues to provide services to consumers, domestic and foreign industry, and other outside groups regarding field programs; scientific analysis and support; cosmetic activities; and policy, planning, and handling of critical issues related to food.

User Fees

The Budget includes currently authorized user fees for food reinspection, recall, and the third party auditor program. The Budget proposes a new fee program to modernize FDA's regulatory oversight of innovative biotechnology products and emerging food production technologies.

INVESTMENTS TO ADDRESS EMERGING ISSUES

The Budget includes $15 million to address newly emerging challenges that cut across medical product and food safety.

Artificial Intelligence and Other Emerging Technologies

Research and development into artificial intelligence (AI) has produced cutting-edge, transformative technologies that have improved lives and grown innovative industries. Further employing AI at FDA will transform food and device safety by using the vast data generated on these products. For FDA-regulated products, the supply chain from manufacturer to consumer is complex, and the variety of imported products has increased. Using AI for import screening will allow FDA to conduct oversight more quickly and efficiently while ensuring trade is not adversely affected. In addition, as AI use expands within the medical product community, FDA must ensure products are safe and customer-friendly.

The Budget includes an $8 million increase to support an agency-wide AI strategy to invest in workforce, algorithmic capabilities, data, and technical infrastructure. This investment will allow FDA to deploy AI solutions to identify potential problems associated with chronic, long-term consumption of food constituents and contaminants, and to advance and promote consumer-friendly AI and digital health medical devices. For example, by applying AI solutions to food safety, FDA will speed the review of adverse event reports for food, supplements, and cosmetics. This technology will allow FDA to intervene earlier to remove unsafe products from the marketplace.

The Budget also includes $2 million for a track and trace initiative, described under the "Smarter Food Safety" section.

Cannabis and Cannabis Derivatives

FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer, and acknowledges the significant interest in these possibilities. FDA is aware that companies market products containing cannabis and cannabis-derived compounds in ways that violate the law and may put consumer health and safety at risk. Questions remain regarding the safety of these compounds. FDA is committed to protecting the public health and improving regulatory pathways for the lawful marketing of cannabis and cannabis-derived products within the agency's jurisdiction.

The Budget provides $5 million to support FDA regulatory activities for cannabis and cannabis derivatives. FDA will develop policies and continue to perform its existing regulatory responsibilities including review of product applications, inspections, surveillance, enforcement, and research.

REDUCING THE USE AND HARMS OF TOBACCO

FDA carries out the Family Smoking Prevention and Tobacco Control Act of 2009, which provides FDA broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. FDA's Center for Tobacco Products advances the mission to protect Americans from tobacco-related death and disease by regulating the manufacturing, distribution, and marketing of tobacco products and by educating the public (especially young people) about tobacco products and their harmful health effects. Tobacco use remains the leading cause of preventable death and disease in the United States. Nearly 9 out of 10 adult daily smokers began smoking by age 18. In December 2019, the President signed into law an increase to the federal legal age for purchasing tobacco from 18 to 21 (P.L. 116-94).

Youth Vaping

In 2019, over 5 million youths used e-cigarettes, making them the most commonly used tobacco product among youth. The Administration is deeply committed to preventing youth from using all tobacco

YOUTH VAPING

FDA committed to stopping the youth vaping epidemic

In 2019,

over 5 million youths

used e-cigarettes, making them the most commonly used tobacco products among youths.

As part of FDA's ongoing efforts to protect youth from the dangers of tobacco use, the agency is expanding its successful youth tobacco prevention campaign, **"The Real Cost,"** to reach the more than 10 million youth ages 12-17 who have used e-cigarettes or are open to trying them.

In addition to a suite of digital content on "The Real Cost" campaign website and social media channels, new ads will run on several digital platforms where age is verified.

products including e-cigarettes. In 2020, FDA announced a policy of prioritizing enforcement of premarket authorization requirements for flavored cartridge-based e-cigarettes known to be most appealing to youths, requiring that these products receive pre-market authorization before returning to the market.

In addition, FDA holds retailers and manufacturers accountable for marketing and sales practices that increase youth accessibility and appeal of e-cigarettes. For example, FDA issued more than 8,600 warning letters and more than 1,000 civil money penalties to online and brick-and-mortar retail stores for the sale of e-cigarettes and their components to minors. FDA also issued warning letters that led to removal of dozens of e-liquid products resembling kid-friendly juice boxes, cereal, and candy from the market.

The Budget includes $812 million in user fees to support the FDA tobacco program. The Budget includes a legislative proposal to increase user fee collections in support of the tobacco program by $100 million, and make e-cigarette manufacturers and importers subject to the user fees. The proposal supports FDA's goal to prevent a new generation of children from becoming addicted to nicotine through e-cigarettes.

The Budget also proposes to reform tobacco regulation by moving the Center for Tobacco Products out of FDA and creating a new agency within HHS to strengthen accountability and more effectively respond to tobacco related public health concerns. This reorganization will also allow the FDA Commissioner to focus on its traditional mission of ensuring the safety of our nation's drug, food, and medical products supply.

FDA INFRASTRUCTURE AND FACILITIES

FDA strategically manages infrastructure and facilities, including 56 laboratories located across the continental United States and Puerto Rico. FDA creates and maintains high-quality work environments that support FDA's public health responsibilities, optimizes the use of taxpayer dollars, enhances workforce productivity, and ensures efficient and effective operations. Optimally functional facilities foster scientific innovation, improve healthcare, expand access to medical products, and advance public health.

The Budget invests $466 million, $6 million above FY 2020, in FDA infrastructure, which will support rent, utilities, maintenance, and infrastructure improvements. This amount includes $28 million dedicated to repairs and improvements of FDA's infrastructure, offices, and laboratories nation-wide.

ADVANCING MEDICAL COUNTERMEASURES

FDA works with local, state, national, and international stakeholders to advance the development and availability of medical countermeasures to support public health preparedness and response. Together with federal partners through the Public Health Emergency Medical Countermeasures Enterprise, FDA works to build and sustain medical countermeasure programs necessary to protect against chemical, biological, radiological, nuclear, and emerging infectious disease threats. In FY 2019, FDA approved 33 medical countermeasures, including the first vaccine for the prevention of monkey pox disease.

FDA also works closely with the Department of Defense to understand the military's medical needs, expedite review of priority military medical products, and provide ongoing technical advice to speed development and manufacturing of medical products for military use.

The Budget includes $120 million for medical countermeasure activities, of which $37 million is for the Medical Countermeasure Initiative, a $5 million increase above FY 2020. Additional resources will support carrying out the Executive Order modernizing Influenza vaccines in the United States. FDA will also support the development and availability of medical products necessary to support United States military personnel.

Health Resources and Services Administration

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
Primary Healthcare				
Health Centers	5,617	5,626	5,728	+102
Discretionary Budget Authority [non-add]	1,497	1,506	1,608	*+102*
Current Law Mandatory [non-add]	4,000	2,575	--	*-2,575*
Proposed Law Mandatory [non-add]	--	1,425	4,000	*+2,575*
Ending HIV Epidemic Initiative [non-add]	--	*50*	*137*	*+87*
Health Centers Tort Claims/Free Clinics	121	121	121	--
Subtotal, Primary Care	**5,618**	**5,627**	**5,729**	**+102**
Health Workforce				
National Health Service Corps	430	430	430	--
Discretionary Budget Authority [non-add]	120	120	120	--
Current Law Mandatory [non-add]	310	200	--	*-200*
Proposed Law Mandatory [non-add]	--	110	310	*+200*
Training for Diversity	88	91	24	-67
Training in Primary Care Medicine	49	49	--	-49
Oral Health Training	40	41	--	-41
Teaching Health Centers Graduate Medical Education	127	127	127	--
Current Law Mandatory [non-add]	127	81	--	*-81*
Proposed Law Mandatory [non-add]	--	46	127	*+81*
Area Health Education Centers	39	41	--	-41
Behavioral Health Workforce Development Programs	112	139	139	--
Public Health and Preventive Medicine Programs	17	17	--	-17
Nursing Workforce Development	233	260	83	-177
Children's Hospital Graduate Medical Education	323	340	--	-340
National Practitioner Data Bank User Fees	19	19	19	--
Other Workforce Programs	71	96	5	-92
Subtotal, Health Workforce	**1,548**	**1,650**	**826**	**-824**
Maternal and Child Health				
Maternal and Child Health Block Grant	675	688	761	+73
Sickle Cell Demonstration Program	4	5	--	-5
Autism and Other Developmental Disorders	50	52	--	-52
Heritable Disorders	16	18	--	-18
Healthy Start	122	126	126	--
Early Hearing Detection and Intervention	18	18	18	--
Emergency Medical Services for Children	22	22	--	-22
Pediatric Mental Healthcare Access Grants	10	10	10	--
Screening and Treatment for Maternal Depression	5	5	5	--
Home Visiting (Mandatory)	400	400	400	--
Family-to-Family Health Information Centers (Mandatory)	6	6	6	--
Subtotal, Maternal and Child Health	**1,329**	**1,350**	**1,325**	**-25**
Ryan White HIV/AIDS Program				
Emergency Relief - Part A	656	656	656	--
Comprehensive Care - Part B	1,315	1,315	1,315	--
AIDS Drug Assistance Program [non-add]	900	900	900	--

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
Early Intervention - Part C	201	201	201	--
Children, Youth, Women, and Families - Part D	75	75	75	--
AIDS Education and Training Centers - Part F	34	34	34	--
Dental Services - Part F	13	13	13	--
Special Projects of National Significance (SPNS)	25	25	25	--
Ending HIV Epidemic Initiative	--	70	165	+95
Subtotal, Ryan White HIV/AIDS	**2,319**	**2,389**	**2,484**	**+95**
Healthcare Systems				
Organ Transplantation	25	28	31	+3
Discretionary Budget Authority [non-add]	25	28	17	-10
PHS Evaluation Funds [non-add]	--	--	13	+13
Cord Blood Stem Cell Bank	16	17	8	-9
C.W. Bill Young Cell Transplantation Program	25	30	30	--
Poison Control Centers	23	23	23	--
340B Drug Pricing Program	10	10	34	+24
Discretionary Budget Authority [non-add]	10	10	10	--
User Fees [non-add]	--	--	24	+24
Hansen's Disease Programs	16	16	14	-2
Subtotal, Healthcare Systems	**115**	**124**	**139**	**+15**
Rural Health				
Rural Outreach Grants	77	80	90	+10
Rural Hospital Flexibility Grants	53	54	--	-54
Telehealth	24	29	29	--
Rural Health Policy Development	9	10	5	-5
State Offices of Rural Health	10	13	--	-13
Radiation Exposure Screening and Education	2	2	2	--
Black Lung Clinics	11	12	12	--
Rural Communities Opioids Response Program	120	110	110	--
Rural Residency Program	10	10	--	-10
Subtotal, Rural Health	**316**	**318**	**247**	**-71**
Other Activities				
Family Planning	285	286	286	--
Program Management	155	155	152	-3
Vaccine Injury Compensation Program Direct Operations	9	10	16	+6
Subtotal, Other Activities	**449**	**452**	**455**	**+3**
Total, Discretionary Budget Authority	**6,832**	**7,047**	**6,305**	**-742**
Mandatory Funding	4,843	4,843	4,843	--
User Fees	19	19	43	+24
Evaluation Funds	--	--	13	+13
Total, Program Level	**11,693**	**11,909**	**11,204**	**-705**
Full-Time Equivalents	2,114	2,173	2,111	-62

1/ Reflects FY 2019 required and permissive transfers. Funding level does not include supplemental hurricane appropriations ($80 million).

The mission of the Health Resources and Services Administration is to improve health and achieve health equity through access to quality services, a skilled health workforce, and innovative programs.

The Health Resources and Services Administration (HRSA) is the primary federal agency improving healthcare for Americans who are geographically isolated and economically or medically vulnerable. Tens of millions of Americans receive quality, affordable healthcare and other services through HRSA's programs, which provide direct healthcare, place providers in areas that need them most, oversee organ donation, and provide community-based responses to public health.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $11.2 billion for HRSA. This total includes $6.3 billion in discretionary budget authority and $4.9 billion in mandatory funding and other sources. The Budget invests in a number of actionable public health challenges identified by the President and his Administration, including the *Ending the HIV Epidemic* initiative, *Improving Maternal Health in America* initiative, transforming rural health in America, and implementing the Executive Order on Advancing Kidney Health.

ENSURING ACCESS TO HIGH-QUALITY HEALTHCARE SERVICES

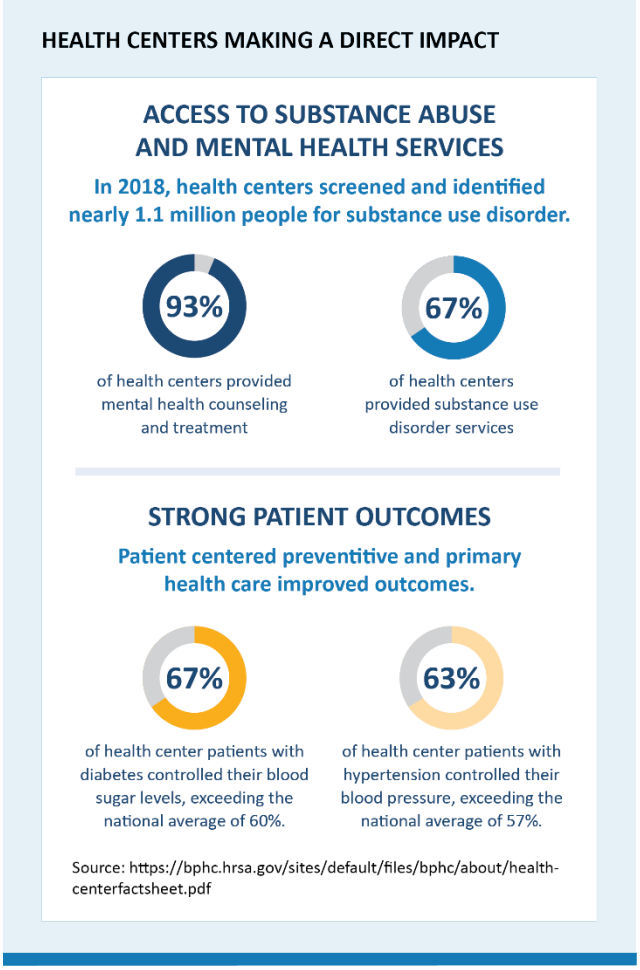
The Budget supports the delivery of direct healthcare services through Health Centers and the Ryan White HIV/AIDS Program. These programs deliver affordable, patient-centered, and high-quality services to more than 28 million people across the United States.

Health Centers

Health centers have delivered accessible, high-quality, and cost-effective primary healthcare services to patients for more than 50 years. The FY 2021 Budget provides $5.7 billion for health centers, including $4 billion in mandatory resources. Included in the Budget is an additional $15 million targeted to areas with high numbers of unsheltered homeless individuals to provide for their healthcare needs.

Health centers provide coordinated, comprehensive, and patient-centered preventive and primary healthcare, integrating a wide range of medical, dental, mental health, substance use disorder, and other patient services. Approximately 1,400 health centers operate more than 12,000 service delivery sites nationwide, serving more than 28 million people. In 2018, nearly half of all health centers served rural areas, providing care to 8.9 million patients or one in five people living in rural areas.

Health centers deliver outstanding health outcomes to the communities they serve. For example, 63 percent of health center patients with hypertension controlled their blood pressure, exceeding the national average of 57 percent. Among health centers patients with diabetes, 67 percent controlled their blood sugar levels, exceeding the national average of 60 percent. National organizations accredited more than 77 percent of health centers as Patient Centered Medical Homes, an advanced model of patient-centered primary care that drives strong patient outcomes at lower cost by emphasizing quality and care coordination through a team-based care approach. Health centers integrate care for their patients across the full range of services, including medical, oral health, vision, behavioral health, and pharmacy services.



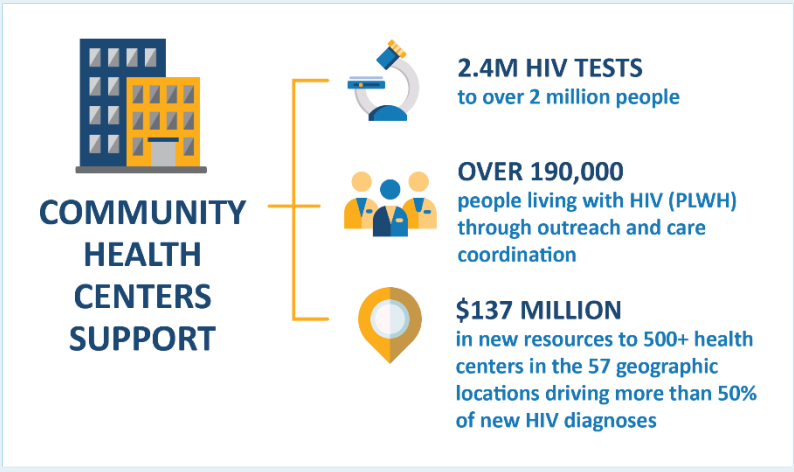
Health Centers and the Ending HIV Initiative

Health centers are a key component in the *Ending the HIV Epidemic* initiative by serving as a key point of entry for prevention and diagnosis of people living with

HIV. The initiative's goals are to reduce new HIV infections by 75 percent within 5 years, and by 90 percent within 10 years, averting more than 400,000 HIV infections in that time period. In 2018, health centers provided over 2.4 million HIV tests to more than 2 million patients and treated 1 in 6 patients diagnosed with HIV nationally. In FY 2021, the Health Center Program will expand support for the *Ending the HIV Epidemic* initiative. HRSA will dedicate $137 million to increase access to HIV prevention services, including pre-exposure prophylaxis (PrEP), outreach efforts, and care coordination in approximately 500 community health centers. This funding will allow health centers to reach more than 20,000 patients in the 57 geographic locations that contain more than 50 percent of new HIV infections.

ENDING THE HIV EPIDEMIC

Health centers key role in prevention and treatment

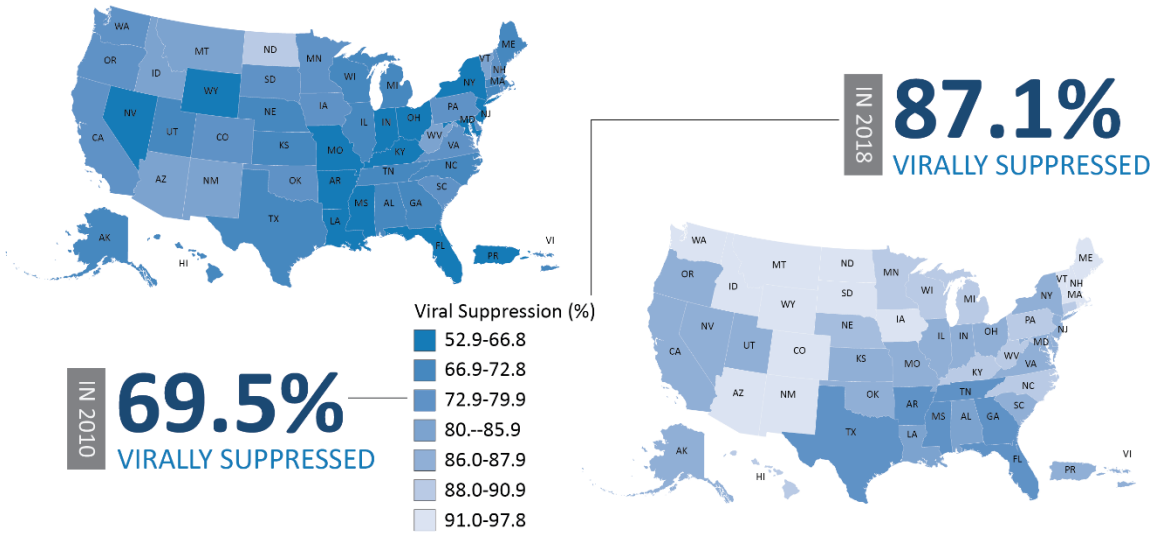


Ryan White HIV/AIDS Program

HRSA's Ryan White HIV/AIDS Program provides a comprehensive system of primary medical care, essential support services, and medication for low-income people living with HIV, serving about 50 percent of people living with diagnosed HIV infection in the United States. The Ryan White HIV/AIDS Program is a core component of the *Ending the HIV Epidemic* initiative strategy to treat the infection rapidly and effectively after diagnosis, achieving sustained viral suppression in 87 percent of patients and preventing transmission.

The Ryan White HIV/AIDS Program supports the *Ending the HIV Epidemic* initiative. The Budget requests an additional $95 million above 2020 enacted, for a total of $2.5 billion, for the Ryan White HIV/AIDS Program.

VIRAL SUPPRESSION AMONG RYAN WHITE CLIENTS, BY STATE, 2010 AND 2018—UNITED STATES AND TWO TERRITORIES[1]



Note: Viral suppression: >1 OAHS visit during the calendar year and >1 viral load reported, with the last viral load result <200 copies/mL
1 Puerto Rico and the Virgin Islands

This total includes $900 million for the AIDS Drug Assistance Program. The request includes $165 million specifically for the Ryan White HIV/AIDS Program's role in the *Ending the HIV Epidemic* initiative. The increase will support HIV care and treatment for an estimated 43,000 clients in the 57 geographic locations that currently have more than 50 percent of new HIV diagnoses nationally, expand evidence-informed practices to link, engage, and retain people with HIV in care, and support capacity building, technical assistance, program implementation, and oversight.

To support the *Ending the HIV Epidemic* initiative, the Budget also proposes to reauthorize the Ryan White HIV/AIDS Program to further target populations experiencing high or increasing levels of HIV infections and new diagnoses, while supporting Americans already living with HIV. The Budget seeks data-driven programmatic changes to simplify, modernize, and standardize statutory requirements and definitions to reduce burden on recipients.

Title X Family Planning Program

For more than 40 years, Title X family planning clinics have ensured access to a broad range of family planning and related health services for millions of low-income or uninsured individuals. The Budget provides $286 million, to support family planning services. Approximately 90 percent of Title X patients have family incomes at or below 200 percent of the federal poverty level.

IMPROVING MATERNAL AND CHILD HEALTH

Addressing high maternal mortality and morbidity rates in the United States is a top priority for HRSA. Despite medical care advances and improved access to care, the pregnancy-related death rate has risen from 7.2 deaths per 100,000 live births in 1987 to 16.9 deaths per 100,000 live births in 2016. Severe maternal morbidity (SMM) has significant short-and long-term consequences for a woman's health. Moreover, significant racial and ethnic disparities have persisted over time. Specifically, Black, American Indian, and Alaska Native women are two to three times more likely to die from pregnancy-related causes than white women are – and this disparity increases with age. Geographic disparities in maternal health outcomes also persist, and county-level access to obstetric care services varies widely across states.

Improving Maternal Health in America Initiative

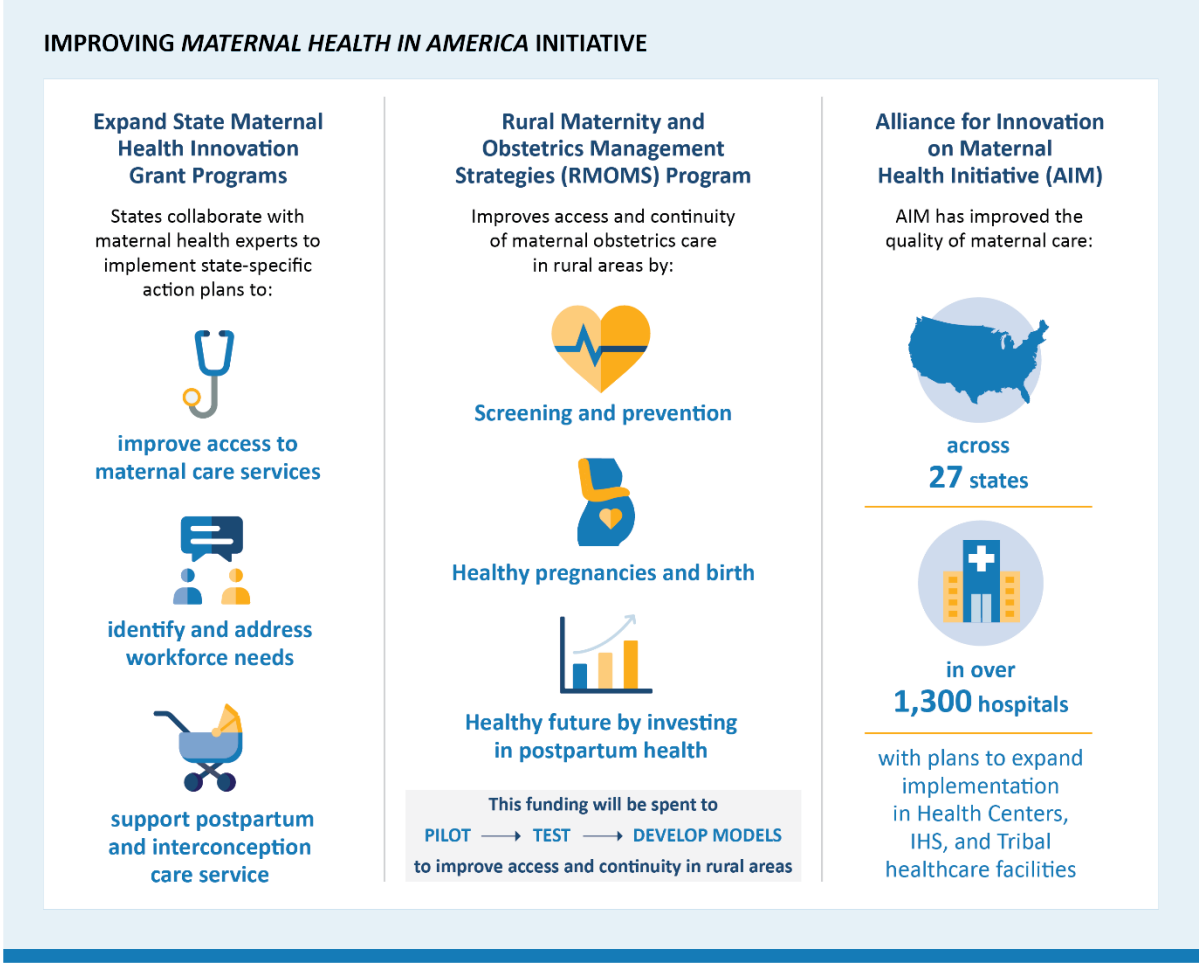
In FY 2021 HRSA will dedicate $80 million, which is an additional $50 million above FY 2020, towards the HHS's *Improving Maternal Health in America* initiative, which focuses on a four pillar strategy to achieve: 1) Healthy Outcomes for All Women of Reproductive Age by improving prevention and treatment, 2) Healthy Pregnancies and Births by prioritizing quality improvement, 3) Healthy Futures by optimizing post-partum health, and 4) Improved Data and Bolster Research to inform future interventions. This initiative builds on HRSA's ongoing work to address maternal mortality and morbidity.

Specifically, HRSA will support the *Improving Maternal Health in America* initiative as follows:

1) Expanding the State Maternal Health Innovation Grant program by $30 million above FY 2020, to a total of $53 million, to reach additional states. This program is funded through the Maternal and Child Health Block Grant's Special Projects of Regional and National Significance and supports innovation among states to improve maternal health outcomes and address disparities in maternal health. With this funding, states collaborate with maternal health experts to implement state-specific actions plans in order to improve access to maternal care services, identify and address workforce needs, and support postpartum and interconception care services. This program allows states the flexibility to implement all four parts of the *Improving Maternal Health in America* initiative, including Improved Data and Research, as states are required to collect and analyze state-level data on maternal mortality and SMM.

2) Increasing funding for the Rural Maternity and Obstetrics Management Strategies (RMOMS) program by $10 million above FY 2020, to a total of $12 million, to develop and test models that improve access to and continuity of maternal obstetrics care in rural communities. This program is funded through the Federal Office of Rural Health Policy's Outreach Grant program and focuses on Healthy Pregnancies and Births by improving the quality of obstetrics care in rural areas.

3) Expands the Alliance for Innovation on Maternal Health (AIM) program by $10 million above FY 2020, for a total of $15 million, to develop and implement safety bundles (small, straightforward sets of evidence-based practices shown to improve patient



outcomes) that address preventable maternal mortality and severe maternal morbidity among pregnant and postpartum women outside of hospitals and other birthing facilities. This program is funded through the Maternal and Child Health Block Grant's Special Projects of Regional and National Significance. Early reports from states that have successfully implemented AIM safety bundles have shown improvement in key maternal health outcomes. For example, the State of Maryland (one of the first AIM states) implemented the "Safe Reduction of Primary Cesarean Birth" bundle in 2015 and reported a 4.7 percent reduction in first-birth cesarean section rates in participating hospitals from 2015 to 2018.

The increased AIM funding will expand implementation to health centers and IHS and Tribal healthcare facilities. This increase allows HRSA to meet the goal of Healthy Pregnancies and Birth and Healthy Futures by implementing evidence-based practices within outpatient clinical settings and community based organizations.

Maternal and Child Health Services Block Grant to States

The Budget requests $618 million for the Maternal and Child Health Block Grant to states, an increase of $60 million over FY 2020. This increase of $60 million provides states with additional flexibility to support the types of activities previously funded through the following programs: Sickle Cell Disease Treatment Demonstration, Autism and Other Developmental Disabilities, Heritable Disorders in Newborns and Children, and Emergency Medical Services for Children. In FY 2021, the Maternal and Child Health Block Grant expects to provide services benefitting more than 50 million mothers and children in the United States. In FY 2018, the program reached an estimated 55 million women, infants, and children, including 91 percent of pregnant women, 99 percent of infants, and 54 percent of children.

States and territories use Block Grant funds to enhance and expand public health services as a necessary foundation for efforts to promote maternal health, address maternal morbidity and severe maternal

mortality, and improve infant and child health outcomes. Many states have adopted a life course approach in their Title V program planning. Assuring optimal health and preventing/controlling chronic conditions before, during, and after pregnancy through improved access to quality healthcare, preventive health screenings, health education, and advancement of health equity are key strategies being utilized by state Title V programs to advance maternal health.

Healthy Start

Healthy Start targets communities with infant mortality rates at least one and a half times the United States national average. The Budget provides $126 million for the Healthy Start program. This funding provides healthcare services, social services, and public health services to children and families across the nation, including prenatal, postpartum and well-baby care, case management, and immunization and health education services. Funding will continue to enable grantees to hire clinical service providers to provide direct access to well woman care and maternity care services. This will reduce barriers to care and better address health disparities among high-risk and underserved women.

TRANSFORM RURAL HEALTH IN AMERICA

There are 57 million Americans living in rural communities, facing a number of unique challenges. Rural residents tend to be older and in poorer health than urban counterparts. For example, rural residents are more likely to die from four of the leading causes of avoidable or excess death (cancer, unintentional injury, heart disease, and chronic lower respiratory disease) than their urban counterparts. Rural communities face challenges to access to care, financial viability, and the important link between healthcare and economic development.

The Budget requests $247 million for the Federal Office of Rural Health Policy, which will provide grants to improve rural area service delivery by strengthening health networks and encouraging collaboration among rural providers. The Budget supports critical rural health activities and services such as Telehealth, Rural Health Policy Development, Black Lung Clinics, and the Rural Communities Opioids Response Program to support the well-being of the Americans living in rural communities.

Rural Communities Opioids Response Program

The Budget requests $110 million for Rural Communities Opioid Response Program, which supports substance abuse prevention, treatment, and recovery services for opioids and other substance use in the highest-risk rural communities. The Budget targets new pilot programs to respond to the evolving needs of the opioid epidemic in rural counties, including workforce and service delivery challenges, and aims to reduce the morbidity and mortality of substance use disorder in high-risk rural communities. In FY 2019, HRSA awarded 80 Rural Communities Opioid Response Program implementation grants to strengthen infrastructure and capacity within rural communities to provide needed prevention, treatment, and recovery services to rural residents.

Recent data from the Centers for Disease Control and Prevention indicates a rise in drug overdose deaths involving methamphetamine and other psychostimulant misuse in rural communities, with synthetic opioids increasingly contributing to those deaths. The Rural Communities Opioids Response Program will expand to include activities that combat methamphetamine, stimulant, alcohol, and other substance misuse in rural communities.

Telehealth

HRSA supports telehealth services to increase healthcare quality, expand provider trainings, and improve health outcomes in rural areas. The Budget requests $29 million for Telehealth to promote health services and distance learning with telehealth technologies through the Telehealth Network Grant Program, Telehealth Resource Center Program, and the Telehealth Center of Excellence Program. In FY 2021, HRSA will continue the Telehealth Network Grant Program that focuses on Tele-Emergency services to provide real-time emergency care consultation between a central emergency healthcare center and a distant hospital emergency department. The Budget also proposes to expand telehealth benefits in Medicare Fee-for-Service and provide authority for Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth services. This would allow Rural Health Clinics and Federally Qualified Health Centers to be eligible for reimbursement for services provided via telehealth.

OPTIMIZING THE NATION'S HEALTH WORKFORCE

The Budget provides $826 million in mandatory and discretionary resources for HRSA health workforce programs. While approximately 16 percent of the U.S. population lives in rural America, only about 11 percent of physicians practice in rural locations. Over 60 percent of primary care health professional shortage areas are rural. The Budget prioritizes funding for health workforce programs requiring service commitments in underserved areas, and makes investments for behavioral health professionals.

National Health Service Corps

The National Health Service Corps provides scholarships and loan repayment to improve access to quality primary care, dental, and behavioral health in underserved urban, rural, and tribal areas. Approximately 10,939 primary care medical, dental, and mental and behavioral health professionals have served in the National Health Service Corps since it began in 1972.

The Budget requests $430 million for the National Health Service Corps, $120 million in discretionary budget authority and $310 million in mandatory resources for FY 2021. In FY 2019, an estimated 13.1 million patients received care from 13,053 National Health Service Corps clinicians. Another 1,479 future primary care professionals are either in school or in residency preparing for future service with the Corps programs. More than one in three (39 percent) of National Health Service Corps clinicians is a behavioral health provider, and the Corps provides care to an estimated 5.34 million urban and rural residents.

National Health Service Corps clinicians ensure access to care for vulnerable individuals, including checkups, preventative screenings, vaccines, and routine dental and medical care. The National Health Service Corps Loan Repayment Program offers primary care medical, dental, and mental and behavioral health providers the opportunity to have their student loans repaid, in exchange for providing healthcare in urban, rural, or tribal communities with limited access to care. In FY 2019, HRSA provided 4,012 new awards and 2,385 continuation awards totaling more than $236 million to clinicians serving in communities with health profession shortages to assist in repaying their qualifying educational loans.

Behavioral Health Workforce Development

In Academic Year 2018-2019, HRSA supported training for 6,476 future providers across the behavioral health spectrum, including community health workers, social workers, psychology interns and post-doctoral residents. These programs advance an integrated approach to training through academic and community partnerships, and enable clinicians to provide integrated behavioral healthcare and treatment services in underserved communities.

The FY 2021 Budget provides $139 million for the Behavioral Health Workforce Development Programs (BHWD). The Budget supports an addiction medicine fellowship to expand behavioral health provider training in community sites, including health centers. These funds will enable HRSA to strengthen the health workforce to address the opioid epidemic by training professionals in team-based prevention, treatment, and recovery services.

Over 50 percent of the BHWD trainees received training in substance use treatment. By the end of the Academic Year, 3,940 students graduated from institutions and certificate-bearing programs and entered the behavioral health workforce.

NURSE Corps Scholarship and Loan Repayment Program

The NURSE Corps Scholarship and Loan Repayment Program increases access to a high quality-nursing workforce through scholarships and loan repayment for nurses and nursing students committed to working in underserved communities. The Budget provides $83 million to support 1,733 primary care providers in communities experiencing nurse shortages.

The Budget also proposes to expand tax-exempt status to the NURSE Corps Scholarship Program, Native Hawaiian Health Scholarship Program, and the NURSE Corps Loan Repayment Program similar to that provided to the National Health Service Corps. This change will enhance recruitment of students and clinicians who commit to serve in critical shortage facilities.

Teaching Health Center Graduate Medical Education Program

The National Center for Health Workforce Analysis projects the total demand for primary care physicians will grow by 38,320 full time equivalents between 2013 and 2025, estimating a shortage of 23,640 primary care physicians by 2025. Teaching Health Center Graduate Medical Education Program increases primary care

physicians and dental residents across the nation, and supports training in community-based ambulatory care settings. The Budget requests $127 million in mandatory funding to support a maximum resident cap of up to 801 FTEs to expand the number of physicians trained in community-based settings, such as rural health clinics and health centers.

OTHER HRSA PROGRAMS

340B Drug Pricing Program

As a condition of participating in Medicaid, the 340B Drug Pricing Program (340B Program) requires drug manufacturers to provide discounts on outpatient prescription drugs to certain safety net healthcare providers. The 340B Program helps approximately 12,000 designated safety-net hospitals and clinics to purchase pharmaceuticals at savings between 25 to 50 percent on what they would have otherwise paid for covered outpatient drugs. In CY 2018, the 340B Program provided $24 billion in discounted medications to safety-net providers.

The Budget provides $34 million to improve operations and oversight of the 340B Program. These funds include a new discretionary user fee based on 340B sales. The FY 2021 Budget also includes appropriations language that would improve program integrity by providing explicit general regulatory authority over the 340B Program. General regulatory authority would allow for clear, enforceable standards of participation and will help ensure covered entities maintain compliance with 340B program requirements and the program benefits low-income and uninsured patients.

Supporting Organ Transplantation Program

There are 113,000 Americans on waitlists for lifesaving organ transplants – 20 of whom die each day. The Organ Transplantation Program extends and enhances the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment. According to the latest Donate Life America Annual Update Report, there were approximately 155 million people registered to be organ donors in 2018, an all-time high.

The Budget requests $31 million for the Organ Transplantation Program, an increase of $3 million above FY 2020. In FY 2021, HRSA will reduce financial barriers for living organ donors to reduce the number of patients waiting for kidney transplants and provide educational awareness about living organ donation. This supports the Administration's new *Advancing American Kidney Health* initiative. HRSA will reimburse for donor travel, lost wages, child care, elder care, and other subsistence expenses.

Program Management

The Budget requests $152 million to support investments in information technology, cybersecurity, program integrity, and other operational costs.

Indian Health Service

	dollars in millions			
	2019 /1	2020 /2	2021 /3	2021 +/- 2020
Services Programs				
Clinical Services	3,740	3,935	4,178	+243
Hospitals and Health Clinics (non-add)	*2,147*	*2,325*	*2,433*	*+108*
Maternal Health (non-add)	-	-	*5*	*+5*
Ending HIV Epidemic/Hepatitis C Initiative (non-add)	-	-	*27*	*+27*
Electronic Health Record System	-	*8*	*125*	*+117*
Purchased/Referred Care (non-add)	*965*	*965*	*965*	-
Indian Healthcare Improvement Fund (non-add)	*72*	*72*	*72*	-
Preventive Health	175	178	142	-36
Public Health Nursing (non-add)	*89*	*92*	*95*	*+3*
Community Health (non-add) /6	*83*	*84*	*44*	*-44*
Other Services	188	*203*	*188*	*-15*
Tribal Management Grant Program (non-add)	*2*	*2*	*0*	*-2*
Direct Operations (non-add)	*72*	*72*	*81*	*+10*
Subtotal, Services Programs	**4,103**	**4,315**	**4,507**	**+192**
Contract Support Costs				
Contract Support Costs 7/	822	820	855	+35
Subtotal, Contract Support Costs	**822**	**820**	**855**	**+35**
Payments for Tribal Leases				
Payments for Tribal Leases /4	-	-	101	-
Subtotal, Section 105*(l)* Leases	**-**	**-**	**101**	**-**
Facilities Programs				
Healthcare Facilities Construction	243	259	125	-134
Sanitation Facilities Construction	192	194	193	-1
Facilities and Environmental Health Support	252	262	260	-2
Maintenance and Improvement	168	169	168	-1
Medical Equipment	24	28	24	-4
Subtotal, Facilities Programs	**879**	**912**	**769**	**-142**
Total Discretionary Budget Authority	**5,804**	**6,047**	**6,233**	**+185**
Collections	1,202	1,202	1,279	+67
Diabetes Grants /5	150	150	150	-
Current Law Mandatory	150	97	-	-97
Proposed Mandatory	-	53	150	+97
Subtotal, Diabetes Grants	**150**	**150**	**150**	**-**
Subtotal, Other Sources	**1,352**	**1,352**	**1,429**	**+77**
Total Program Level	**7,156**	**7,399**	**7,661**	**+262**
Full-Time Equivalents	15,218	15,218	15,261	+43

1/ Reflects the FY 2019 Enacted level.
2/ Reflects P.L. 116-94, FY 2020 Consolidated Appropriations Act.
3/ The Budget requests a total of $36.6 million for staffing of newly-constructed healthcare facilities and $42 million for current services allocated across several funding lines, and includes $2.2 million for the Alaska Immunization Program.
4/ The Budget requests a new, indefinite discretionary appropriation for section 105*(l)* leases.
5/ P.L. 116-94, FY 2020 Consolidated Appropriations Act provides $96.6 million for Diabetes Grants, through May 22, 2020. The Budget assumes it will be extended through the end of FY 2020 at $150 million total funding.
6/ Includes Community Health Representatives and Health Education in FY 2019 and FY 2020 and adds an expansion of the Community Health Aide Program into the lower 48 States in FY 2021.
7/ The Congressional Budget office score for FY 2020 Contract Support Costs is $820 million and is included in the table. The Budget estimate for Contract Support Costs is $855 million.

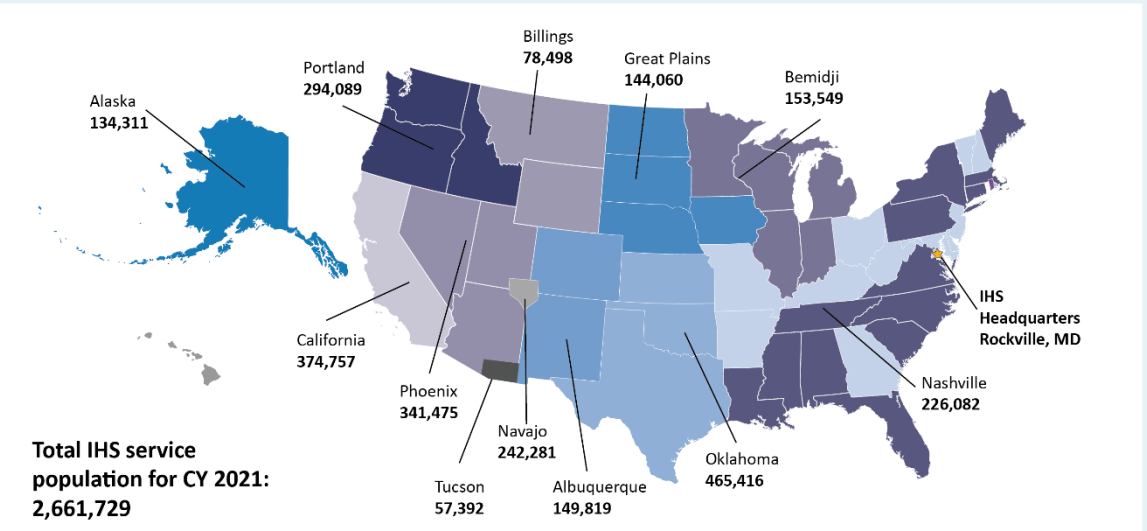
The mission of the Indian Health Service is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

The Indian Health Service (IHS) provides comprehensive primary healthcare and disease prevention services to approximately 2.6 million American Indians and Alaska Natives through a network of over 605 hospitals, clinics, and health stations on or near Indian reservations. Facilities are predominantly located in rural primary care settings and are managed by IHS, tribal, and urban Indian health programs.

The federal government has a unique government-to-government relationship with 574 tribes. The Administration is committed to the health and well-being of American Indians and Alaska Natives. IHS consults and partners with tribes to maximize participation in programs that affect their communities. More than 60 percent of the IHS budget funds services administered directly by tribes through self-determination agreements.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $6.2 billion for the IHS. The Budget invests strategically to make the greatest impact on health outcomes across Indian Country, and supports direct healthcare services. It also includes critical funding to improve healthcare quality, fully fund operational costs to support tribal self-determination, and modernize the electronic health record (EHR) system. The Budget supports IHS's goal to ensure that comprehensive, culturally appropriate public health services are available and accessible to American Indian and Alaska Native people.

IHS SERVICE POPULATION MAP



FULFILLING THE UNIQUE ROLE OF IHS

The FY 2021 Budget provides $4.2 billion for Clinical Services which provide essential health services and community-based disease prevention and promotion services. This funding will support direct healthcare services across the IHS system, including inpatient, outpatient, ambulatory care, dental care, and medical support services such as laboratory, pharmacy, nutrition, behavioral health services, and physical therapy. In response to the IHS Tribal Budget Formulation Workgroup's budget recommendation to HHS, the Budget supports direct healthcare services across Indian Country, including hospitals and health clinics, dental health, and mental health.

Healthcare Quality Improvement and Recruitment and Retention

The Budget focuses on improving quality and the management and operations of IHS, honoring the Administration's commitment to American Indians and Alaska Natives. The Budget provides $7 million for Quality and Oversight to advance the IHS mission in accordance with the recently updated Strategic Plan, and improve the quality and safety of care for IHS patients. The Budget continues to invest $58 million for accreditation emergencies to support IHS facilities in efforts to meet CMS conditions of participation.

The Budget provides $12 million for a range of recruitment and retention strategies to enhance and support the mission of IHS. Investments include housing subsidy incentives, new and supplemental Loan Repayment awards, new Scholarship awards, support to expand recruitment and outreach, and authorities to provide special compensation for critical positions.

To improve recruitment and retention of quality healthcare professionals in rural Native communities, the Budget provides $20 million for the replacement and addition of new staff housing quarters in isolated and remote locations. The Budget also includes key legislative proposals to improve recruitment and retention of providers to meet the IHS workforce needs. These investments will build and support a dedicated, competent, and caring IHS workforce.

Eliminating Hepatitis C and Ending the HIV Epidemic in Indian Country

American Indian and Alaska Native people face significant health disparities in rates of sexually transmitted infections, including HIV. IHS estimates between 40,000 and 100,000 American Indian and Alaska Native people are living with Hepatitis C (HCV). From 2010 to 2016, the annual number of HIV diagnoses increased 46 percent among American Indians and Alaska Natives. Sexually transmitted disease (STD) rates are also rising in Indian Country, further increasing the risk of HIV transmission.

The Budget includes $27 million to enhance HIV testing and linkages to care to advance the *Ending the HIV Epidemic: A Plan for America* initiative and accelerate efforts to eliminate HCV in Indian Country. With these funds, IHS can expand access to HIV testing, provide treatment to suppress the virus in HIV patients, and prescribe pre-exposure prophylaxis (PrEP) that can greatly reduce the spread of HIV among this population. The funds support expedited partner therapy to those at greater risk for contracting HIV and other STDs. These funds also support disease surveillance and public health enhancements through the 12 Tribal Epidemiology Centers. Funding will enable IHS to conduct HIV/HCV/STD outreach, education, and training to staff and provide consistent outreach in high-risk American Indian and Alaska Native communities.

The Budget also supports treatment, medication, public health surveillance, and case management services to prevent and treat HCV infection due to injection drug use. IHS will make medications readily available to American Indian and Alaska Native people living with HCV. These funds will cure nearly 1,100 people and will accelerate IHS efforts to eliminate HCV in Indian Country.

Addressing Behavioral Health and Substance Abuse Disparities

American Indians and Alaska Natives suffer disproportionately from drug abuse and have significant behavioral health challenges. Native communities have the highest drug use rate of 1.7 percent, substantially higher than other ethnicities: whites (0.7 percent), Hispanics (0.5 percent), Asians (0.2 percent), and African-Americans (0.1 percent).

The Budget includes $364 million for Mental Health and Alcohol and Substance Abuse programs. IHS's programs prioritize integrated behavioral health and primary care while respecting the balance, wellness,

and resilience of American Indian and Alaska Native people.

Improving Maternal Health

American Indian and Alaska Native women are more than two times more likely to die from pregnancy-related causes than white women regardless of education and socioeconomic status. The President is committed to reducing maternal mortality and morbidity and making the United States one of the safest countries in the world for women to give birth. In FY 2021 IHS will dedicate $5 million towards the HHS-wide *Improving Maternal Health in America Initiative*, which focuses on a four-part strategy to 1) Achieve Healthy Outcomes for All Women of Reproductive Age by improving prevention and treatment, 2) Achieve Healthy Pregnancies and Births by prioritizing quality improvement, 3) Achieve Healthy Futures by optimizing post-partum health, and 4) Improve Data and Bolster Research to inform future interventions.

The Budget provides $5 million to advance Native Maternal Health. This funding supports standardized screening, addresses social determinants of health for pregnant women, and increases cultural awareness to improve health outcomes. IHS will update the agency's standards of care, train providers, provide outreach and education to patients, and support IHS and tribal hospitals that provide labor and delivery services. The funds also will allow IHS to increase targeted outreach to pregnant women and women of childbearing age at risk for substance abuse disorders.

Purchased/Referred Care

IHS contracts with hospitals and healthcare providers through the Purchased/Referred Care program for services it cannot directly provide within its network. The Budget provides $965 million for this program. These funds support medical care, including essential services such as inpatient and outpatient care, routine and emergency care, and medical support services such as diagnostic imaging, physical therapy, and laboratory services.

Preventive Health Services

The Budget supports evidence-based and outcome-driven programs that will improve the health of American Indians and Alaska Natives, particularly for tribal members that live in rural communities. The Budget includes $44 million for a new Community Health Program, which consolidates the Community Health Representatives program, Health Education, and the Community Health Aide Program (CHAP). The approach supports the nationwide expansion of the evidence-based CHAP to the lower 48 states, to build a network of health aides to collaborate with healthcare providers and provide healthcare, health promotion, and disease prevention services. The Budget supports continued funding for the Alaska CHAP. Community Health Aides will expand access to health services in areas that are challenging to serve due remoteness and provider vacancies. This approach supports self-determination and provides tribal communities flexibility to administer community health programs at the local level to meet their unique needs and improve the health and wellbeing of tribal citizens.

Staffing Increases

The Budget provides $37 million to fully fund staffing and operating costs for four newly constructed healthcare facilities, including Yukon-Kuskokwim Primary Care Center in Bethel, Alaska; Naytahwaush Health Center in Naytahwaush, Minnesota; Yakutat Tlingit Health Center in Ykutat, Alaska; and Ysleta Del Sur Health Center in El Paso, Texas. These investments will expand access to healthcare services and address critical needs in these communities. All four projects are part of the Joint Venture Construction program, where tribes fund construction of a new or replacement facility, and IHS works with Congress to fund staffing and operating costs.

Health Insurance Reimbursements

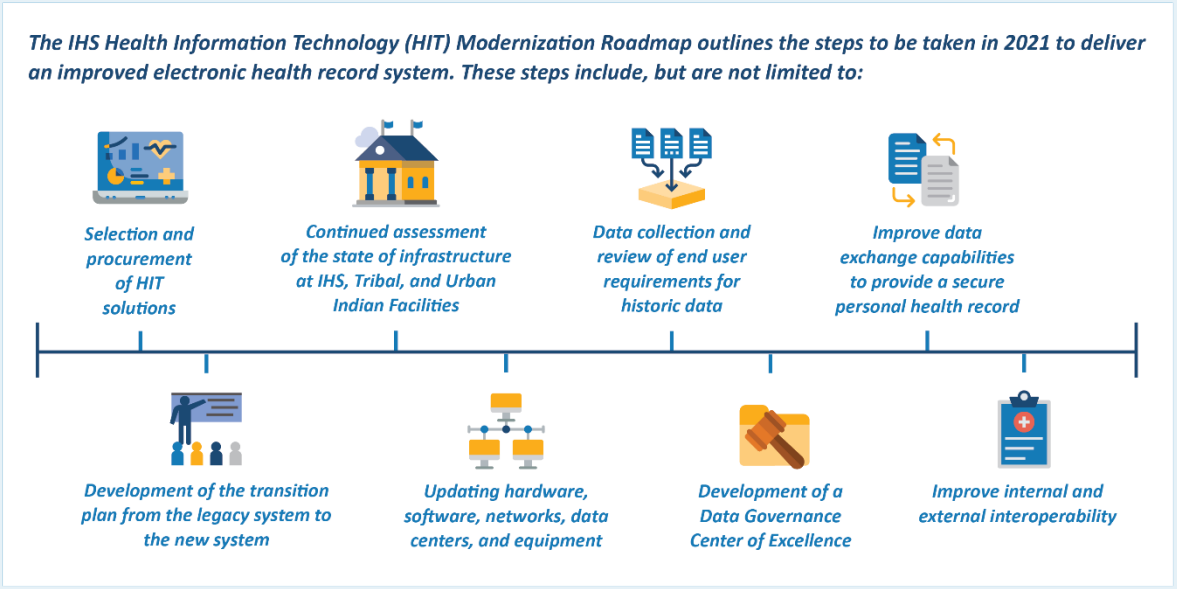
The Indian Healthcare Improvement Act authorizes IHS to collect Medicaid, Medicare, Veterans Health Administration, and private health insurance reimbursement for services provided by IHS to eligible beneficiaries. The Budget for IHS estimates $1.3 billion in health insurance reimbursement, which IHS and tribally-operated facilities use to maintain accreditation standards through hiring additional medical staff, purchasing and updating equipment, and making necessary building improvements.

HEALTH INFORMATION TECHNOLOGY MODERNIZATION

The IHS Health Information Technology infrastructure provides critical support for the IHS, tribal, and Urban healthcare system that cares for 2.6 million American Indian and Alaska Native people. IHS requires a secure, certified EHR system to improve healthcare delivery

MODERNIZED ELECTRONIC HEALTH RECORD SYSTEM VITAL TO QUALITY CARE

IHS will invest $125M for an updated system that will provide high-quality care, ensure patient safety, and protect from cybersecurity threats



and quality, enhance access to care, reduce medical errors, and provide high quality services.

In 2017, the Department of Veterans Affairs announced it will phase out support of the EHR system IHS currently utilizes. Over the coming years, IHS must update its overall Health Information Technology system with a modern, innovative, and practical solution to improve health and healthcare across Indian Country.

In FY 2021, the Budget invests $125 million to support IHS's transition to an improved and modernized EHR system. This funding continues efforts started in FY 2019 to support a modern system for the delivery of care, revenue collection, and interoperability. A new system supports IHS's ability to provide high quality care, increase efficiency, ensure patient safety, protect from cybersecurity threats, and participate in CMS demonstration projects.

FACILITIES AND CONSTRUCTION

IHS provides facilities infrastructure services on or near Indian reservations in 37 states. The facilities program improves access to medical care and facilitates collaboration and partnership between tribes and IHS. The Budget provides $769 million for IHS facilities programs to support projects on the Health Facilities Construction Project Priority List, fund Sanitation Construction projects, purchase medical equipment, and support the Facilities and Environmental Health Support program.

Healthcare Facilities Construction

The Health Facilities Construction Project Priority List, developed in 1992 by IHS in consultation with tribes, governs new and replacement facilities construction. The 2010 reauthorization of the Indian Healthcare Improvement Act incorporated the Priority List in statute. The Budget provides $125 million to support new and replacement construction of healthcare facilities on the Priority List. This funding supports the Whiteriver Hospital in Whiteriver, Arizona; new and replacement Staff Quarters; and Albuquerque Central Health Center in Albuquerque, New Mexico.

PARTNERSHIP WITH TRIBES

Self-determination provides tribes an opportunity to assume the responsibility for providing healthcare for their members. Tribal governments and tribal organizations administer over 60 percent of IHS resources through Indian Self-Determination and Education Assistance Act contracts and compacts. Tribes design and manage the delivery of individual and community health services through 22 hospitals, 285 health centers, 54 health stations, 127 Alaska village

clinics, and 5 school health centers across Indian Country.

Contract Support Costs

Contract Support Costs are the necessary and reasonable costs for activities tribes and tribal organizations must perform to ensure compliance with the contract and prudent management but that IHS either does not normally perform in its direct operation of the program or provided from resources other than those transferred under contract. The Budget fully funds Contract Support Costs at an estimated $855 million and continues an indefinite appropriation to support this need.

Section 105(l) Leases

The Indian Self-Determination and Education Assistance Act requires compensation for reasonable operating costs associated with facilities leased or owned by tribes and tribal organizations to carry out health programs under the Act. The Budget provides full funding for section 105*(l)* leases at an estimated $101 million through a new, separate indefinite appropriation, and reforms to improve management of tribal lease payments.

Centers for Disease Control and Prevention

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
CDC Programs /2				
Immunization and Respiratory Diseases	783	790	830	+40
Prevention and Public Health Fund (non-add)	321	370	303	-67
Vaccines for Children	4,176	4,418	4,951	+534
HIV/AIDS, Viral Hepatitis, Sexually Transmitted Infection and Tuberculosis Prevention	1,124	1,274	1,553	+279
Emerging and Zoonotic Infectious Diseases	624	636	550	-85
Prevention and Public Health Fund (non-add)	52	52	137	+85
Chronic Disease and Health Promotion	1,185	1,240	813	-427
Prevention and Public Health Fund (non-add)	255	255	454	+199
Birth Defects, Developmental Disabilities, Disabilities & Health	155	161	112	-49
Environmental Health	209	214	182	-31
Prevention and Public Health Fund (non-add)	17	17	0	-17
Injury Prevention and Control	648	677	730	+53
Public Health and Scientific Services	526	578	521	-57
Public Health Service Evaluation Funds (non-add)	0	0	463	+463
Occupational Safety and Health	335	343	190	-153
Public Health Service Evaluation Funds (non-add)	0	0	79	+79
Global Health	494	571	532	-39
Public Health Preparedness and Response	835	827	802	-25
Buildings and Facilities	30	25	30	+5
CDC-Wide Activities and Program Support	327	359	155	-204
Prevention and Public Health Fund (non-add)	160	160	0	-160
Agency for Toxic Substances and Disease Registry (ATSDR)	75	77	62	-15
Total Program Level	**12,094**	**12,787**	**12,612**	**-175**
Less Funds from Other Sources				
Vaccines for Children	4,176	4,418	4,951	+533
Energy Employee Occupational Illness Compensation Program	51	55	55	0
World Trade Center Health Program	517	541	540	-1
Public Health Service Evaluation Funds	0	0	542	+542
Prevention and Public Health Fund	805	854	894	+40
User Fees	2	2	2	0
Total Discretionary Budget Authority	**6,544**	**6,917**	**5,627**	**-1,289**
Full-Time Equivalents (including ATSDR)	11,318	11,318	11,471	+153

1/ Reflects the FY 2019 Final level, post required and permissive transfers. Funding level does not include supplemental disaster appropriations ($20 million).
2/ FY 2019 and FY 2020 totals are shown comparably adjusted for FY 2021 realignments.

The Centers for Disease Control and Prevention (CDC) works 24/7 to protect America from health, safety, and security threats, both foreign and in the United States. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish its mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

The Centers for Disease Control and Prevention (CDC) is the nation's public health protection agency, committed to saving lives and protecting Americans at home and abroad. CDC prevents and responds to domestic and foreign health, safety, and security threats, and promotes the health and wellbeing of Americans of all ages. CDC accomplishes its public health mission through core competencies, including: putting data into action; maintaining state-of-the-art laboratory capacity, developing a robust public health workforce; responding quickly to outbreaks, and fighting diseases before they reach our nation's borders.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $12.6 billion for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR). This total includes $5.6 billion in discretionary budget authority, $894 million from the Prevention and Public Health Fund, and $542 million in Public Health Service Evaluation Funds. The Budget prioritizes funding to protect Americans from infectious and chronic diseases, end the HIV epidemic, promote global health security, and advance data modernization efforts to ensure the evidence CDC collects and generates is accurate, timely, and can be used effectively and efficiently.

HIV/AIDS, VIRAL HEPATITIS, SEXUALLY TRANSMITTED INFECTIONS AND TUBERCULOSIS PREVENTION

Scientific advancements in prevention and treatment tools have made a future free of HIV, viral hepatitis, sexually transmitted infections (STI), and tuberculosis possible. CDC prioritizes cost-effective, scalable programs, policies, and research to achieve the greatest reduction in the incidence of these conditions, all of which have significant personal, societal, and economic costs. The Budget includes $1.6 billion for CDC's efforts to support state, tribal, local, and territorial health departments' response to disease outbreaks, and to maintain CDC's state-of-the-art laboratories that make vital discoveries and develop cutting-edge technology to prevent the spread of infection.

Ending the HIV Epidemic: A Plan for America

The Budget provides $1.2 billion for CDC's domestic HIV/AIDS surveillance and prevention efforts, which includes $371 million for the second year of HHS's *Ending the HIV Epidemic* initiative. The multi-year initiative targets 48 counties, Washington, D.C., and San Juan, Puerto Rico, which together account for more than 50 percent of new HIV diagnoses, and 7 states that have a substantial rural HIV burden with additional expertise, technology, and resources. These investments will advance HHS's efforts to reduce new HIV diagnoses by 75 percent in 5 years and by 90 percent by 2030.

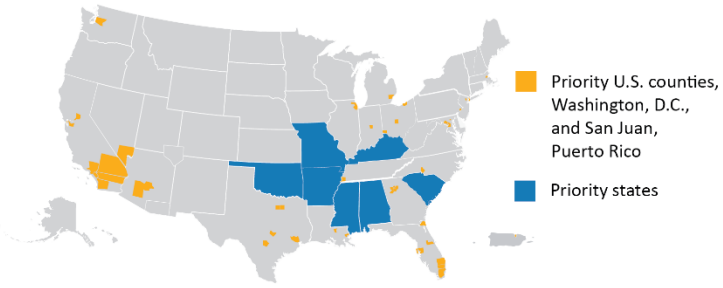
In FY 2021, CDC will significantly increase efforts within the 57 jurisdictions to implement proven and innovative activities across all four strategies of the initiative: prevent, diagnose, treat, and respond. These activities include increasing HIV testing in clinical settings, making testing more accessible in non-traditional settings, promoting rapid and comprehensive care for all persons diagnosed with HIV, improving use of Pre-exposure prophylaxis (PrEP), and detecting potential clusters of HIV transmission early to prevent outbreaks.

Infectious Disease and Drug Use

CDC estimates 28,000 people have been diagnosed with Hepatitis A due to recent outbreaks, 862,000 Americans are living with chronic Hepatitis B, and 2.4 million are living with Hepatitis C. The opioid crisis has fueled increases in new viral hepatitis infections due in large part to increased rates of injection drug use. Hepatitis A outbreaks comprise the largest increases in Hepatitis A infection in the U.S. in nearly two decades. The nation has seen a 4-fold increase in reported cases of Hepatitis C from 2010 to 2017. In addition to ongoing Viral Hepatitis activities, the FY 2021 Budget includes $58 million to provide awards to select jurisdictions to address the infectious disease

CDC SUPPORT FOR *ENDING HIV EPIDEMIC* INITIATIVE

A CDC analysis of HIV data found that more than 50% of new HIV diagnoses[1] occurred in only 48 counties, Washington, D.C., and San Juan, Puerto Rico. The analysis also found that seven states had a substantial rural burden.[2]



1 2016–2017 data
2 States where 10% or more of new diagnoses in 2016 and 2017 were in rural areas (less than 50,000 population); at least 75 total new diagnoses statewide; and the state did not have a priority county

CDC'S ROLE

DIAGNOSE
All people with HIV as early as possible

TREAT
HIV rapidly and effectively to reach sustained viral suppression

PREVENT
new HIV transmissions by using proven interventions including PrEP and syringe services programs

RESPOND
quickly to clusters of new cases to get needed prevention and treatment services

consequences of the opioid epidemic and support prevention and surveillance interventions in high-risk areas to reduce the spread of infectious disease.

Sexually Transmitted Infections

Sexually Transmitted Infections (STIs) compromise Americans' health and is a significant cost to the healthcare system. The United States is experiencing a significant increase in STIs; in 2018 there were more than 2 million cases of chlamydia, gonorrhea, and syphilis (including congenital syphilis in babies) combined, more than ever previously reported. The FY 2021 Budget includes $161 million to support CDC's unique role providing national leadership, research, and policy development to prevent STIs nationwide. HHS is currently developing the nation's first federal action plan on STIs. The plan, scheduled for release in 2020, will outline evidence-based actionable strategies across multiple agencies to address STIs. In alignment with the plan, CDC will continue to bridge science, public health program management, and STI prevention services that are high-impact, scalable, cost-effective, and sustainable.

IMMUNIZATION AND RESPIRATORY DISEASES

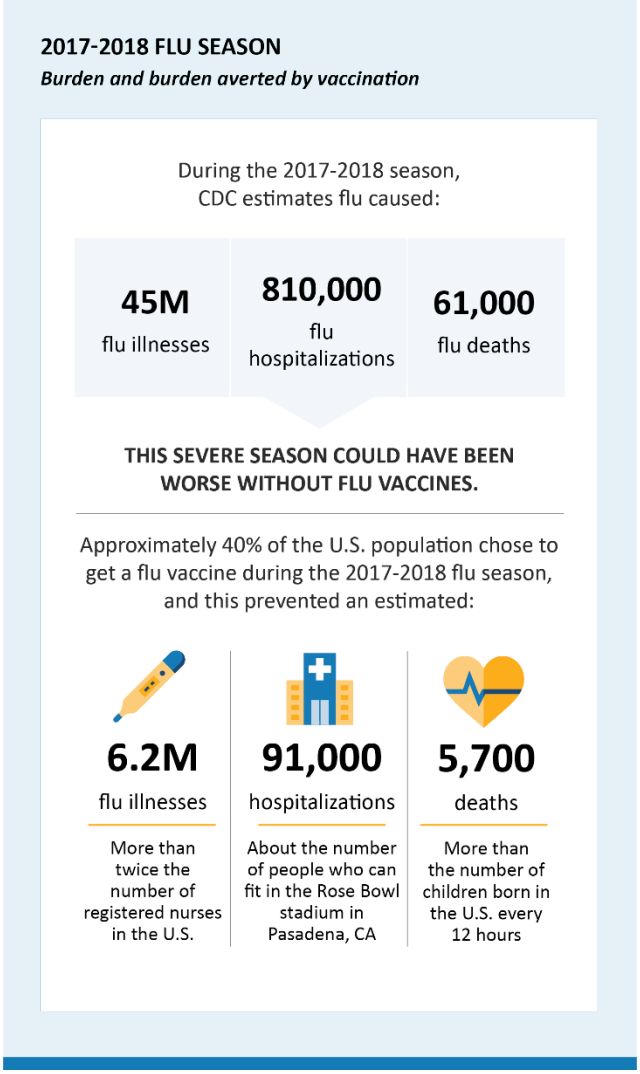
Immunizations and control of respiratory diseases are critical to CDC's goal to protect Americans from infectious diseases locally and globally. Through the discretionary Immunization Program and mandatory Vaccines for Children (VFC) Program, CDC improves access to immunization services for uninsured and underinsured United States populations. CDC also provides critical epidemiology and laboratory capacity to detect, prevent, and respond to vaccine-preventable respiratory and related infectious disease threats, and conducts preparedness planning for pandemic influenza.

The FY 2021 Budget includes $5.7 billion for these activities, of which $830 million is for discretionary immunization and respiratory diseases programs.

Addressing the Threat of Influenza

Influenza poses one of the world's greatest infectious disease challenges and threats. CDC provides technical expertise, resources, and leadership to support diagnosis, prevention, and control of influenza domestically and to address the threat posed by seasonal and pandemic influenza. Influenza is a contagious respiratory disease which can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people experience illness, hundreds of thousands are hospitalized, and tens of thousands die from influenza every year. An annual seasonal vaccine for everyone 6 months and older is the best way to protect against influenza. CDC estimates that, for the 2017-2018 influenza season, vaccinations prevented over 6 million illnesses and more than 3 million influenza-associated medical visits.

The Budget includes an additional $40 million to support implementation of activities outlined in the



President's September 2019 Executive Order, "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health." CDC will rapidly expand monitoring systems to compare the effectiveness of different vaccines, enhance vaccine virus development for use by industry, strengthen the evidence base for enhanced influenza vaccines, and remove barriers that stop people from getting vaccinated.

Combatting Acute Flaccid Myelitis

Acute Flaccid Myelitis (AFM) is a rare but serious condition affecting the nervous system, particularly in children. CDC collaborates with leading experts, clinicians, and state and local health departments to understand the causes of AFM and how to prevent and treat it. CDC conducts active surveillance of AFM through the National Viral Surveillance Network and reviews medical charts of each AFM case. The Budget provides $10 million to implement AFM Task Force recommendations, which includes promoting AFM awareness among front-line clinicians, monitoring AFM activity nationwide, identifying and updating treatment options, and tracking long-term outcomes.

Vaccines for Children

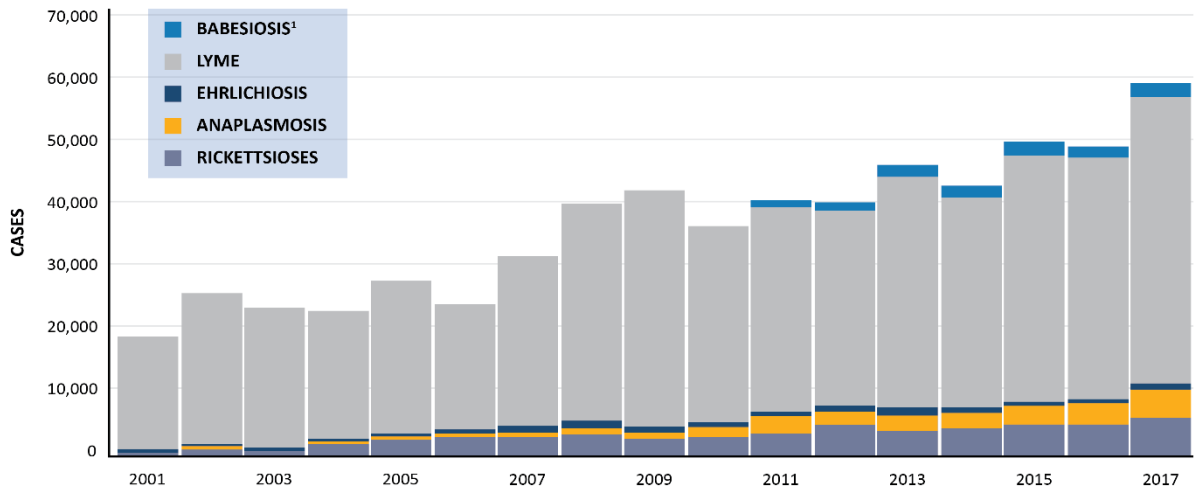
The VFC Program provides recommended vaccines, free of charge, to children and teens who may not otherwise have access. CDC buys vaccines at a discount and distributes them to grantees, such as state health departments and certain local and territorial public health agencies. These groups distribute the vaccines at no charge to private physicians' offices and public health clinics registered as VFC providers. Over half of young children and one-third of adolescents in the United States are eligible to receive vaccinations through this program. CDC estimates vaccination prevented over 400 million illness, more than 26 million hospitalizations, and 930,000 deaths among children born in the last 25 years. Further, CDC estimates that every dollar invested in childhood vaccination ultimately saves over 10 dollars. The FY 2021 Budget includes $4.95 billion in mandatory funding for the VFC program.

EMERGING AND ZOONOTIC INFECTIOUS DISEASES

CDC defends the country against a wide range of infectious diseases caused by bacterias (like anthrax or *Salmonella*), by viruses (like Zika virus or Ebola), or by fungi (like Valley fever). CDC's world-class scientists, researchers, laboratorians, and emergency responders protect America's health, safety, and security by reducing illness and death associated with these infectious diseases, spread intentionally or unintentionally, through several core functions, including: outbreak response, surveillance, laboratory expertise, and support to state and local health departments. The FY 2021 Budget includes $550 million for CDC's National Center for Emerging and Zoonotic Infectious Diseases, and prioritizes funding to address the rising threat of tick and mosquito-borne diseases in the United States, and to improve CDC's lab capacity. The Budget includes an additional $10 million to support lab technologies, equipment, and training to enhance CDC's ability to respond to outbreaks.

CASES OF TICKBORNE DISEASE ON THE RISE

Reported cases of leading tickborne disease by year — United States, 2001 – 2017



1 Babesioisis became nationally notifiable in 2011.

Addressing Tick-borne Diseases

Tick-borne diseases 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. The number of reported cases has doubled since 2004 and reached a record high of more than 59,000 cases in 2017. The geographic ranges of ticks have also expanded further north, west, and south in recent years, which leads to increased risk for human exposure to the bites of infected ticks. HHS is committed to addressing the public health challenge posed by the rising numbers of tick-borne diseases in the United States.

The FY 2021 Budget includes a total of $66 million for CDC's vector-borne disease activities. This includes an additional $14 million to address the growing threats of Lyme disease and other tick-borne diseases. The additional funding will support the development of better diagnostics, new or improved surveillance and prevention strategies (including efforts to address insecticide resistance), and will expand support for state grants, with a focus on Lyme disease and related tick-borne disease activities. CDC will continue to provide support for vector-borne disease prevention and control to 64 jurisdictions and will provide enhanced support to at least nine states and one city at high-risk for vector-borne disease outbreaks through the Epidemiology and Laboratory Capacity cooperative agreement.

Combating Antibiotic Resistance

CDC's *2019 Antibiotic Resistance Threats Report* estimates that more than 2.8 million illnesses and about 35,000 deaths are caused by Antibiotic Resistance in the United States each year, leading to billions in excess costs to the U.S. healthcare system. In addition, when *Clostridioides difficile* is added to these, the U.S. toll of these threats exceed 3 million infections and 48,000 deaths. The Budget includes $137 million to detect, respond to, and contain antibiotic resistant infections associated with healthcare, food, and the community. In alignment with the National Action Plan for Combating Antibiotic-Resistant Bacteria, CDC will continue to work with states and communities to strengthen detection and tracking of antibiotic resistant threats, fund seven regional labs to assist in outbreak response, improve antibiotic use in healthcare settings, and support research to identify new approaches to combat antibiotic resistance.

PUBLIC HEALTH SCIENTIFIC SERVICES

Strategic thinking, new ideas, flexibility, and readiness to connect across disciplines are critical to address factors affecting our health, including new and changing health threats, natural disasters, bioterrorism, access to healthcare, and the growing burden of noncommunicable diseases. CDC leads,

promotes, and facilitates science standards and policies to protect the health of Americans at home and abroad. The Budget provides a total of $521 million to train more than 300 fellows, modernize public health surveillance systems, and improve access to information that public health professionals need to address disease outbreaks and other health threats.

The National Center for Health Statistics is the nation's principal health statistics agency. These statistics provide critical information and evidence to shape policies, monitor programs, track progress, and measure change. The Budget includes $169 million to continue CDC's critical data collection activities, including the National Vital Statistics System and the National Health and Nutrition Examination Survey.

Public Health Data Modernization Initiative

The Budget includes $30 million to support the Public Health Data Modernization Initiative, a multi-year initiative to transform how CDC collects and uses public health data. This approach will allow CDC and state and local health departments to effectively address the wide range of new and changing health threats with data that can drive action more efficiently, flexibly, rapidly, and with enhanced impact. This investment will bring CDC and public health into the 21st century, through shared data platforms, networked systems, and accessible sharing of data. CDC will:

- Modernize the public health data infrastructure through support to state and local health departments to enhance their data capacities;
- Improve CDC internal capacity to support advanced data tools and capabilities;
- Support strategic human capital and workforce development activities that enhance data science; and
- Engage public health organizations, academic institutions, and the private sector to accelerate and sustain data modernization.

Overall, this investment will increase the effectiveness of public health data systems and allow the public health community to move toward enhanced predictive analytics that can help detect threats prior to their emergence as full-blown health crises.

INJURY PREVENTION AND CONTROL

Injuries and violence can affect anyone, regardless of age, race, or economic status. In the first half of life (ages 1-44), more Americans die from violence and injuries, such as motor vehicle crashes, falls, or homicides, than from any other cause. CDC is the nation's leading authority on injury and violence, which includes detecting, understanding, and addressing alarming public health trends like suicide and substance use disorders. Like diseases, injuries are preventable, and CDC approaches injury prevention using the same methods as disease prevention: surveillance, understanding risk factors, designing and evaluating targeted interventions, and implementing proven strategies in communities nationwide. The FY 2021 Budget includes $730 million for injury prevention and control activities.

Combating the Opioids and Methamphetamine Crisis

The Administration has made progress in the fight against opioid addiction. According to the CDC's National Center for Health Statistics, provisional overdose mortality fell by 5 percent for the 12 months ending in the second quarter of 2018. Despite this progress, the drug addiction crisis faced by the United States continues to evolve and is becoming more

complex, including the emergence of increased methamphetamine use. More than 70,000 Americans died from drug overdoses in 2017 alone. Opioids, mainly synthetic opioids (other than methadone), are currently the main driver of drug overdose deaths. Opioids were involved in 47,600 (68 percent) of all drug overdose deaths in 2017. Additionally, overdose deaths involving methamphetamine and other stimulants are increasing, and in a growing number of states are responsible for more deaths than opioids.

The FY 2021 Budget continues to prioritize opioid activities at CDC, with a total funding level of $476 million. CDC is contributing to Department wide efforts by supporting states and jurisdictions as they collect data, respond to overdoses, and provide care to those in their communities. To apply its public health expertise, CDC conducts surveillance and research, builds state, local, and tribal capacity, supports providers, health systems, and payers, partners with public safety, and empowers consumers to make safe choices.

In FY 2021, CDC will continue to support 66 jurisdictions to build upon current progress in tracking and preventing overdose deaths. These awards expand capacity at the state and local level for overdose monitoring, tracking problematic prescribing patterns, and detecting changes in the supply of illicit drugs. These activities will enhance states' abilities to monitor the epidemic by improving the timeliness and quality of surveillance data for both fatal and nonfatal opioid overdose as well as to leverage timely data to target effective responses.

Drug Free Communities Program

The Drug Free Communities Act of 1997 established the Drug Free Communities Program to prevent and reduce substance abuse among youth by establishing and strengthening coalitions between communities, public and private non-profit agencies, and governments. The FY 2021 Budget provides $100 million to CDC to administer the Drug Free Communities Program. In FY 2019, Congress appropriated $100 million to the Office of National Drug Control Policy, and provided authority to transfer resources to other federal departments and agencies. By appropriating funds directly to CDC, the Drug Free Communities program will benefit directly from CDC's public health expertise and robust network of grantees for other CDC state, local, territorial, and tribal substance abuse prevention programs.

COMBATING THE OPIOID EPIDEMIC

CDC supports prevention of drug- and opioid-specific overdose by:

Using data to monitor emerging trends and direct prevention activities

Strengthening state and local capacity to respond to the epidemic

Working with providers, health systems, and payers to reduce unsafe exposure to opioids and treat addiction

Coordinating with public safety and community-based partners to rapidly identify overdose threats, reverse overdoses, link people to effective treatment, and reduce harms associated with illicit opioids

Increasing public awareness about the risks of opioids

BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Every 4.5 minutes, a baby in the United States is born with a major birth defect, and 1 in 6 children have developmental disabilities. CDC enriches the quality of life of vulnerable populations through efforts to identify and address the causes of birth defects, infant disorders, and developmental disabilities. Through surveillance, research, and prevention efforts, CDC translates scientific findings to increase the understanding of the potential causes, leading to recommendations, policies, and services to help prevent them. CDC is working toward a day when every child is born with the best health possible. The FY 2021 Budget includes $112 million to prevent birth defects and developmental disabilities, while providing CDC the flexibility to efficiently manage resources while addressing the most pressing public health issues.

Emerging Threats to Mothers and Babies

The FY 2021 Budget includes $10 million for activities to protect mothers and babies from emerging threats. The *Surveillance for Emerging Threats to Mothers and Babies* initiative, launched in FY 2019, currently

supports 13 jurisdictions and public health organizations to monitor and determine the impact of serious threats, such as Zika virus, syphilis, and Hepatitis C, on mothers and babies, and to track the occurrence of birth defects and developmental disabilities as children age. Findings will help CDC address critical threats, develop appropriate prevention strategies, and inform the clinical and public health communities about the needs of and optimal care for children and families.

Neonatal Abstinence Syndrome

Every 15 minutes, a baby is born with neonatal abstinence syndrome, which occurs when newborn babies experience withdrawal after being exposed to drugs in the womb. CDC is on the front lines of understanding the impact of the opioid and substance-use crisis on adults, infants, and children. To date, CDC has improved surveillance to provide more consistent and comparable data on the incidence and impact of exposure to opioids during pregnancy on infant health. The FY 2021 Budget provides $2.25 million to continue CDC's work to advance the understanding of neonatal abstinence syndrome and translate these findings to improve the care of mothers and babies.

CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Chronic diseases, such as heart disease, cancer, chronic lung diseases, stroke, and diabetes, account for the majority of deaths in the United States every year, and are the major causes of sickness, disability, and healthcare costs. While chronic diseases affect all populations, disease rates vary by race, ethnicity, education, and income level. The most disadvantaged Americans often bear the most significant consequences of chronic disease.

The FY 2021 Budget includes $813 million for chronic disease prevention and health promotion activities. CDC will continue to lead efforts to prevent and control chronic diseases and associated risk factors by implementing targeted chronic disease prevention interventions though state, tribal, local, and territorial health departments and non-governmental organizations, monitoring national chronic disease trends, and evaluating effective interventions.

The FY 2021 Budget proposes the America's Health Block Grant as an opportunity to reform state-based chronic disease programs. States may use their Block Grant resources to address chronic disease priorities, including: tobacco control and prevention; nutrition and physical activity; heart disease and stroke; diabetes, and arthritis. This $350 million Block Grant program will provide states flexibility to support interventions that best address chronic diseases with the highest incidence in their state.

The Budget also includes $337 million to continue CDC's crosscutting cancer prevention and control programs and partnerships. CDC helps Americans lower their cancer risk and detect cancer early, through screening recommendations and other effective interventions.

Improving Maternal Health in America Initiative

In FY 2021, CDC will dedicate an additional $12 million, for a total of $24 million, toward the HHS-wide *Improving Maternal Health in America Initiative*, a cross-agency approach to improving maternal mortality focused on four strategic goals: (1) achieving healthy women by improving screening and prevention; (2) achieving healthy pregnancies and births by identifying and treating risk factors, morbidities, and complications during pregnancy; (3) achieving healthy futures by optimizing post-partum health through continued engagement in managing risk factors; and (4) improving data and bolstering research. This initiative builds on CDC's ongoing work to address maternal mortality and morbidity.

With this additional funding, CDC will expand Maternal Mortality Review Committees to all 50 states and DC. Through these committees, every state will examine every case of pregnancy-related death to understand the circumstances surrounding the death and identify effective prevention opportunities.

ENVIRONMENTAL HEALTH

Safe and healthy environments promote healthier people and communities. CDC protects Americans against everyday hazards found in air, water, or food. In particular, CDC is committed to protecting the health and wellbeing of populations who are especially vulnerable to environmental health threats, including children, the elderly, and individuals with disabilities.

The FY 2021 Budget includes $182 million to support CDC's environmental health activities. CDC will continue to monitor health outcomes resulting from environmental exposures, develop guidance to address

environmental health issues, and build partnerships to discuss health impacts and support collaborative decision making. The Budget maintains funding for the Childhood Lead Poisoning Prevention Program, and includes additional resources to support CDC's work with private labs and device manufacturers to harmonize results on more high priority lab tests.

OCCUPATIONAL SAFETY AND HEALTH

The National Institute for Occupational Safety and Health (NIOSH) is the lead research agency focused on worker safety and health. Through NIOSH's efforts, CDC helps protect the nation's 163 million workers and provides the only dedicated federal investment for research needed to prevent occupational injuries and illnesses that cost the United States $250 billion annually.

The FY 2021 Budget includes $190 million for occupational safety and health activities. CDC works cooperatively with employers and employees to adapt research findings into effective and feasible solutions to prevent illness and injury in the workplace. In addition to the discretionary resources provided for these activities, the Budget provides $55 million for the mandatory Energy Employee Occupational Injury Compensation Act program.

World Trade Center Health Program

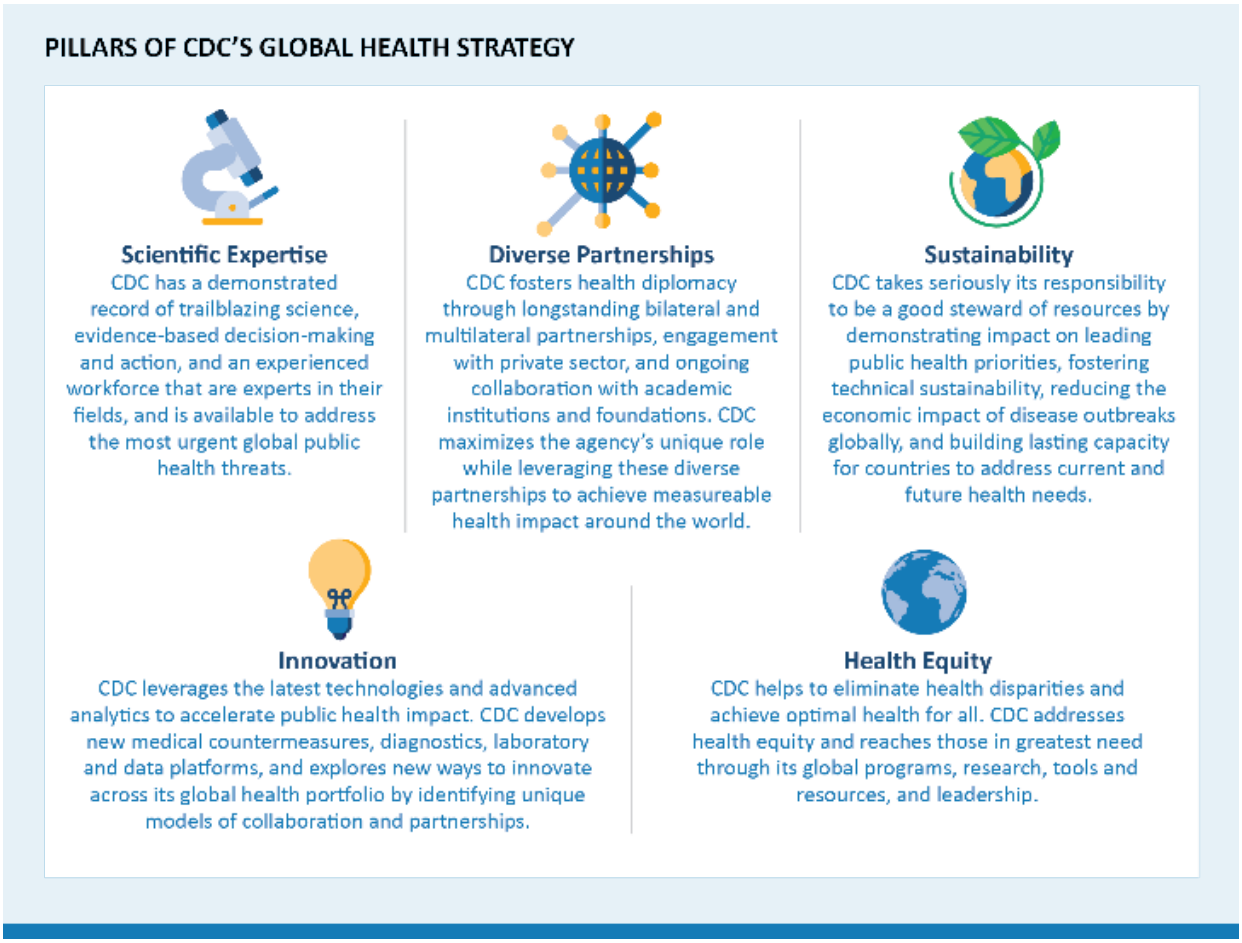
The September 11, 2001 terrorist attacks required extensive response, recovery, and cleanup activities exposing thousands of responders and survivors to toxic smoke, dust, debris, and psychological trauma. The World Trade Center Health Program was established by the James Zadroga 9/11 Health and Compensation Act of 2010 and reauthorized in 2015 until 2090 to serve all eligible responders, as well as survivors who were in the New York City disaster area.

The Budget includes $540 million in mandatory Federal share funding to provide monitoring and treatment benefits to eligible responders and survivors, conduct research on related health conditions, and maintain a health registry to collect data on those affected. To date, the program has enrolled over 99,000 eligible participants and paid claims for treatment and medication for more than 32,000 enrollees.

PUBLIC HEALTH PREPAREDNESS AND RESPONSE

The United States faces growing health threats in today's increasingly connected world. Disease outbreaks and natural disasters can escalate into emergencies. CDC's public health preparedness and response programs protect Americans before, during, and after public health emergencies. CDC's world-class laboratories, public health surveillance, epidemiology, and incident management expertise, combined with long-standing relationships with federal, state, territorial, tribal, local, and global partners, uniquely qualify CDC to prepare for, detect, and respond to public health emergencies. The Budget provides $802 million for CDC's public health preparedness and response activities.

State and local public health capacity is central to effective preparation, response, and recovery from public health emergencies. The Budget includes $675 million for the Public Health Emergency Preparedness cooperative agreements. In FY 2021, CDC will continue to provide funding to 62 awardees, which includes all 50 states, 4 major cities, and 8 territories, and will continue support for more than 2,600 staff that provide critical public health expertise at the local level which enables faster and more effective responses. Staff work in jurisdictions as laboratorians, epidemiologists, data analysts, health professionals, communication specialists, and evaluators. CDC also assigns highly skilled, senior professionals, called Career Epidemiology Field Officers, to state, territorial, and local health departments across the country to strengthen nationwide public health capacity and preparedness.



GLOBAL HEALTH

In today's interconnected world, diseases can spread from a remote village to a major city in as little as 36 hours. CDC works globally to detect and respond to diseases where they occur. Through these efforts, including deployments of scientists and health experts, CDC can detect epidemic threats earlier, respond more effectively, and prevent avoidable catastrophes. CDC's work worldwide supports the overarching goal of ensuring global health security, while building the nation's domestic defense against health threats. The Budget includes $532 million for CDC's global health activities that help protect Americans from major health threats such as Ebola, *Zika virus*, and pandemic influenza. CDC's global health programs are led by world experts in epidemiology, surveillance, informatics, laboratory systems, and other essential disciplines, and provide strong global health leadership capacity. CDC works with non-governmental organizations to identify, direct, and coordinate global health strategies and priorities.

Global Health Security

The FY 2021 Budget includes an additional $50 million, for a total of $175 million, to continue efforts to help protect the American people from health threats around the world, focused on helping high risk countries build their own public health capacity to respond to outbreaks. CDC collaborates on and supports country-lead response efforts to confront the most challenging health epidemics, often in complex geopolitical settings. However, it is critical that CDC maintain the capacity to address contagious disease threats where they occur – from Ebola in West Africa, to polio in Pakistan and Afghanistan, to 2019 Novel Coronavirus (2019-nCoV) in China.

In FY 2020, CDC began the process of building a robust, tangible presence in strategic regions across the globe. With new resources in FY 2021, CDC will continue efforts to increase the geographic and strategic positioning of CDC's expertise to ensure early disease detection and rapid response capabilities, and will allocate funding to meet public health security challenges worldwide. CDC will continue to partner with individual countries to help develop and augment

their public health capacity and health security expertise to ensure that diseases are contained at their source.

INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND

Congress established the Infectious Diseases Rapid Response Reserve Fund in FY 2019 to allow CDC to rapidly and effectively respond to emerging infectious disease outbreaks, such as the 2019 Ebola outbreak in the DRC. The FY 2021 Budget provides an additional $50 million for the Reserve Fund within CDC to allow HHS to rapidly and effectively respond to current or emerging infectious disease threats domestically or globally.

BUILDINGS AND FACILITIES

CDC infrastructure investments support the dedicated staff who protect Americans from public health threats every day. CDC maintains safe, secure, and fully operational laboratories nationwide as a requirement to fulfill its mission and respond to evolving public health needs. The FY 2021 Budget includes $30 million to support required renovations and repairs to maintain and make necessary improvements to CDC facilities.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

For 3 decades, the ATSDR, a nonregulatory, congressionally-mandated public health agency, has protected American communities from exposures to harmful substances in our soil, water, and air. ATSDR works to better understand the human health effects of hazardous substances and builds local capacity to investigate and take action to reduce harmful exposures. ATSDR staff and partners trained by ATSDR are ready 24/7 to respond to environmental threats from natural disasters, chemical spills, and other emergencies. In FY 2019, ATSDR responded to over 700 requests from community, state, and federal entities to investigate potential health risks, and trained 30,000 health professionals about ways to examine the impact of exposure to Per- and Polyfluoroalkyl exposure, a large group of man-made chemicals.

The FY 2021 Budget includes $62 million for ATSDR, with a focus on activities related to children's health, safe drinking water, and innovative laboratory methods.

National Institutes of Health

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
Institutes/Centers				
National Cancer Institute	6,121	6,440	5,881	-559
National Heart, Lung, and Blood Institute	3,482	3,625	3,298	-327
National Institute of Dental and Craniofacial Research	461	478	435	-43
National Institute of Diabetes and Digestive and Kidney Diseases	2,176	2,265	2,074	-191
National Institute of Neurological Disorders and Stroke	2,246	2,447	2,245	-201
National Institute of Allergy and Infectious Diseases	5,545	5,876	5,446	-430
National Institute of General Medical Sciences	2,822	2,937	2,672	-265
Eunice K. Shriver National Institute of Child Health and Human Development	1,501	1,557	1,416	-141
National Eye Institute	794	823	749	-74
National Institute of Environmental Health Sciences: Labor/HHS Appropriation	772	803	730	-72
National Institute of Environmental Health Sciences: Interior Appropriation	79	81	74	-7
National Institute on Aging	3,080	3,546	3,226	-320
National Institute of Arthritis and Musculoskeletal and Skin Diseases	603	625	568	-56
National Institute on Deafness and Communication Disorders	473	491	446	-44
National Institute of Mental Health	1,872	2,043	1,845	-198
National Institute on Drug Abuse	1,408	1,458	1,432	-26
National Institute on Alcohol Abuse and Alcoholism	525	547	497	-49
National Institute of Nursing Research	163	172	157	-16
National Human Genome Research Institute	575	604	550	-54
National Institute of Biomedical Imaging and Bioengineering	388	405	368	-37
National Institute on Minority Health and Health Disparities	313	336	305	-30
National Center for Complementary and Integrative Health	146	152	138	-14
National Center for Advancing Translational Sciences	816	833	788	-45
Fogarty International Center	78	81	74	-7
National Library of Medicine	441	457	416	-41
Office of the Director /2	1,908	2,247	2,099	-148
21st Century Cures Innovation Accounts	196	157	109	-48
Buildings and Facilities	199	200	300	100
National Institute for Research on Safety and Quality /3	--	--	355	355
Total, Program Level	**39,184**	**41,685**	**38,694**	**-2,991**
Less Funds from Other Sources				
Public Health Service Evaluation Funds	-1,147	-1,231	-741	+490
Current Law Mandatory Funding – Type 1 Diabetes /4	-150	-97	--	+97
Proposed Law Mandatory Funding – Type 1 Diabetes /4	--	-53	-150	-97
Patient-Centered Outcomes Research Trust Fund /3	--	--	-98	-98
Total, Discretionary Budget Authority	**37,887**	**40,304**	**37,704**	**-2,600**

	dollars in millions			
	2019 /1	2020	2021	2021 +/- 2020
Appropriations				
Labor/HHS Appropriation	37,808	40,223	37,630	-2,593
Interior Appropriation	79	81	74	-7
Full-Time Equivalents /5	17,227	18,101	18,339	+238

1/ Reflects the FY 2019 Final Level including funding authorized by the 21st Century Cures Act and directed or permissive transfers. Funding level does not include supplemental hurricane appropriations ($1 million).
2/ Amount for FY 2020 reflects directed transfer of $5 million to the HHS Office of Inspector General.
3/ The FY 2021 Budget consolidates the highest priority activities of the Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality (NIRSQ). AHRQ's appropriation in FY 2019 and FY 2020 was $454 million and $445 million, respectively. AHRQ funding levels include mandatory transfers from the Patient-Centered Outcomes Research Trust Fund.
4/ P.L. 116-94, FY 2020 Consolidated Appropriations Act provides $96.6 million for Diabetes Grants, through May 22, 2020. The Budget assumes it will be extended through the end of FY 2020 at $150 million total funding.
5/ Full-time equivalent levels include NIRSQ in FY 2021. Excludes 4 FTEs funded by the Public Health Service trust funds in all years, and also excludes 7 FTEs funded by the PCORTF in FY 2021.

The National Institutes of Health's (NIH) mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

The National Institutes of Health (NIH) conducts and supports biomedical research that fosters fundamental creative discoveries, innovative research strategies, and their applications to improve human health. NIH supports a world-class research workforce and plays a critical role in supporting basic research and its translation into tangible medical and healthcare improvements.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $38.7 billion for NIH. Of this total, $248 million is in mandatory resources and $404 million is in resources available through the 21st Century Cures Act. The Budget prioritizes biomedical research to respond to the opioids crisis, accelerate progress on treating childhood cancer, end the HIV epidemic, and prevent and control tick-borne illness. NIH funds over 50,000 research grants to more than 300,000 individuals at more than 2,500 universities, medical schools, research facilities, small businesses, and hospitals.

RESEARCH PRIORITIES IN FY 2021

Combatting the Opioid and Methamphetamine Crisis

Initial data suggests the Administration has made progress in decreasing the number of drug overdose deaths. According to the Centers for Disease Control and Prevention's National Center for Health Statistics, provisional overdose mortality fell by 5 percent for the 12 months ending in the second quarter of 2018. Despite this progress, an estimated 2 million Americans lived with an opioid use disorder in 2018. The Budget continues to prioritize opioids and pain research and includes $1.4 billion across NIH Institutes and Centers. NIH is driving towards breakthroughs in opioids and pain research to develop long lasting preventive and therapeutic solutions to the opioids crisis that are implementable across the country. The Budget dedicates $533 million to the Helping to End Addiction Long-term (HEAL) Initiative and more than $900 million to support ongoing research. The HEAL Initiative was launched in 2018 to reduce opioid misuse and addiction. The HEAL Initiative takes an "all hands on deck" approach to the opioid crisis, applying expertise from almost every NIH Institute and Center to accelerate research and comprehensively address this public health emergency. HEAL translates treatment for opioid addiction research to practice, expands pain management approaches to help the more than 50 million Americans who suffer from chronic pain, half of whom lack effective and safe non-opioid options for pain management, and supports research to inform clinical care for infants born with opioid withdrawal syndrome.

There are multiple effective evidence-based treatments and programs for opioid use disorder, yet many people at risk do not receive appropriate treatment. NIH will test integrated evidence-based interventions in an array of settings. This will advance the understanding of how promising strategies and treatments might help people with opioid use disorder. One example is NIH's Justice Community Opioid Innovation Network. A total of 15 percent[1] of individuals in jails and prisons have an opioid use disorder, making the criminal justice system an opportunity for intervention. This network will test strategies to expand effective treatment and care in partnership with local and state justice systems and community-based treatment providers.

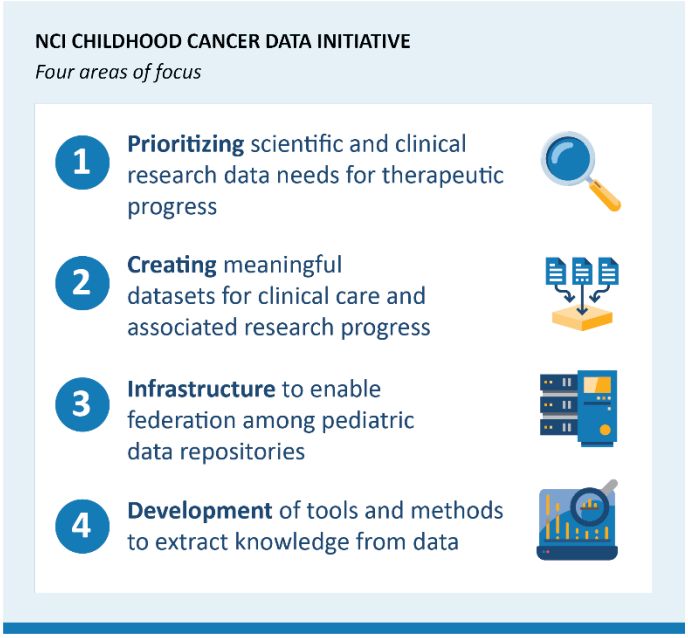
The HEAL Initiative will also help establish evidence-based guidelines for treating pain with non-opioid therapies to reduce the use of prescription opioid medications and possible subsequent addiction. Lower back pain is one of the most common forms of chronic pain among adults worldwide. NIH's Back Pain Consortium will address critical gaps in chronic lower back pain characteristics and treatment, and will test the safety and efficacy of complementary and alternative medicine approaches, non-addictive drugs, biologics, and devices to relieve chronic lower back pain and improve physical function.

NIH will allocate an additional $50 million to develop medication-assisted treatment and evidence-based psychosocial treatment to support the Department's strategy for reducing methamphetamine and other stimulant use. The reduction in opioid availability has led some people to seek alternative drugs like methamphetamines and other stimulants. NIH will increase support for this critical area of research and expedite the development of new treatments for stimulant use disorders including testing of compounds approved for other conditions for their potential in treating methamphetamine addiction, research on neurostimulation for treatment, interventions to repair effects of methamphetamine toxicity on mood and cognition, and research on web-based and smartphone-based behavioral treatments. NIH is currently soliciting research to develop medications and devices for the treatment of substance use disorders, and emphasizing the urgent need for medications or devices treating stimulant use disorders in particular.

Changing the Course of Childhood Cancer

Cancer is the leading cause of death from disease among children and adolescents in the United States. While treatment for some childhood cancers has improved dramatically, current therapies are often highly toxic for these young patients, and there are areas where progress has been limited. Survivors may face lifelong health problems even after successful treatment has ended. Data generated by NIH programs focused on pediatric cancer research and care will support the development of new, effective, and safer treatments for children and adolescents suffering from cancer, and improve the quality of life for survivors. NIH's National Cancer Institute (NCI) supports a broad range of research to better understand the causes, biology, and patterns of childhood cancers and then identify the best ways to successfully treat children with cancer. NCI utilizes that research to expand scientific knowledge through clinical trials where researchers treat and learn from young cancer patients.

In FY 2020, NCI launched the Childhood Cancer Data Initiative to establish a comprehensive and coordinated data resource to support current and future cancer



[1] National Academies of Sciences, Engineering, and Medicine. 2019. Medications for Opioid Use Disorder Save Lives. Washington, DC: The National Academies Press. https://doi.org/10.17226/25310.

research. To ensure every child can benefit from the initiative, NCI will:

- Build a connected data infrastructure to share childhood cancer data from multiple sources and expand data accessibility across the research community;
- Identify opportunities to better generate and utilize data for patients, clinicians, and researchers; and
- Develop and enhance tools and methods to extract knowledge from data to directly address challenges in caring for children with cancer.

In FY 2021, NCI will invest $50 million for the second year of this initiative. Building on NIH's vast cancer research portfolio, and the Initiative's progress to date, NCI will:

- Expand NCI's data infrastructure to include connections to childhood cancer data repositories, healthcare systems, and registries;
- Establish an interactive data commons with pediatric preclinical models and clinical data to enhance the development of novel precision therapies; and
- Advance and support creation of new research grant opportunities that focus on rare and hard-to-treat pediatric, adolescent and young adult tumors.

Ending the HIV Epidemic: A Plan for America

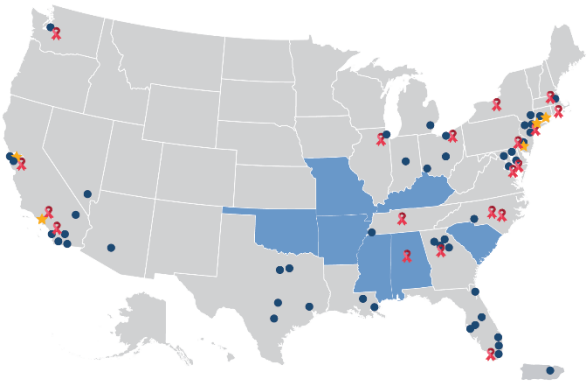
FY 2021 is the second year of the President's *Ending the HIV Epidemic* initiative to eliminate new HIV infections across the nation. By accelerating proven public health strategies, HHS's goal is to reduce new infections by 75 percent by 2025 and by 90 percent by 2030, averting more than 400,000 new HIV infections.

NIH-supported basic research was instrumental to the current deep understanding of the biology of HIV. This enabled effective treatments, rapid diagnostics, and other approaches that now allow HIV-infected individuals to live a nearly normal lifespan.

In addition to ongoing HIV biomedical research, NIH leads evaluation efforts to identify effective interventions to treat and prevent HIV. The FY 2021 Budget provides $16 million for NIH-sponsored Centers for AIDS Research to design and evaluate integrated delivery of prevention and treatment across multiple locations and settings including the areas where most new HIV infections occur. These efforts will ensure effective implementation of prevention and treatment services in the parts of the country most impacted by HIV.

NIH-funded research will lead to the creation of sustainable systems for the implementation of prevention and treatment interventions, with a focus on implementing strategies at scale that will be the most effective. This will ensure that promising strategies, such as the use of long-acting

NIH SUPPORT FOR *ENDING THE HIV EPIDEMIC* INITIATIVE



CENTERS FOR AIDS RESEARCH ACTIVITIES

Develop new strategies for the delivery of integrated HIV prevention and treatment

Design and evaluate sustainable systems for the implementation of interventions

Collect and disseminate data on the effectiveness of interventions

Ensure that promising strategies, such as the use of long-acting sustained-release medications for prevention and treatment, are brought rapidly into clinical use

NIH-FUNDED CENTER FOR AIDS RESEARCH

NIMH AIDS CENTER

HIGH BURDEN COUNTY

STATE WITH SUBSTANTIAL RURAL BURDEN

sustained-release medications for prevention and treatment, are brought rapidly into clinical use.

Promoting Influenza Research Innovation

Circulating and emerging influenza viruses present a public health threat and affect health in the United States and worldwide. Each year seasonal influenza infection causes nearly 650,000 deaths worldwide and up to 56,000 deaths in the United States. In addition, highly unpredictable influenza pandemics can vastly increase this total. Influenza is a respiratory infection that can be easily spread person to person. The easiest and most effective way to prevent influenza is through vaccination. Traditional vaccine development relies on predicting which strains will be in circulation each year. NIH's goal is to establish new vaccine products and platforms that can provide broad protection over the course of the lifespan.

The Budget prioritizes the advanced development of improved vaccines in response to the President's Executive Order on *Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health* to develop vaccines that provide robust, long-lasting protection against multiple subtypes of flu, rather than a select few. The FY 2021 Budget provides $423 million for innovative research to diagnose, treat, and prevent influenza infection and protect against future pandemics. This research informs new and improved therapies, diagnostics, and vaccines. Within the total, the Budget dedicates $200 million to develop a universal vaccine to protect adults and children by eliminating the need to update and administer the seasonal flu vaccine each year. Several universal vaccine strategies are currently being tested in NIH-supported clinical trials.

NIH's National Institute of Allergy and Infectious Diseases (NIAID) conducts research to find new and improved ways to diagnose, treat, and prevent influenza infection. This research strengthens fundamental knowledge, enhances seasonal flu vaccines for all age groups, and supports several seasonal and universal influenza vaccines. NIH also supports pandemic influenza research to develop a strong evidence base for vaccine candidates for a global outbreak.

Tick-borne Diseases Research

In October 2019, NIH published the NIH Strategic Plan for Tick-borne Disease Research to further the agency's commitment to address the public health challenge posed by the rising numbers of tick-borne diseases (including Lyme disease) in the United States. The number of reported cases more than doubled from 2004 to 2016, and reached a record high of more than 59,000 cases in 2018. Current strategies to address these types of diseases are limited by challenges with diagnostics, treatment options, and the lack of vaccines.

The Budget includes $115 million in FY 2021 to accelerate NIH's progress toward priorities outlined in the new strategic plan through basic, translational, and clinical research to better understand the complex interplay between ticks, hosts impacted by ticks and their defenses against ticks. In FY 2020 NIH will:

- Support Investigator-initiated research and NIH-led research including studies on red meat allergies associated with tick bites;
- Fund training grants and fellowships to encourage new investigators to enter the tick-borne research field;
- Conduct clinical trials for vaccines and other preventative strategies; and
- Support preclinical services to improve diagnosis, prevention, and treatments for tick-borne diseases.

NIAID will build on and expand current research to fund new grants to improve understanding of the disease and encourage new investigators to enter the field of study. This research fosters the development of effective tools that can advance prevention, diagnostic, and treatment efforts.

Artificial Intelligence for Chronic Disease

The annual economic impact of chronic diseases is estimated at $3.7 trillion, equivalent to nearly one-fifth of the United States economy. The FY 2021 Budget provides $50 million to utilize artificial intelligence to deepen understanding of the underlying causes of chronic diseases and identify successful early treatments, which supports the Administration's Industries of the Future initiative.

NIH will employ artificial intelligence and other advanced techniques using computers that learn and improve analytical functions from experience rather than programming to enhance interpretation of data

on chronic diseases. As a result, more powerful information will be available to researchers.

Using artificial intelligence to advance this effort represents a bold new direction. NIH will jumpstart this initiative by articulating problems for public engagement through prize competitions and code-a-thons. NIH will develop innovative and key data resources and new career pathways for recruiting and retaining investigators.

Gene Vector Production and Innovation

Gene therapy and gene editing approaches are among the most promising treatment methods for a growing number of diseases and conditions including cancer, muscular dystrophies, and many others. Vectors are the vehicle by which a gene can be delivered to a targeted location in the body.

In order to ensure gene-based therapies reach the people who need them, the Budget includes $30 million in new funding to create a consortium with industry, academic, and federal stakeholders. Currently, it can take up to two years to produce vector therapies that meet manufacturing standards necessary for clinical trials. This consortium will scale up and increase the efficiency of vector production to speed up new gene therapy clinical trials and patient treatments. This effort will expand production capacity, improve the design of vectors, and promote standardization and data sharing to replicate successful results.

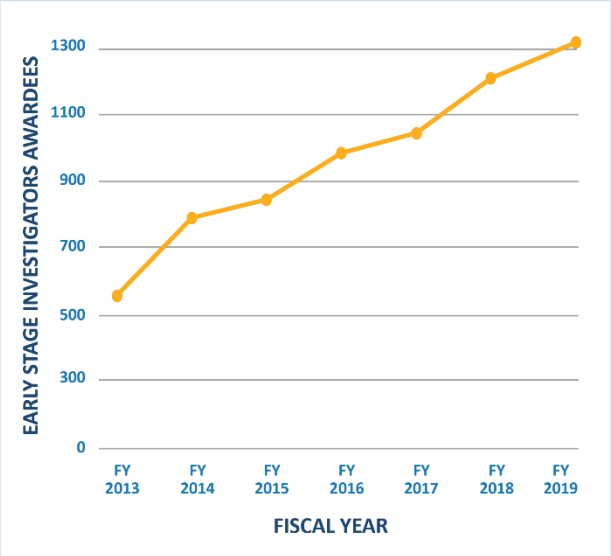
Supporting World-Class Researchers

NIH aims to sustain and diversify the biomedical research workforce to foster creative discoveries and innovative research to protect and improve health. Over the last decade, NIH implemented policies to expand opportunities for early-career investigators to secure funding. NIH focuses resources on the long-term stability of the biomedical research workforce by prioritizing meritorious applications from early stage investigators and developing evidence-based strategies to support research-specific workforce issues. NIH will continue to identify and pursue activities to improve management of the biomedical research enterprise.

NIH is also committed to a robust portfolio of training grants to prepare scientists at all academic levels for careers that have a significant impact on the health-related research needs of the nation. This includes the Ruth L. Kirschstein Institutional National Research Service Award which enables institutions to recruit a diverse pool of highly trained scientists in adequate numbers and appropriate research areas to carry out the nation's biomedical and behavioral research agenda. The Budget includes an estimated $848 million to support 16,305 research scientist trainees through this program.

NIH EARLY STAGE INVESTIGATORS FOR FY 2013 – FY 2019

NIH promotes the growth, stability, and diversity of the biomedical research workforce through ESIs who help foster the creative discoveries and innovative research that will protect and improve health



Data Science

The complexity and volume of research data generated by NIH-supported investigators continues to rapidly increase. NIH is focused on catalyzing new capabilities in biomedical data science by modernizing its data resource ecosystem.

NIH's Office of Data Science Strategy leads the development and implementation of a new NIH-wide infrastructure to lower the barrier for researchers to access datasets. In support of the optimal use of cloud systems to access data, NIH is moving high-priority datasets to Google and Amazon Web Services. In FY 2021, NIH will launch new programs to develop artificial intelligence and other tools that will enable computing across diverse datasets in a cloud environment.

IDeA States Pediatric Clinical Trials Network

NIH's Institutional Development Award (IDeA) program supports expansion and enhancement of research

infrastructure to broaden the geographic distribution of NIH funding. The IDeA program also serves the unique populations of these areas, such as rural and medically underserved communities. Leveraging research institutions supported by the IDeA program, the IDeA States Pediatric Clinical Trials Network broadens access to cutting-edge clinical trials, applies findings from other relevant pediatric studies to children in IDeA state locations, and builds national pediatric research capacity.

The Budget provides $15 million for the IDeA States Pediatric Clinical Trials Network to continue studies such as the multi-site clinical trial. This clinical trial evaluates the dosing, safety, and efficacy of drugs that are commonly prescribed to children. NIH-funded activities will also advance a study that aims to decrease pediatric obesity rates in rural areas through use of mobile health technology.

Improving Research to Save America's Youngest Lives

The Administration wants every child to have the very best chance to live and thrive. In order to help save more pre-mature babies, the Budget prioritizes funding for neonatal research and provides an additional $100 million over 2020 and 2021 dedicated to advancing research and care for America's youngest patients.

Buildings and Facilities

The National Academies of Sciences, Engineering, and Medicine released an independent review of NIH's facility needs in August 2019. The report highlights pressing campus-wide infrastructure needs and recommends improvements to NIH's capital planning and funding processes. The dynamic nature of biomedical and clinical research requires state-of-the-art facilities. The Budget includes $300 million to continue the long-term effort to strengthen stewardship of NIH facilities and ensure the infrastructure is conducive to cutting-edge research.

The Budget also increases flexibility for Institutes and Centers to fund repair and improvement projects.

MAXIMIZING RESEARCH INFRASTRUCTURE

The Budget leverages the current NIH research infrastructure by consolidating the highest priority Agency for Healthcare Research and Quality (AHRQ) programs into a new institute, the National Institute for Research on Safety and Quality (NIRSQ). NIRSQ will continue activities to improve the quality and safety of care through health services research, data collection and analysis, and prevention of risk and harms in healthcare settings. NIRSQ will support the Administration's efforts to move healthcare organizations from volume to value by focusing on improving outcomes, reducing cost, and expanding choices for consumers.

The Budget requests $355 million for NIRSQ. This includes $257 million in discretionary budget authority and $98 million in mandatory transfers from the Patient Centered Outcomes Research Trust Fund. The Budget supports health services research, data and analytics, and activities to address multiple chronic conditions, and maternal mortality and morbidity. NIRSQ research investments will also focus on the affordability, efficiency, and quality of healthcare for all Americans

ADVANCING HEALTH SERVICES RESEARCH

NIRSQ will continue a wide range of health services research that informs decision-making and improves healthcare services through the implementation of evidence. The Budget provides $57 million for the Health Services Research, Data, and Dissemination research portfolio. Health services research generates new knowledge to improve healthcare quality by addressing current data gaps. NIRSQ will support activities such as the Consumer Assessment of Healthcare Providers and Systems. This program uses consumer assessments to help increase scientific understanding of patient's experiences with healthcare providers, health plans, and healthcare facilities. The healthcare community uses this information to help improve the patient experience. NIRSQ will also evaluate primary care models that can improve healthcare for individuals with multiple chronic conditions. Nearly one in three American adults and four of Medicare beneficiaries have multiple chronic conditions and represent a growing segment of the population.

Improving Maternal Health

More than 700 American women die each year as a result of pregnancy and childbirth and over 50,000 experience severe complications. In FY 2021 NIRSQ will dedicate $7 million towards the HHS-wide *Improving Maternal Health in America Initiative,* which focuses on

a four-part strategy that includes improving data and bolstering research to inform future interventions.

NIRSQ will ensure federal, state, and local policymakers have timely and accurate data and useful analytic resources to address maternal morbidity and mortality. NIRSQ will focus on three areas during the first year of this initiative:

- Partnering with states to improve social service data and provide a 360 degree view of the pregnancy, delivery, and early childhood support systems;
- Creating a predictive analytic program to address data requests; and
- Expanding the Medical Expenditure Panel Survey to include an additional 1,000 interviews.

ENHANCING PATIENT SAFTEY

NIRSQ's patient safety activities will address healthcare quality gaps, monitor adverse events to prevent future risks and harms in healthcare settings, and give healthcare professionals tools to improve patient safety. An example of this work is the Quality and Safety Review system, which is a resource for local hospitals to identify and measure adverse events to inform safety improvements. The FY 2021 Budget provides $60 million for patient safety research to reduce patient safety risks and harms, support patient safety organizations, and address healthcare-associated infections.

MEDICAL EXPENDITURE PANEL SURVEY

NIRSQ's Medical Expenditure Panel Survey (MEPS) is the only national source for comprehensive annual data on how Americans use and pay for medical care. The survey collects detailed information from families on patient access, use of healthcare services, expenses, insurance coverage, and quality. MEPS provides valuable data on health status, demographics, employment, and healthcare access and quality. The FY 2021 Budget provides $72 million for MEPS. This total supports the first year of a $2 million investment to expand the sample size for MEPS by redistributing the sample across states.

Overview by Mechanism

	dollars in millions			
	2019 /1	2020 /2	2021 /3	2021 +/- 2020
Mechanism				
Research Project Grants (dollars)	22,368	23,850	22,090	-1,760
[# of Non-Competing Grants]	*27,624*	*29,508*	*30,109*	*+601*
[# of New/Competing Grants]	*11,020*	*11,379*	*9,505*	*-1,874*
[# of Small Business Grants]	*2,023*	*2,140*	*1,993*	*-147*
[Total # of Grants]	*40,667*	*43,027*	*41,607*	*-1,420*
Research Centers	2,691	2,664	2,406	-258
Other Research	2,574	2,663	2,440	-223
Research Training	865	910	848	-62
Research and Development Contracts	3,165	3,349	3,077	-272
Intramural Research	4,144	4,446	4,077	-369
Research Management and Support	1,883	2,015	1,926	-89
Office of the Director /4	1,197	1,477	1,343	-134
NIH Common Fund (non-add)	*619*	*639*	*596*	*-43*
Office of Research Infrastructure Programs (non-add)	*288*	*288*	*269*	*-20*
OD Appropriation (non-add)	*2,104*	*2,404*	*2,208*	*-196*
Buildings and Facilities /5	217	230	315	+85
National Institute of Environment Health Services Interior Appropriation (Superfund)	79	81	74	-7
Patient Centered Outcomes Research Trust Fund /3	--	--	98	+98
Total, Program Level	**39,184**	**41,685**	**38,694**	**-2,991**
Less Funds from Other Sources				
Public Health Service Evaluation Funds (NIGMS) /6	-1,147	-1,231	-741	+490
Current Law Mandatory Funding – Type 1 Diabetes (NIDDK) /7	-150	-97	--	+97
Proposed Law Mandatory Funding – Type 1 Diabetes (NIDDK) /7	--	-53	-150	-97
Patient Centered Outcomes Research Trust Fund /3	--	--	-98	-98
Total, Discretionary Budget Authority	**37,887**	**40,304**	**37,704**	**-2,600**
Appropriations				
Labor/HHS Appropriation	37,808	40,223	37,630	-2,593
Interior Appropriation	79	81	74	-7
Full-Time Equivalents /8	17,227	18,101	18,339	+238

1/ Reflects the FY 2019 Final Level including funding authorized by 21st Century Cures Act and directed and permissive transfers.
2/ Reflects the FY 2020 Enacted level including the $5 million directed transfer to the HHS Office of Inspector General and the proposed extension of the Type 1 Diabetes mandatory program.
3/ Includes the proposed consolidation of Agency for Healthcare Research and Quality activities into NIH as the National Institute for Research on Safety and Quality (NIRSQ), distributed by mechanism. This includes mandatory transfers from the Patient-Centered Outcomes Research Trust Fund (PCORTF), not distributed by mechanism.
4/ Number of grants and dollars for the Common Fund and Office of Research Infrastructure Programs components of the Office of the Director (OD) are distributed by mechanism and the dollars are noted here as a non-add. OD appropriations are noted as a non-add because the remaining funds are accounted for under OD-Other.
5/ Includes Buildings and Facilities appropriation and funds for facility repairs and improvements at the National Cancer Institute Federally Funded Research and Development Center in Frederick, Maryland.
6/ Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above; therefore, the amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.
7/ Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above; therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.
8/ Full-time equivalent levels include NIRSQ which is consolidated within NIH. Excludes 4 FTEs funded by the Public Health Service trust funds in all years, and also excludes 7 FTEs funded by the PCORTF in FY 2021.

Substance Abuse and Mental Health Services Administration

	dollars in millions			
	2019	2020	2021	2021 +/- 2020
Mental Health				
Community Mental Health Services Block Grant	723	723	758	+35
PHS Evaluation Funds (non-add)	*21*	*21*	*21*	--
Programs of Regional and National Significance	453	530	510	-20
Prevention and Public Health Fund (non-add)	*12*	*12*	--	*-12*
Certified Community Behavioral Health Clinics	150	200	225	+25
Children's Mental Health Services	125	125	125	--
Projects for Assistance in Transition from Homelessness	65	65	65	--
Protection and Advocacy for Individuals with Mental Illness	36	36	14	-22
Subtotal, Mental Health	**1,552**	**1,678**	**1,696**	**+18**
Substance Abuse Prevention				
Programs of Regional and National Significance	205	206	97	-109
Subtotal, Substance Abuse Prevention	**205**	**206**	**97**	**-109**
Substance Abuse Treatment				
Substance Abuse Prevention and Treatment Block Grant	1,858	1,858	1,858	--
PHS Evaluation Funds (non-add)	*79*	*79*	79	--
Formula Grants to States to Address Opioids	1,500	1,500	1,585	+85
Programs of Regional and National Significance	459	480	365	-115
PHS Evaluation Funds (non-add)	*2*	*2*	--	*-2*
Subtotal, Substance Abuse Treatment	**3,817**	**3,838**	**3,808**	**-30**
Health Surveillance and Program Support				
Program Support	79	79	73	-6
Health Surveillance	47	47	34	-13
PHS Evaluation Funds (non-add)	*30*	*30*	31	+1
Public Awareness and Support	13	13	12	-1
Drug Abuse Warning Network	10	10	10	--
PHS Evaluation Funds (non-add)	--	--	*10*	*+10*
Performance and Quality Information Systems	10	10	10	--
Data Request and Publications, User Fees	2	2	2	--
Behavioral Health Workforce Data and Development, PHS Eval.	1	1	1	--
Subtotal, Health Surveillance and Program Support	**162**	**162**	**141**	**-21**
SAMHSA Budget Totals				
Total, Program Level	**5,735**	**5,884**	**5,742**	**-142**
Less Funds from Other Sources:				
Prevention and Public Health Fund	*-12*	*-12*	*-12*	--
PHS Evaluation Funds	*-134*	*-134*	*-143*	*-9*
Data Request and Publications User Fees	*-2*	--	*-2*	*-2*
Total, Discretionary Budget Authority	**5,588**	**5,737**	***5,598***	***-139***
Full-Time Equivalents	491	606	616	+10

The Substance Abuse and Mental Health Services Administration leads public health efforts to advance the behavioral health of the nation and to reduce the impact of substance abuse and mental illness on America's communities.

The Substance Abuse and Mental Health Services Administration (SAMHSA) leads HHS efforts to reduce the impact of substance misuse and mental illness on America's families and communities. SAMHSA is the lead agency in the Administration's efforts to combat substance abuse issues, including opioids, stimulants, and other substances.

The Fiscal Year (FY) 2021 President's Budget (Budget) provides $5.7 billion for SAMHSA. The Budget prioritizes prevention and treatment for opioid use disorder, methamphetamine use disorder, addressing serious mental illness, preventing suicide, and supporting the mental health needs of students.

SUBSTANCE ABUSE

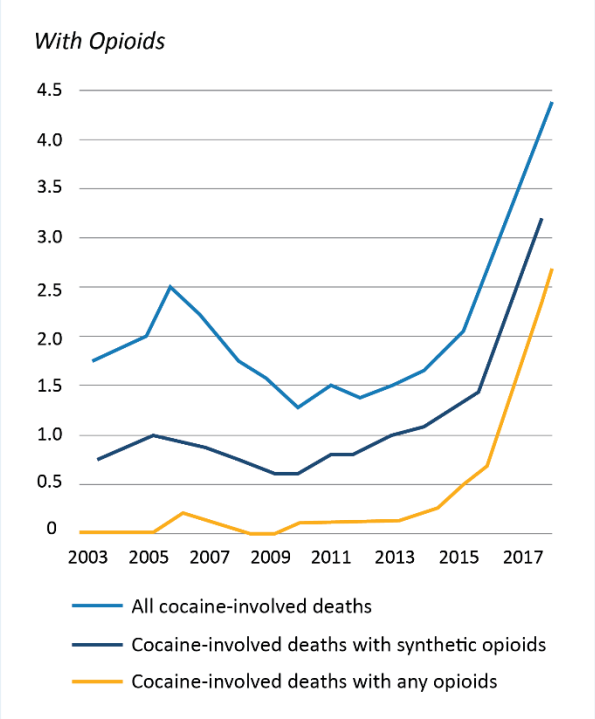
An estimated 21.2 million Americans needed treatment for a serious substance abuse problem in 2018. Substance misuse complicates existing health issues, causes social and emotional costs, and increases healthcare costs. It increases the likelihood of homelessness, loss of employment, loss of family unity, failure to complete education, and other negative life impacts. Drug overdose deaths have risen the past two decades, and are the leading cause of death from injury in the United States. From 2000 to 2018, it is estimated that nearly 754,000 people died from drug overdoses. In 2018, the age-adjusted rate of drug overdose deaths in the United States was 4.6 percent lower than the rate in 2017. The Budget provides $4 billion for substance abuse prevention and treatment activities. The Budget also includes a legislative proposal to better align substance use disorder treatment privacy protections with the Health Insurance Portability and Accountability Act (HIPAA).

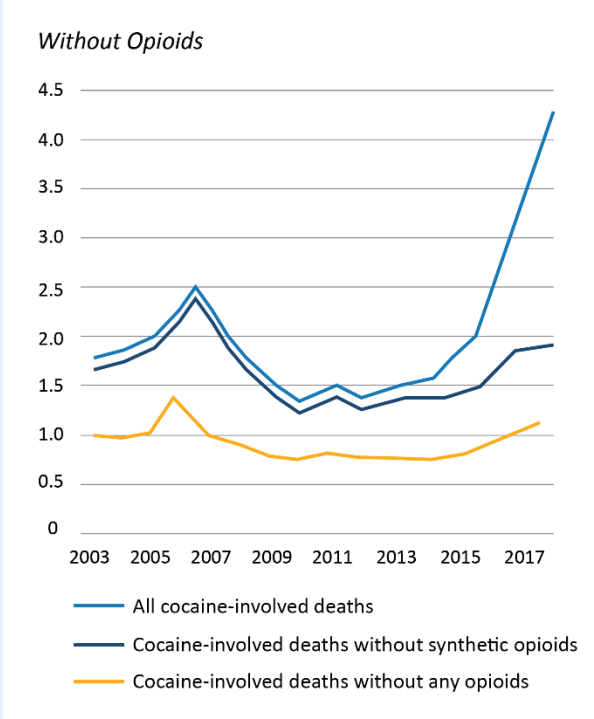
Fighting the Opioid Crisis and Expanding Efforts on Methamphetamine and Stimulants

The FY 2021 Budget increases funding for opioid use disorder prevention and treatment, and expands supports for individuals suffering from stimulant use disorder, including methamphetamine.

The Administration has made progress in slowing opioid use. According to the Centers for Disease

OVERDOSE DEATHS DUE TO METHAMPHETAMINE AND OTHER STIMULANTS ARE ON THE RISE





Control and Prevention's National Center for Health Statistics, overdose mortality fell by 4.1 percent from 2017. In 2018, the number of individuals who misused opioids in the past year declined by more than one million. Despite this progress, the epidemic remains a public health emergency, as first declared by the Acting Secretary in October of 2017. Opioids contribute to over two-thirds of the 192 deaths that occur daily from drug overdose. SAMHSA data released in September of 2019 indicated more than 2 million Americans met diagnostic criteria for opioid use disorder in the past year, including 652,000 who had a heroin use disorder—the highest number recorded in 15 years. While opioids are at the forefront of the drug landscape, the substance abuse epidemic continues to evolve.

Overdose deaths involving methamphetamine and other stimulants are increasing; in a growing number of states, they are responsible for more deaths than opioids. From 2012 through 2018, the rate for deaths involving psychostimulants with abuse potential increased from 0.8 percent to 3.9 percent. FDA has approved medications and clinicians have identified a gold standard treatment protocol for opioid use disorder. However, that is not the case for methamphetamine and other stimulants.

HHS requests $5.2 billion for programs across the Department to address the opioid crisis. Of that amount, $2.0 billion is specifically for SAMHSA programs that combat opioid misuse, abuse, and overdose death. In light of current trends, the Budget also continues to prioritize and expand the ability to use funding to address the abuse of methamphetamine and other stimulants, in addition to opioids.

The Budget prioritizes evidence-based practices, including the use of Medication-Assisted Treatment which show the greatest likelihood of driving systems change.

The Budget increases State Opioid Response program funding to $1.6 billion, or $85 million above FY 2020, for grants to States and tribes to address opioids and methamphetamine, and other stimulants. All states and the full range of tribes are eligible to receive State Opioid Response Grants. The Budget continues to expand the use of State Opioid Response grants to include methamphetamine and other stimulants, giving states and tribes flexibility to address their unique community needs.

The Budget provides $70 million for drug courts, to serve 7,000 clients. Drug courts combine the sanctioning power of courts with effective treatment services and represent the coordinated efforts of stakeholders to improve the lives of clients recovering from substance and alcohol addiction, and develop the skills to become fully functioning members of the community. Grantees use evidence-based treatment practices in combination with the judicial system to ensure solid client outcomes. Further, the Budget provides $10 million for the Drug Abuse Warning Network, to continue this national public health surveillance system and to provide more accurate estimates of emerging behavioral health issues including methamphetamine use disorder.

In addition to ongoing efforts to fight the opioids crisis, the Budget includes $16 million for programs authorized by the SUPPORT for Patients and Communities Act (SUPPORT Act) to increase access to treatment, recovery, and workforce support services. This includes $4 million for a program expands access to qualified providers by making 10 grants to accredited medical schools and teaching hospitals to develop curricula that would satisfy requirements for graduates to prescribe medication-assisted treatment.

Substance Abuse Prevention and Treatment Block Grant

The Substance Abuse Prevention and Treatment Block Grant is the largest federal grant addressing substance use, providing one-third of all public funds spent for this purpose. This flexible formula grant is a cornerstone of states' substance abuse funding—it can fund activities that third party insurance does not reimburse, services for hard-to-reach populations, payment systems, and anti-fraud efforts, as well as other critical services. Approximately 2 million people receive care in facilities that receive block grant funding each year. The Budget provides $1.9 billion, the same as FY 2020, for this program.

Tribal Behavioral Health Grants

Consistent with the goals of the Tribal Behavioral Health Agenda, a collaborative tribal-federal blueprint that highlights the extent to which behavioral health challenges affect Native communities, the Tribal Behavioral Health Grant program addresses the high incidence of substance use and suicide among American Indian/Alaska Native populations. The Budget provides $40 million to support new and continuing grants that promote mental health and

prevent substance misuse activities for high-risk American Indian/Alaska Native youth and their families. This program supports tribal entities with the highest rates of suicide by providing effective strategies that address substance misuse, trauma, and suicide.

Preventing Substance Abuse

Preventing substance abuse is more effective and less expensive than breaking the cycle of addiction. The Budget includes $97 million for substance abuse prevention efforts that will reach 26.2 million people, including, demonstration programs to prevent underage drinking and expand tribal behavioral health services. These funds also support the Strategic Prevention Framework-Prescription Drugs program through state grants for coordinated, comprehensive, data-driven planning to reduce substance abuse.

Fighting HIV/AIDS

The Minority AIDS program enhances and expands effective, culturally competent HIV/AIDS-related mental health and substance misuse prevention and treatment services among vulnerable populations. The Budget provides a total of $116 million for grants to community-level entities, tribes, and tribal organizations to reduce domestic HIV transmission and support those with HIV/AIDS. This will support new substance abuse prevention grants for an additional 17 counties, states, and territories.

MENTAL HEALTH

In 2018, approximately 19 percent of American adults met the medical standard for a mental, behavioral, or emotional disorder that substantially interfered with major life activities. Of these 48 million people, approximately 11 million people—or 4.6 percent of all American adults—had a serious mental illness.

The Budget provides $1.7 billion for mental health activities to meet the needs of those with the most serious mental health issues.

Mental Health Needs of Students

In response to the tragedy in Parkland, Florida, the President established the Federal Commission on School Safety in March 2018. The Commission heard testimony from the public and key stakeholders about the importance of a positive school climate and the mental health needs of the nation's students.

School administrators, local officials, members of the public, teachers, and mental health professionals spoke at the listening sessions, site visits, and Commission meetings on the need for state level buy-in to develop a strong school-based mental health system and positive school climate. The Budget provides $156 million, an increase of $2 million, for school-based mental health programs such as Project AWARE, Healthy Transitions, and Mental Health First Aid. These programs support the Federal Commission on School Safety recommendations through grants to states and communities to increase access to mental health services, train school personnel, emergency first responders, law enforcement, and families to recognize signs and symptoms of mental disorders, particularly serious mental illness. The funds will also support hiring 30 behavioral health aides for rural populations, development and implementation of telehealth strategies, and training to identify signs of mental illness and appropriate response. This new effort will reach 40,000 students across 5 states.

Addressing Serious Mental Illness

The Budget continues efforts to proactively address serious mental illness by providing $1.1 billion, an increase of $42 million, in targeted funding in the FY 2021 Budget. The Budget prioritizes evidence-based programs, which show the greatest likelihood of achieving positive client outcomes and which intervene earlier after signs of mental illness are discovered.

The Budget provides an increase of $18 million, for a total of $25 million, for the Assertive Community Treatment for Individuals with Serious Mental Illness program to help 33 communities establish, maintain, or expand efforts to engage patients with serious mental illness through emergency and inpatient settings. This funding would serve an additional 1,900 people over the life of the grant. This approach reduces hospitalization of those with serious mental illness by an average of 59 inpatient days per year at the same cost and with higher patient satisfaction by coordinating care among healthcare provider teams.

The Budget includes an increase of $3 million for a total of $9 million for Criminal and Juvenile Justice Programs. This program provides comprehensive treatment and recovery supports for people with co-occurring mental illness and addiction in the criminal justice system, including offenders re-entering the community. In a recent evaluation, participants reported mental health issues declined by 20 percent

in the first 6 months of the program, alcohol, and other drug use declined by 60 percent, and employment rates increased from 36 percent to 45 percent.

The Budget provides $25 million for Assisted Outpatient Treatment to expand SAMHSA's existing grant program. The Program has achieved favorable outcomes in reductions in hospitalization, reductions in Emergency Department visits, reductions in substance use and increases in mental health functioning.

Community Mental Health Services Block Grant

The Budget provides $758 million for the Community Mental Health Services Block Grant, a $35 million increase, to support a new 5 percent set aside in all states and territories to build crisis systems that can quickly deliver high quality services to meet the needs of individuals in mental health crisis. These funds will serve an additional 50,000 people by promoting 24/7 access to well-trained professionals for people facing mental health crises.

This block grant is a flexible funding source that states and territories use to serve adults living with serious mental illness and children experiencing serious emotional disturbances. States will continue to spend at least 10 percent of the funds on early interventions for those experiencing a first episode of psychosis. States target local needs with this funding by prioritizing activities that insurance does not cover such as payment infrastructure, physician training, and anti-fraud efforts.

Children's Mental Health Services

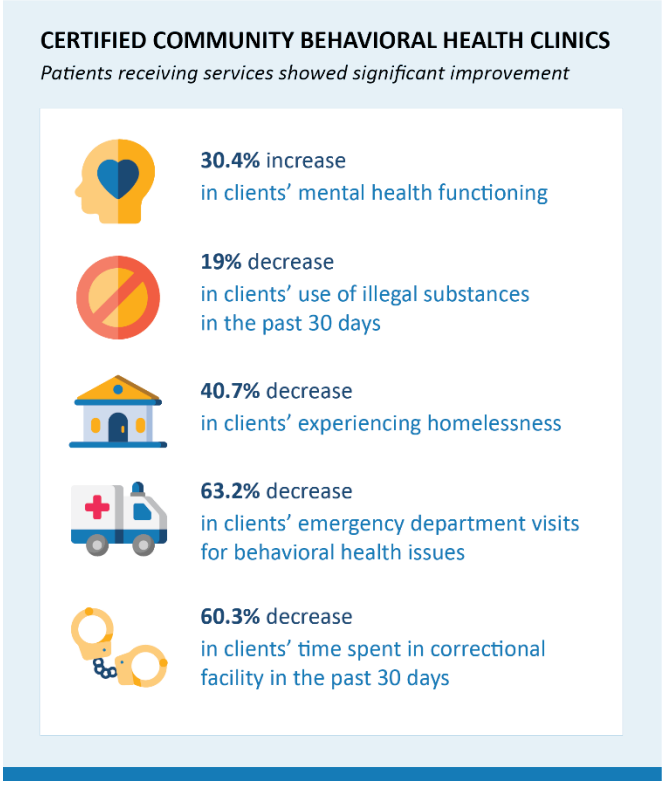
The Budget provides $125 million for Children's Mental Health Services, to help states, tribes, and communities deliver evidence-based services and supports for children and youth with serious emotional disturbances. These competitive grant awards ensure effective collaboration between the juvenile justice, child welfare, and education systems. The Budget proposes that up to 10 percent of the funds support a new demonstration targeting those at risk of developing serious mental illness.

Certified Community Behavioral Health Clinics

The Budget provides $225 million for the Certified Community Behavioral Health Clinics grant program. These organizations provide comprehensive, coordinated, high quality state-certified behavioral health services at the local level to meet six key standards of improved care. Eighty-four percent of these organizations made changes to the range of services they provide as a result of program participation. They most often added outpatient mental health and substance misuse, psychiatric rehabilitation, and crisis behavioral health services.

The Certified Community Behavioral Health Clinics program has served over 24,000 individuals as of August 2019. Patients receiving services for six months or more showed significant improvement between their intake and reassessment, including a reduction in:

- Criminal justice involvement,
- Homelessness, and
- Hospitalization and emergency room use for mental health problems (refer to graphic below).



Preventing Suicide

Suicide is a leading cause of death in the United States with over 47,143 people dying from suicide in 2017. This exceeds the number of deaths from automobile accidents. However, many of these suicide deaths may be preventable by improving the training of healthcare providers in existing health systems. Most of those who committed suicide received treatment in a health system in the year prior to their death.

The Budget provides $93 million for 38 grants in Suicide Prevention programs in SAMHSA, an increase of $3 million to screen an additional 550,000 individuals for suicide risk. These new resources will expand the Zero Suicide Initiative and will specifically target hospitals or health systems in need of suicide prevention and intervention programs and well-developed behavioral health programs. The Zero Suicide model is a comprehensive, evidence-based approach to suicide prevention in health systems that reduces deaths through screening and risk assessment, developing care protocols, collaborating for safety planning, providing evidence-based treatments, and maintaining continuity of care during high-risk periods.

HEALTH SURVEILLANCE AND PROGRAM SUPPORT

SAMHSA invests in Health Surveillance efforts, as well as monitoring and oversight to help communities tackle local challenges. The Budget includes $141 million to monitor and provide program oversight to SAMHSA programs and to support nationwide Health Surveillance efforts. SAMHSA will prioritize activities for which there is a unique federal role, such as the National Survey on Drug Use and Health.

Centers for Medicare & Medicaid Services: Overview

	dollars in millions			2021 +/-
	2019	2020	2021	2020
Current Law /1 /2				
Total Net Outlays, Current Law	**1,085,936**	**1,184,873**	**1,242,982**	**+58,109**
Proposed Law /1 /3				
Total Proposed Law /4	--	20	-10,458	-10,478
Total, Net Outlays, Proposed Law /5	**1,085,936**	**1,184,893**	**1,232,524**	**+47,631**

1/ Current law Medicare outlays net of offsetting receipts.
2/ Reflects other CMS health insurance programs.
3/ Reflects hospital payments proposed to be administered by CMS but financed outside of the Part A Trust Fund.
4/ Total Proposed Law number for FY 2021 includes non-PAYGO savings from the proposal "Address Patient Abuse or Neglect in Non-Institutional Settings", which is described in the Program Integrity chapter.
5/ Total net proposed law outlays equal current law outlays plus the impact of proposed legislation and offsetting receipts. Includes Trust Fund outlays for the Medicare Hearings and Appeals account for Fiscal Years 2019-2021.

The Centers for Medicare & Medicaid Services supports innovative approaches to improve healthcare quality, accessibility, and affordability.

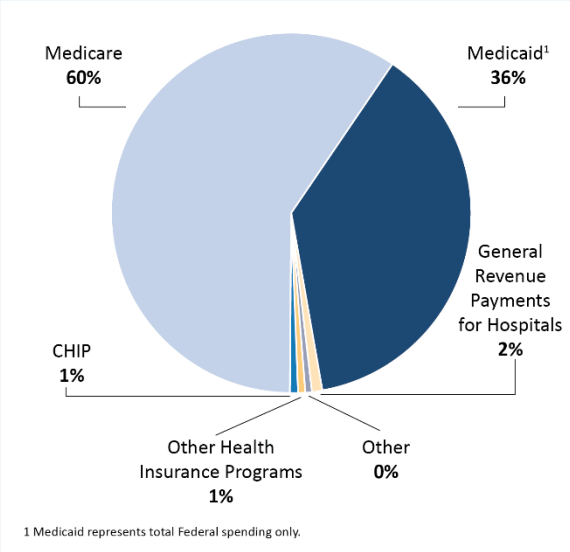
The Centers for Medicare & Medicaid Services (CMS) funds Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Center for Medicare and Medicaid Innovation (Innovation Center), other health insurance programs, program integrity efforts, and operating costs. The President's Fiscal Year (FY) 2021 Budget (Budget) estimates $1.2 trillion in mandatory and discretionary outlays for CMS, a net increase of $47.6 billion above FY 2020. The Budget proposes targeted savings of $1.6 trillion in CMS mandatory programs over the next decade.

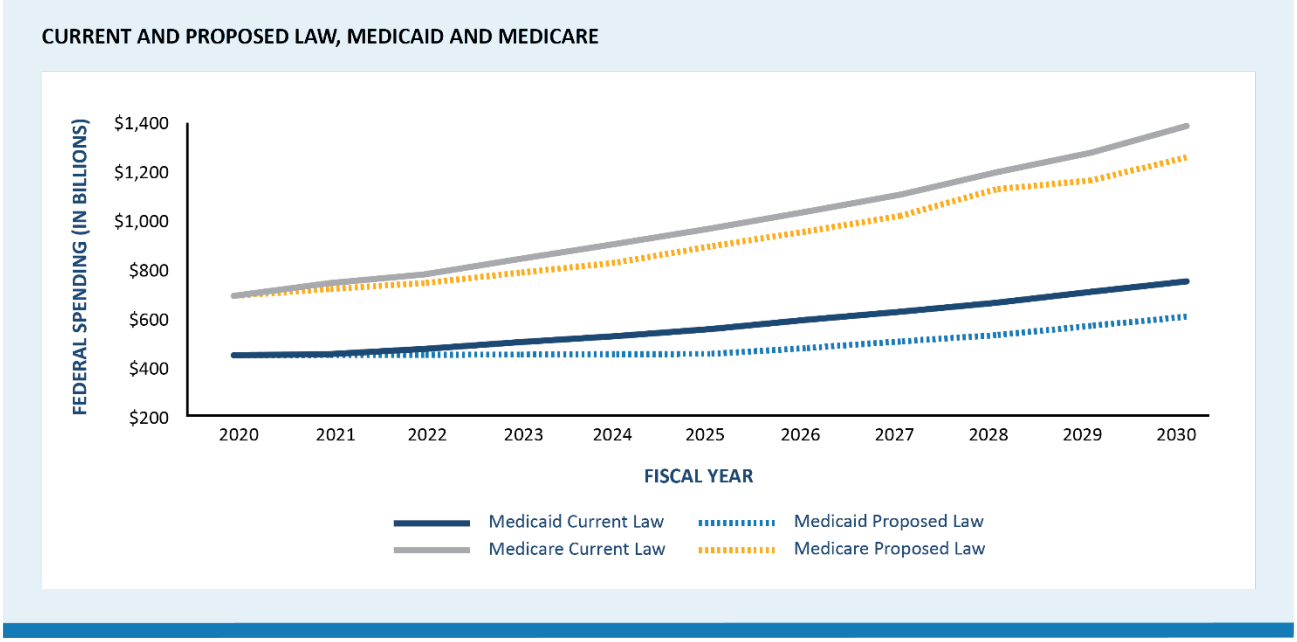
Better health is the fundamental goal of President Trump's vision for our healthcare system, understanding the vital importance that health holds for every American. His vision for healthcare is a system with affordable, personalized care that puts patients in control, provides peace of mind, and treats each patient like a human being, not a number.

The key to building a better system at all levels, and the President's promise, is to protect what works in our system and fix what's broken. The Administration is working to improve America's healthcare system through three strategies:

- Facilitate patient-centered markets by reforming how healthcare is financed and deriving better value from that care;
- Protect life and lives by addressing impactable health challenges; and
- Promote independence by treating serious mental illness and incentivizing community engagement.

CMS FY 2021 NET FEDERAL OUTLAYS PROPOSED LAW $1.2 TRILLION





FACILITATE PATIENT-CENTERED MARKETS

Protecting what works and fixing what's broken means protecting Medicare and private insurance, improving those programs, and fixing the failures of the Patient Protection and Affordable Care Act (ACA).

Reform Healthcare

CMS is working to put American consumers back in charge of their health coverage and care, ensuring they receive value for their premium dollars and to ensure there is a safety net for those that need it.

Protect Medicare

Under President Trump's bold leadership, the Administration has taken significant steps to improve healthcare markets and streamline insurance rules. The President's vision for healthcare reform will further strengthen and protect Medicare and private insurance, including through proposals that extend the solvency of the Medicare Hospital Insurance Trust Fund for at least the next 25 years and lower costs in the individual health insurance market.

President Trump's 2019 Executive Order, "Protecting and Improving Medicare for Our Nation's Seniors," builds on those aspects of the Medicare program that work well, including market-based approaches in the current system. The Budget furthers these goals for the Medicare program and saves proposes approximately $756 billion in gross Medicare savings over 10 years.

Transforming Medicaid

This Administration has ushered in a new era of state flexibility in Medicaid program administration, and has reset and restored the federal-state relationship while modernizing the program to deliver better outcomes for the people it serves. CMS has adopted new strategies for more efficient approval of State Plan Amendments and waivers under Sections 1115 and 1915 of the Social Security Act. CMS is offering states unprecedented flexibility to design health programs that meet their residents' specific needs. By fostering state innovation and pairing it with enhanced accountability and program integrity measures, we are now on a path to ensuring program sustainability while improving health outcomes for beneficiaries.

The Budget continues to promote Medicaid reforms by saving approximately $920 billion over 10 years.

Ensure Program Integrity

The Budget continues a commitment to the integrity of the Medicare and Medicaid programs, including paying the right amount to the right entity for the right beneficiary. CMS is improving payment accuracy, enhancing provider and program oversight, and supporting law enforcement. In FY 2017, the Administration's Medicare program integrity initiatives saved the Medicare program an estimated $15.5 billion, for an annual return on investment of $10.8 for each $1 spent on such initiatives. The 2019 Medicare Fee-for-Service improper payment rate was 7.25 percent, the lowest since 2010. The Budget will

continue these positive trends and save approximately $31.4 billion over 10 years for Medicare and Medicaid through proposed program integrity reform.

The rapid increase in Medicaid spending and enrollment in recent years highlights CMS's responsibility to ensure sound stewardship and oversight of program resources. Since 2014, the Medicaid program has added more than 15 million new working-age, adult enrollees; however, findings from the HHS Office of Inspector General and state audits indicate some states did not always determine Medicaid eligibility for the expansion population in accordance with federal and state requirements. Further, in 2019, $1 of every $7 the federal government spent on Medicaid was considered an improper payment. The Budget builds on CMS's June 2018 Medicaid Program Integrity Strategy by giving CMS and states the tools needed to reduce improper payments and protect taxpayer dollars.

Bring Value to Healthcare

The Administration is working to deliver better value in our healthcare delivery system through additional transparency around price and quality, advancing patient-centered care, reforming regulations that impede care coordination, incentivizing outcomes not procedures, and lowering prescription drug costs.

Provide Price and Quality Transparency

President Trump's Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, signed in 2019, sets the goal of making healthcare information – including its price and quality – available to patients easily, immediately, and before having to make a healthcare decision. To make fully informed decisions about their healthcare, patients must know the price and quality of a good or service in advance. Pursuant to the Executive Order, CMS implemented a policy to require hospitals to disclose information about their negotiated rates in a public format that is understandable and usable for patients. Following the Executive Order, CMS proposed another rule that would require insurance companies to provide patients with information about out-of-pocket costs before they receive services, and providers are empowered to help determine high and low value clinical interventions for their patients through data. The Budget implements several of the President's price and quality transparency reforms to deliver better value for patients and providers alike. HHS is also undertaking action to enhance price and quality transparency as well as improved value for all patients served by Medicare, Medicaid, the Children's Health Insurance Program, and other federal health programs. HHS hosted a Quality Summit to bring together key industry stakeholders and government leaders to discuss how HHS quality programs can be further evaluated, adapted, and streamlined to deliver greater transparency and improve quality outcomes for American patients. HHS will publish a Health Quality Roadmap to steer implementation of the actions identified at the Quality Summit.

Pay for Outcomes

This Administration is putting patients at the center by paying clinicians and providers help patients stay healthy and eliminating regulatory barriers to effective care coordination. Addressing regulations that impede care coordination is part of a much broader regulatory reform effort at HHS. In FY 2018, HHS accounted for more than half of the Administration's deregulatory savings, at more than $12 billion, with five deregulatory actions for every one new regulatory action.

In the past year, the CMS Innovation Center announced testing a number of new, innovative models that seek to transform the way healthcare is delivered and financed. These include the Primary Care First Model, which builds on the Comprehensive Primary Care Plus model to offer physicians a set of voluntary, innovative payment options that reward value and quality, and support delivery of advanced primary care. The new Direct Contracting Model focuses on primary care redesign as a platform for payment reform, and will test whether population based payment arrangements encourage better care and align financial incentives to reduce unnecessary use of high-cost settings and services in Medicare Fee-for-Service. In 2019, the Innovation Center also released an updated Medicare Advantage Value-Based Insurance Design Model, which tests the impact of allowing Medicare Advantage organizations to develop plan benefit designs that are targeted to specific groups of enrollees based on socioeconomic status, health conditions, or both. The model also expands the scope of rewards and incentives programs, includes requirements for wellness and healthcare planning (advanced care planning), and in FY 2021 will allow for an integrated hospice benefit.

Lower Drug Prices

High drug costs are not just a drain on seniors' budgets. When financial barriers prevent patients from accessing the medication they need, it often has serious impacts on health. This is why the President has laid out a vision for reducing costs through more competition, better negotiation, incentives for lower list prices, and lower out-of-pocket costs. This strategy is achieving results. In December 2018, for the first time in 46 years, the official government measure of inflation in drug prices dropped for that entire year.

Under the leadership of President Trump, CMS has taken steps to lower drug prices in Medicare and Medicaid. This includes modernizing the Part D program by providing beneficiaries the opportunity to choose among plans with greater negotiating tools that have been developed in the private market and by providing patients with more transparency on drug prices. Due to these types of reforms, the average basic premium for Medicare Part D prescription drug plans will decline in FY 2020 for the third year in a row. Over the past three years, average Part D basic premiums have decreased by 13.5 percent, saving beneficiaries about $1.9 billion. Part D continues to be an extremely popular program, with enrollment increasing 12.2 percent since 2017. In addition to these premium savings, the continued decline in Medicare Advantage and Part D bid amounts over the past three years is estimated to save taxpayers nearly $6 billion in the form of lower Medicare premium subsidies. Also, CMS has approved Medicaid value-based purchasing agreements at the request of a number of states as an innovative way to lower drug costs. CMS has also improved transparency through the release of updated Medicare and Medicaid data on the CMS Drug Spending Dashboards and new data on drug wastage under Medicare Part B.

PROTECT LIFE AND LIVES

CMS is committed to protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Address Impactable Health Challenges

Transformations to financing and delivery of care are focused on one goal: better health. As part of the Administration's reform efforts, the President and his Administration have identified a number of actionable public health challenges to address.

Advancing American Kidney Health

In July 2019, the President launched an initiative to dramatically improve care for the approximately 37 million Americans with kidney disease. This effort is the most significant initiative undertaken on kidney disease by any Administration, and the single biggest change to how this disease is treated since Medicare began covering End-Stage Renal Disease patients in 1973.

HHS has set specific, ambitious goals: reducing the number of Americans developing end-stage renal disease by 25 percent by 2030, increasing the number of Americans receiving in-home dialysis or receiving a transplant to 80 percent by 2025, and doubling the number of kidneys available for transplant by 2030. The Budget advances these goals by proposing statutory changes, such as establishing a new federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage, to ensure long-term transplant success and prevent transplant rejection and reversion to dialysis.

Improving Maternal Health

The United States has the highest maternal mortality rate in the developed world, yet over half of such deaths are completely preventable. High maternal mortality rates particularly affect low-income and minority communities and communities in rural areas. Medicaid pays for nearly half of the births in this country, and is key in amplifying innovative local solutions, as well as exploring new ways to improve maternal health outcomes. For example, on June 12, 2019, CMS co-hosted a forum with other federal and private partners to identify ways to improve maternal health access, quality, and outcomes for rural communities.

In January 2020, the Innovation Center began testing the Maternal Opioid Misuse (MOM) model, which addresses fragmentation in care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder through delivery system reforms. To meet the model goals, including improving care quality and creating sustainable coverage and payment strategies, states will encourage coordinated and integrated care delivery, use state flexibility, and strengthen capacity and infrastructure to integrate care.

Transforming Rural Health

Approximately 57 million Americans live in rural areas – including millions of Medicare and Medicaid beneficiaries. CMS recognizes the many obstacles rural Americans face because they are more likely to live in communities with disproportionately high poverty rates, have more chronic conditions, be uninsured or underinsured, lack access to specialty services, and experience a fragmented healthcare delivery system.

The Administration has made it a priority to improve availability of healthcare in rural areas. In 2019, CMS temporarily increased the wage index for hospitals in low-wage areas. These primarily rural hospitals will receive an increase in Medicare payments. Higher revenues should enable hospitals to immediately increase wages and maintain a higher wage index. This action preserves the rural health workforce and protects access to services. As a first step toward comprehensive wage index reform, the Budget proposes the Secretary conduct and report on a demonstration to improve the Medicare inpatient hospital wage index.

Telehealth capabilities enable patients to access services not available locally, and participate in their care through a long-distance relationship with their caregivers. CMS is identifying ways to leverage technology and innovation to deliver more timely and cost-effective care to rural communities. In April 2019, in accordance with the Bipartisan Budget Act of 2018, CMS issued a final rule bringing an innovative telehealth benefit to Medicare Advantage, allowing plans to include additional telehealth benefits for enrollees in bids for basic benefits starting in plan year 2020.[2] The Budget proposes a comprehensive package to promote rural access to care and telehealth in Medicare fee-for-service, including allowing Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth services.

Combating the Opioid and Methamphetamine Crisis

Under the President's leadership, HHS has continued a comprehensive approach to addressing the opioid overdose and misuse crisis in America. The nation has made real progress—progress that is saving lives every day. CDC provisional data shows that drug overdose deaths in the United States declined by 5.1 percent from 2017 to 2018. 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 the fourth wave of the crisis, underscored by increases in overdose deaths involving psychostimulants, particularly methamphetamine. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271) included several of the Administration's prior Budget proposals to improve access to opioid use disorder treatment for Medicare and Medicaid beneficiaries. These proposals included a demonstration to expand access to comprehensive substance use disorder treatment for Medicare beneficiaries, requiring plan participation in a program to prevent prescription drug abuse in Part D, and a requirement for states to cover Medication-Assisted Treatment under Medicaid. CMS is implementing these critical changes, along with many other actions to improve treatment and access to care for Medicare and Medicaid beneficiaries.

The Budget builds on these successes and includes several proposals to address Medicare and Medicaid beneficiaries impacted by the opioids crisis. The Budget also proposes to make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder.

PROMOTE INDEPENDENCE

CMS is committed to facilitating adequate care and maximizing independence, for older Americans, for people with disabilities, and for those affected by mental illness.

Strengthening Efforts to Treat Serious Mental Illness

Americans with serious mental illness (SMI) face significant challenges getting the care they need. In 2018, 47.6 million adults had a mental illness, of whom 11.3 million suffered from SMI, meaning their mental illness substantially interfered with or limited major life activities. More than one out of every three individuals with SMI do not receive mental healthcare, and those who receive care often encounter a fragmented mental health system that is difficult to navigate.

[2] https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.

In 2018, CMS announced a new Medicaid demonstration opportunity for states to receive authority to pay for short-term residential treatment services in an institution for mental disease (IMD) for adults with SMI and children with serious emotional disturbance. To date, Washington DC, Indiana and Vermont have received approval under this demonstration opportunity. The Budget allows states to receive Medicaid reimbursement for covered services in IMDs for adults with SMI, subject to meeting certain criteria. Medicaid coverage of services will ensure accessible and quality treatment for this population.

Incentivizing Community Engagement in Medicaid

The Budget also supports community engagement activities for working-age, able-bodies adults to promote better mental, physical, and emotional health. Well-designed community engagement incentives have great potential to improve health and well-being while empowering beneficiaries to rise out of poverty.

CROSS-CUTTING LEGISLATIVE PROPOSALS

Cross-cutting proposals represent priorities across CMS, and in many cases, the Department. While they are described in detail below, in some cases the budgetary impacts of these proposals are displayed in either the Medicare, Medicaid, or the Health Resources and Services Administration (HRSA) proposed law tables.

Support the President's Health Reform Vision

The Budget includes an allowance for the President's health reform vision. While Americans have the best healthcare options in the world, rising healthcare costs continue to be a top concern for many Americans. President Trump's healthcare reform 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. Reforms will 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.

Lower Drug Prices

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. In addition, the Budget supports changes to bring lower cost generic and biosimilar drugs to patients. These efforts will increase competition, reduce drug prices, and lower out of pocket costs for patients at the pharmacy counter. The Administration also supports legislative efforts to ensure manufacturers pay an appropriate share of Medicaid rebates, and authorize innovative Medicaid drug payment arrangements to lower costs for taxpayers.

Reform Graduate Medical Education Payments

Current graduate medical education funding is outdated, overly broad, and not sustainable long term due to its fragmented nature across multiple funding streams and lack of transparency and accountability. Effective in FY 2021, this proposal consolidates federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2021 will equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount will then grow at the CPI-U minus one percentage point each year. Payments will be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. The new grant program will be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program will be funded out of the general fund of the Treasury. The Secretary will have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities. These changes modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable. [$52.2 billion in government-wide savings over 10 years]

Reform Medical Liability

The current medical liability system disproportionately benefits a small group of plaintiffs and lawyers at the expense of adding to the healthcare cost for every

American, and imposing a burden on healthcare providers. The Budget proposes medical liability reforms that save HHS programs $27.2 billion, and the federal government $40.3 billion overall, over 10 years. A significant portion of these savings is attributable to the estimated reduction in unnecessary services and curbing the practice of defensive medicine. These medical liability reforms will benefit all Americans by reducing unnecessary healthcare spending while promoting high-quality, evidence-based care.

In addition to reducing healthcare costs by providing a "safe harbor" based on clinical guidelines, physicians can focus on delivering effective patient care and evidence-based medicine rather than on unsubstantiated lawsuits. If an inherently risky medical procedure does not conclude as intended, physicians will be able to express sympathy to a grieving family without fear of giving rise to a lawsuit.

Specifically, the Budget proposes the following medical liability reforms:

- Capping awards for noneconomic damages at $250,000 indexed to inflation;
- Providing safe harbors for providers based on clinical standards;
- Authorizing the Secretary to provide guidance to states to create expert panels and administrative healthcare tribunals;
- Allowing evidence of a claimant's income from other sources such as workers' compensation and auto insurance to be introduced at trial;
- Providing for a 3-year statute of limitations;
- Allowing courts to modify attorney fee arrangements;
- Establishing a fair-share rule to replace the current rule of joint and several liability;
- Excluding provider expressions of regret or apology from evidence; and
- Requiring courts to honor a request by either party to pay damages in periodic payments for any award equaling or exceeding $50,000.

[$40.3 billion in government-wide net deficit reduction over 10 years]

Enforcing Conscience and Protections Against Coercion in HHS Programs

The Weldon Amendment, one of several laws protecting conscience and prohibiting coercion in HHS programs, must be renewed annually by Congress in the appropriations process. This proposal will make Weldon Amendment protections permanent, while ensuring that the scope of protected persons, entities, and beliefs are defined broadly. In addition, the proposal institutionalizes and expands OCR's regulatory and enforcement authority under these conscience protection laws, and aligns with other antidiscrimination laws that allow private parties to file claims in federal court. These changes enhance OCR's ability to enforce these laws, add certainty, and allow private actions to aid enforcement. This proposal will also strengthen, clarify, and further codify the prohibitions against governmental discrimination for healthcare entities that refuse to perform, refer for, participate in, pay for, or provide (or sponsor) coverage of abortion services. [Budget Neutral]

Medicare

	dollars in millions			2021 +/- 2020
	2019	2020	2021	
Current Law Outlays and Offsetting Receipts				
Benefits Spending (gross) /1	769,123	830,395	896,217	+65,822
Less: Premiums Paid Directly to Part D Plans /2	-10,245	-10,057	-10,762	-704
Subtotal, Benefits Net of Direct Part D Premiums Payments	**758,878**	**820,337**	**885,455**	**+65,118**
Related-Benefit Expenses /3	13,666	15,758	16,191	+433
Administration /4	9,976	8,958	8,842	-116
Total Outlays, Current Law	**782,520**	**845,054**	**910,488**	**+65,434**
Premiums and Offsetting Collections	-131,494	-143,233	-151,625	-8,393
Current Law Outlays, Net of Offsetting Receipts	**651,026**	**701,821**	**758,863**	**+57,041**
Proposed Law				
Medicare Proposals, Net of Offsetting Receipts	0	0	-24,335	-24,335
Medicare Trust Fund Administration /5	0	24	38	+14
Subtotal, Medicare Proposed Law	0	24	-24,297	-24,321
Total Net Outlays, Proposed Law	**651,026**	**701,845**	**734,565**	**+32,720**
Mandatory Total Net Outlays, Proposed Policy /6	**643,905**	**696,507**	**728,236**	**+31,729**

1/ Represents all spending on Medicare benefits by either the federal government or through other beneficiary premiums. Includes Medicare Health Information Technology Incentives.
2/ In Part D only, some beneficiary premiums are paid directly to plans and are netted out here because those payments are not paid out of the Trust Funds.
3/ Includes savings from investments in Social Security disability reviews, as well as related benefit payments, including refundable payments made to providers and plans, transfers to Medicaid, and premiums to Medicare Advantage plans paid out of the Trust Funds from beneficiary Social Security withholdings.
4/ Includes CMS Program Management, the Health Care Fraud and Abuse Control Program (HCFAC), Quality Improvement Organizations, and other administration.
5/ A portion of this supports the State Health Insurance Assistance Programs through the Administration for Community Living (ACL). Please see the ACL chapter for more information.
6/ Removes total Medicare discretionary amount: FY 2019 -$7,121 million; FY 2020 -5,338 million; and FY 2021 -$6,329 million

Medicare provides health benefits to individuals who are aged 65 or older, disabled, or have End-Stage Renal Disease. In Fiscal Year (FY) 2021, the Office of the Actuary estimates that gross current law spending on Medicare benefits will total $896.2 billion and the program will provide health benefits to 63.9 million beneficiaries.

HOW MEDICARE WORKS – THE FOUR PARTS OF MEDICARE

Part A

Medicare Part A pays for healthcare services in inpatient hospitals and skilled nursing facilities, home healthcare related to a hospital stay, and hospice care. A 2.9 percent payroll tax, paid by both employees and employers, is the primary financing mechanism for Part A. Part A gross Fee-For-Service spending will total an estimated $221.7 billion in FY 2021.

Individuals who have worked for 10 years (40 quarters) and paid Medicare taxes during that time generally receive Part A benefits without paying a premium, but most services require beneficiary coinsurance. In CY 2020, beneficiaries pay a $1,408 deductible for a hospital stay of 1–60 days, and a $176 daily coinsurance for days 21–100 in a skilled nursing facility.

Part B

Medicare Part B pays for physician, outpatient hospital, End-Stage Renal Disease, laboratory, durable medical equipment, home healthcare unrelated to a hospital stay, and other medical services. Part B coverage is voluntary and 91 percent of all Medicare beneficiaries enroll in Part B through either fee-for-service or Medicare Advantage. Beneficiary premiums finance approximately 25 percent of Part B costs with the remaining 75 percent covered by general revenues from the United States Treasury. Part B gross fee-for-service spending will total $225.9 billion in FY 2021.

The standard monthly Part B premium is $144.60 in CY 2020, an increase of $9.10 from $135.50 in CY 2019. A statutory "hold harmless" provision applies each year to 70 percent of enrollees, limiting the annual rise in Part B premiums to no more than the Social Security cost of living increase. For these enrollees, any increase in Part B premiums must be lower than the increase in their Social Security benefits. Some beneficiaries also pay a higher Part B premium based on income: those with annual incomes above $87,000 (single), or $174,000 (married) will pay from $202.40 to $491.60 per month in CY 2020. The Part B annual deductible in CY 2020 is $198 for all beneficiaries, an increase of $13 from $185 in CY 2019.

Part C

Medicare Part C, the Medicare Advantage Program, pays plans a capitated monthly payment to provide all Part A and B services, and Part D services if offered by the plan. Plans can offer additional benefits or alternative cost-sharing arrangements that are at least as generous as the standard Parts A and B benefits under traditional Medicare. In addition to the regular Part B premium, beneficiaries who choose to participate in Part C may pay monthly plan premiums that vary based on the services offered by the plan and the efficiency of the plan.

In CY 2021, Medicare Advantage enrollment will total approximately 26 million beneficiaries, or 44 percent of all Medicare beneficiaries who have both Parts A and B. Enrollment in Medicare Advantage is growing 27 percent faster than enrollment in traditional Medicare. CMS data confirm 99 percent of Medicare beneficiaries have access to at least one Medicare Advantage plan in CY 2020. Additionally, Medicare Advantage supplemental benefits have increased while premiums have remained stable. Part C gross fee-for-service spending will total $335.0 billion in FY 2021.

MEDICARE ADVANTAGE PROGRAM 2020 SNAPSHOT

More choices and lower costs for beneficiaries

24.6M

projected enrollees, a 7% increase from 22.9M enrollees in 2019

$23

average premiums, a 14% decrease from 2019

39

average plan options in each county, an 18% increase from 33 average plan options in 2019

39.2%

expected beneficiary participation in MA, an increase from 37.5% in 2019

Source: CMS Office of the Actuary

Part D

Medicare Part D offers a standard prescription drug benefit with a CY 2020 deductible of $435 and base beneficiary premium of approximately $32.74 per month. Enhanced and alternative benefits are also available with varying deductibles and premiums. Participating beneficiaries pay a portion of the cost of their prescription drugs. This portion varies based on whether the medication is generic or brand name and the amount the beneficiary has already spent on medications that year. Low-income beneficiaries have varying degrees of cost-sharing, with co-payments ranging from $0 to $8.95 in 2020 and low or no monthly premiums. For CY 2021, CMS expects Medicare Part D enrollment to increase 2.9 percent to 49.6 million, including 13.6 million beneficiaries who

receive the low-income subsidy. CMS estimates Part D gross fee-for-service spending will total $113.6 billion in FY 2021.

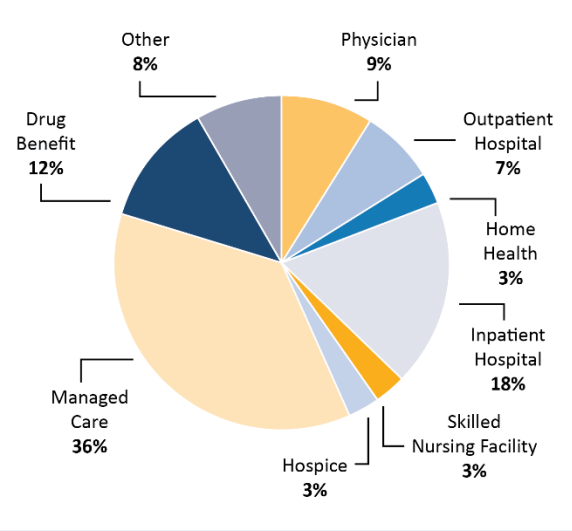
In CY 2020, of beneficiaries that have Part D coverage, approximately 52 percent are enrolled in a standalone Part D Prescription Drug Plan, 45 percent are enrolled in a Medicare Advantage Prescription Drug Plan, and 3 percent are enrolled in an employer plan. Of Medicare beneficiaries overall, approximately 77 percent receive prescription drug coverage through Medicare Part D or employer sponsored retiree health plans, and a significant number of the remaining beneficiaries through other creditable coverage, such as the Federal Employees Health Benefits Program.

Beneficiaries reach the Medicare Part D coverage gap, or "donut hole," once their total drug spending exceeds an initial coverage limit ($4,020 in total drug costs in CY 2020), and stay in the coverage gap until they reach the threshold for qualified out-of-pocket spending ($6,350 in out-of-pocket costs CY 2020), at which point they are generally responsible for five percent of their drug costs. Until 2010, beneficiaries were responsible for 100 percent of drug costs in the coverage gap, but a combination of manufacturer discounts and gradually increasing federal subsidies have closed the gap over time. The Bipartisan Budget Act of 2018 increased manufacturer discounts from 50 to 70 percent, and closed the brand drug coverage gap one year ahead of schedule -- in CY 2019 instead of CY 2020. In CY 2020 and beyond, non-low income subsidy beneficiaries who reach the coverage gap will pay 25 percent of costs for all covered Part D drugs during both the coverage gap and initial coverage phases of the Part D benefit. Low-income subsidy beneficiaries are statutorily excluded from the coverage gap discount program, and Medicare pays the majority of their cost-sharing.

ADMINISTRATION'S ACTIONS TO PROTECT AND IMPROVE MEDICARE

The President's October 2019 Executive Order on "Protecting and Improving Medicare for Our Nation's Seniors" builds on those aspects of the Medicare program that work well, including market-based approaches in the current system, to protect and strengthen Medicare. The Executive Order delivers on the clear promise President Trump made to protect what works in the Medicare system and fix what is broken. America's seniors are overwhelmingly satisfied

MEDICARE BENEFITS BY SERVICE, 2021
CURRENT LAW ESTIMATE: $899.8 BILLION



with the care they receive through traditional Medicare and Medicare Advantage. The Executive Order directs HHS to take steps to improve the financing of Medicare, better coordinate the care American seniors receive from their doctors, and improve their overall health. HHS has already taken steps to ensure Medicare's fiscal sustainability for future generations.

The Administration's strategy to deliver this vision in Medicare is to:

- Facilitate patient-centered markets by reforming healthcare financing and bringing value to healthcare; and
- Protect life and lives by addressing impactable health challenges, like rural health and kidney health;

CMS is working to protect and improve Medicare in these areas to enhance the lives of Medicare beneficiaries.

FACILITATE PATIENT-CENTERED MARKETS

Consistent with the President's Executive Order on Medicare, the Budget keeps the President's promise to protect Medicare beneficiaries while building on HHS's efforts to increase choice, encourage medical innovation, empower patients, and eliminate waste, fraud and abuse to protect seniors and taxpayers. For instance, HHS is taking action to support the Administration's vision of a patient-centered market by

giving beneficiaries more choice of health plans where they receive care.

Protect Medicare

The Administration is advancing site neutral payment to protect the Medicare Trust Fund and beneficiary choice. CMS finalized regulations to pay for outpatient hospital clinic visits at the less expensive physician office rate and promote ambulatory surgical centers as a less expensive setting for beneficiaries to access many common procedures. These regulatory changes ensure patients and their healthcare providers can choose their setting of care based on their patient needs and clinical characteristics, rather than on payment disparities between settings. This change lowers beneficiary copayments and saves Medicare $9.5 billion over 10 years.

Additionally, Medicare Advantage delivers choice to seniors. CMS finalized rules in 2019 to promote innovative plan designs, improve quality, and enhance patient choices. Under these rules, Medicare Advantage plans may now offer additional telehealth benefits in their basic plan benefits, giving seniors more choice about how to receive care. CMS also revised the Star Rating methodology to improve the stability and predictability of ratings.

BRING VALUE TO HEALTHCARE

Americans deserve better, more affordable healthcare. HHS is working to transform our system from one that pays for procedures and sickness to one that pays for outcomes and health. Medicare is a significant, cross-cutting platform where this Administration is working to deliver on this promise.

Pay for Outcomes

CMS continues to implement Pathways to Success, the new direction for Medicare Shared Savings Program Accountable Care Organizations (ACOs). ACOs are groups of healthcare providers that take responsibility for the total cost and quality of care for their patients, and in exchange, can retain a portion of the savings they achieve. CMS published the new regulation for the Medicare Shared Savings Program under the Pathways to Success redesign in December 2018 and the first ACOs under the new participation options started in July 2019. This new direction for ACOs will deliver value to Medicare by paying for outcomes, offering incentives and flexibility to coordinate care and innovate, and accelerating ACO transition to performance based risk more quickly. These new ACO payment arrangements save Medicare an estimated $2.9 billion over 10 years.

Provide Price and Quality Transparency

Patients need transparent price and quality information so they can make informed decisions about their care. Under President Trump, CMS delivered transformational change in this area by issuing new requirements for hospitals to disclose their negotiated rates to consumers, and CMS is working to do the same for insurers. CMS also created the new "What's Covered" smartphone app and "Procedure Price Lookup" tool for Medicare beneficiaries to understand their covered benefits and expected costs before receiving care. These policies will empower consumers to compare providers and shop for the best value.

Remove Regulatory Burdens

CMS took action at President Trump's direction to cut red tape by reducing unnecessary burden for American's healthcare providers allowing them to focus on their first priority – patients. CMS's Omnibus Burden Reduction final rule removes Medicare regulatory requirements identified as unnecessary, obsolete, or excessively burdensome and inefficient for healthcare providers. This rule advances CMS's Patients over Paperwork initiative by saving providers an estimated 4.4 million hours of time previously spent on paperwork with an overall total projected savings to providers of $800 million annually.

In addition, CMS issued a proposed rule on October 9, 2019 to modernize and clarify the regulations that interpret the physician self-referral law (often called the "Stark Law"), which have not been significantly updated since their enactment in 1989. The proposed rule supports HHS's Regulatory Sprint to Coordinated Care by streamlining regulations to remove impediments to coordinated care while reinforcing the Stark Law's goal of protecting patients from unnecessary services and being steered to less convenient, lower quality, or more expensive services because of a physician's financial self-interest. CMS worked closely with the HHS Inspector General in developing proposals to advance the transition to a value-based healthcare delivery and payment system

that improves the coordination of care among physicians and other healthcare providers in both the Federal and commercial sectors. The proposed rule would create new, regulatory exceptions to the Stark Law for value-based arrangements. It would also unleash innovation by permitting physicians and other healthcare providers to design and enter into value-based arrangements that improve quality outcomes, produce health system efficiencies, and lower costs.

Accelerate Drug and Device Approval and Reimbursement

HHS is working to spur innovation and facilitate access to transformative new drugs and devices that are intended to treat serious or life-threatening diseases or conditions for which there are unmet medical needs. CMS finalized an alternative pathway beginning in FY 2020 for new technology add-on payment (NTAP) under the Inpatient Prospective Payment System (IPPS) and pass-through payment status under the Outpatient Prospective Payment System (OPPS) for medical devices that receive the FDA breakthrough device designation for accelerated approval or clearance. CMS also increased the NTAP amount from 50 percent to 65 percent, or for some antimicrobials 75 percent, to more adequately cover the costs, and incentivize use of these new technologies. CMS clarified what it means for a device to meet the substantial clinical improvement criteria necessary to obtain these increased new technology add-on payments. Finally, CMS established a transitional add-on payment adjustment to support the use of new and innovative renal dialysis equipment or supplies furnished by dialysis facilities.

PROTECT LIFE AND LIVES

President Trump's goal for healthcare is better health for every American. His vision includes tackling specific, health challenges, including rural health and kidney disease.

Advancing American Kidney Health

HHS is actively driving regulatory reform to improve kidney health by slowing the progression of kidney disease, improve dialysis care and encourage more home dialysis, and increase access and rates of transplantation of kidneys. In December 2019, CMS issued a proposed rule that would update the Organ Procurement Organization Conditions for Coverage. This rule executes the directive in the President's Executive Order on Advancing American Kidney Health to increase utilization of available organs. The rule seeks to help the more than 113,000 people in the United States currently on the wait list for a lifesaving organ transplant, which far exceeds the number of transplantable organs available. Specifically, it would revise the outcome measures for assessing Organ Procurement Organization performance to ensure they are transparent, reliable, and enforceable; support higher donation rates; shorten transplant wait lists; reduce discarded, but viable organs; and increase safe, timely transplants that save lives.

Transforming Rural Health

A key pillar of the President's healthcare agenda is solving the rural healthcare crisis and building a sustainable model for rural health that leverages technology and innovation. CMS has expanded the availability of telehealth and communication technology-based services to Medicare beneficiaries in rural areas in unprecedented ways, removing geographic barriers that can impede access to healthcare. In 2019, CMS implemented separate payments under the Medicare Physician Fee Schedule for virtual office visit check-ins and remote evaluations of recorded videos and/or images that a patient submits to their clinician, as well as payments for virtual communications with clinicians at Rural Health Clinics and Federally Qualified Health Centers. Additionally, CMS expanded the list of telehealth services eligible for Medicare payment and finalized policies to implement recent legislative changes for telehealth services related to beneficiaries with end-stage renal disease receiving home dialysis, beneficiaries with acute stroke, and treatment of a substance use disorder or a co-occurring mental health disorder.

2021 LEGISLATIVE PROPOSALS

The FY 2021 Budget includes targeted Medicare proposals that support the Administration's priorities to facilitate patient-centered markets, bring value to healthcare, and protect life and lives. These proposals also advance the goals outlined in the President's Executive Order on Medicare.

Together, this legislative package is expected to yield $756 billion in Medicare Trust Fund savings over 10 years. The net impact of Medicare-specific proposals

across the Federal government, including proposals with general revenue or other impacts that offset a portion of these savings, is just over $450 billion over 10 years. Under the President's Budget, the Medicare program is expected to remain solvent for at least the next 25 years, in part by ensuring Medicare payments are directly related to its healthcare financing role, financing certain payments to hospitals for graduate medical education and uncompensated care outside the Trust Fund, and slowing the growth rate.

FACILITATE PATIENT-CENTERED MARKETS

Protect Medicare

HHS is committed to protecting and improving the existing Medicare program by exercising fiscal stewardship of Medicare spending and supporting what works in the current program. The Budget includes a number of proposals that reduce unnecessary Medicare spending and protect the Medicare Trust Funds.

Remove the Cap on Medicare Advantage Benchmarks and Remove the Doubling of the Medicare Advantage Quality Bonus Payments in Qualifying Counties

The Patient Protection and Affordable Care Act changed the methodology for calculating the Medicare Advantage benchmark and capped it at the pre-ACA benchmark. As of 2019, nearly half of all counties (48 percent) have the top rated quality-adjusted bonus capped while over one quarter of all counties (29 percent) have the nominal benchmark itself capped. The cap may make plans less competitive and could discourage quality improvements. This proposal eliminates the benchmark cap in its entirety. The proposal also removes the quality double-bonus for plans in eligible counties. In 2016, 236 counties qualified for the double-bonus, with 52 of them subject to the benchmark cap in some capacity. This proposal provides financial incentives for innovation and quality, and makes Medicare Advantage markets fairer and more competitive across and within county jurisdictions. [$1.2 billion in savings over 10 years]

Give Medicare Beneficiaries with High Deductible Health Plans the Option to Contribute to Health Savings Accounts or Medical Savings Accounts

Medicare beneficiaries in high-deductible health plans, called Medical Savings Account (MSA) plans, are prohibited from accessing flexibilities available in other Medicare Advantage plans, resulting in restricted choice and low enrollment in these types of plans. This proposal includes a robust set of reforms to make Medicare MSA plans more attractive. Beneficiaries enrolled in these plans could contribute to their MSAs, subject to the annual Health Savings Account (HSA) contribution limits determined by the Internal Revenue Service. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSA to their Medicare MSAs and from one MSA to another. Medicare-eligible individuals who have an employer sponsored, high deductible health plan could contribute to their HSAs, although Medicare would not cover any of the deductible. This proposal also incorporates key features of Medicare Advantage plans into MSA plans by allowing them to offer prescription drug plans and mandatory supplemental benefits, and eliminate cost-sharing for preventive services below the deductible. CMS will also retain 15 percent of savings below the fee-for-service based benchmark for MSA plans; CMS already retains a portion of these savings for other Medicare Advantage plans currently. This proposal would give Medicare beneficiaries greater flexibility to take control of their healthcare, using tools that are currently available in the private market. [Budget Neutral]

Modify Reinsurance Arrangements for Medicare Advantage Plans

Medicare Advantage plans can only enter into reinsurance arrangements under limited circumstances. These circumstances are outdated, as compared to common insurance practices. Consequently, plans may not be able to enter into certain common reinsurance arrangements, which may inhibit their ability to grow, particularly in areas with smaller risk pools, such as rural areas. This proposal allows plans to enter into reinsurance arrangements recognized as acceptable by the National Association of Insurance Commissioners and state insurance departments. [$170 million in Medicare costs over 10 years]

Modify Payments to Hospitals for Uncompensated Care

Medicare currently makes two types of payments to hospitals serving a significantly disproportionate number of low-income patients—empirically justified and uncompensated care payments. Effective FY 2022, this proposal establishes the total amount of available uncompensated care payments to be equal to FY 2019 funding levels, grown annually by the Consumer Price Index for all Urban Consumers. Uncompensated care

payments will be funded from the general fund of the Treasury rather than the Medicare Trust Fund. Uncompensated care payments would be distributed according to a hospital's share of charity care and non-Medicare bad debt, as reported on Medicare cost reports. Empirically justified Disproportionate Share Hospital payments will not change. This proposal more closely aligns Medicare payment policy with private insurers, who do not typically cover uncompensated care. [$174.2 billion in Medicare savings over 10 years; this proposal would increase spending from general revenues by $86.3 billion over 10 years, for a net savings to the federal government of $87.9 billion over 10 years]

Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services

Medicare generally pays on-campus hospital outpatient departments substantially more than physician offices for the same services. Effective CY 2021, this proposal makes site neutral payments between on-campus hospital outpatient departments and physician offices for services, such as clinic visits, commonly provided in non-hospital settings. This proposal would eliminate the often significant disparity between what Medicare pays in these different settings for the same services. This proposal also supports access to rural health by exempting rural hospitals from payment reductions. [$117.2 billion in savings over 10 years]

Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care

Medicare payment for post-acute care services can differ substantially for similar beneficiaries depending on the setting, due to variation in supply and lack of evidence-based criteria regarding patient eligibility, the most appropriate setting, and level of care required. Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities will receive a lower annual Medicare payment update from FY 2021 to FY 2025. Beginning in FY 2026, a unified post-acute care payment system would span all four post-acute care settings, including long term care hospitals, with payments based on episodes of care and patient characteristics rather than the site of service, and would include a unified quality reporting program across all four settings. Payment rates would be budget neutral in FY 2026, risk adjusted, and set prospectively on an annual basis, with episode grouping and pricing based on the average cost for providing post-acute care services for a diagnosis, similar to the Diagnosis-Related Group methodology under the Inpatient Prospective Payment System (IPPS). This proposal would reduce costs, increase fairness, and give the Secretary the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors

PAYING HOSPITAL OUTPATIENT DEPARTMENTS (HOPDS) AND AMBULATORY SURGERY CENTER (ASCS) THE SAME AMOUNT FOR MANY COMMON PROCEDURES CUTS COSTS BY 50% OR MORE FOR TAX PAYERS AND BENEFICIARIES

Procedure Type	HOPDs	ASCs	Savings per Procedure[1]	
			Total Savings	% Savings
Upper Gastrointestinal Endoscopy Biopsy	$761	$392	($369)	48%
Cystourethroscopy Bladder Imaging	$561	$288	($273)	49%
Cataract Surgery	$1,916	$976	($940)	49%
Mohs Surgery (Skin Cancer)	$482	$248	($234)	49%
Arthrocentesis Joint Fluid Removal	$246	$28	($218)	89%

1 Includes standard beneficiary cost sharing in FFS Medicare without a Medigap plan

as deemed appropriate. [$101.5 billion in savings over 10 years]

Reduce Medicare Coverage of Bad Debts

Unlike private payers, Medicare currently reimburses most institutional provider types for 65 percent of bad debts resulting from beneficiaries' non-payment of cost-sharing requirements. The proposal eliminates Medicare reimbursement for bad debt at disproportionate share eligible hospitals, exempting rural hospitals. The proposal will more closely align Medicare policy with private payers, who do not typically reimburse for bad debt. [$33.6 billion in savings over 10 years]

Pay All Hospital-Owned Physician Offices Located Off-Campus at the Physician Office Rate

Medicare pays most off-campus hospital outpatient departments higher rates than the Physician Fee Schedule for the same services. These facility types include emergency departments, cancer hospitals, and grandfathered off-campus hospital outpatient departments billing under the OPPS or under construction before November 2, 2015. This proposal requires all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule, effective CY 2021. This change will promote site neutrality by aligning payment rates to hospital outpatient departments with payment rates to physician offices, regardless of hospital ownership or facility type. [$47.2 billion in savings over 10 years]

Modify Payment for Hospice Care Provided to Beneficiaries in Skilled Nursing and Nursing Facilities

Medicare pays hospices the same rate for routine home care provided in skilled nursing facilities and nursing facilities as it does for other settings, such as private homes. This approach results in an overpayment to hospice providers since skilled nursing facilities and nursing facilities often receive payment for this care from third-party payers, such as Medicaid. This proposal reduces Medicare payment for hospice services under the routine home care level of care when furnished in skilled nursing facilities, to account for separate Medicare and Medicaid payments already provided for personal care services in the facility. Reducing the payment rate will align hospice payment between nursing facilities and other settings, and reduce the incentive for hospices to seek out beneficiaries in nursing facilities. [$4.5 billion in savings over 10 years].

Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria

Medicare pays a higher prospective payment rate to long term care hospitals when admissions follow an acute care hospital stay with three or more days in an intensive care unit, or the hospital provides at least 96-hours of mechanical ventilation services. Absent one of these circumstances, these hospitals receive a lower Medicare payment rate, comparable to acute care hospitals under the IPPS. Effective FY 2021, this proposal raises the intensive care unit stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care provided by long term care hospitals. This change would promote site neutrality by basing payment on clinical characteristics and the needs of patients rather on location of care. [$9.4 billion in savings over 10 years]

Reform and Expand Durable Medical Equipment Competitive Bidding

Under the Medicare Durable Medical Equipment (DME) Competitive Bidding Program, DME suppliers can submit low bids during the competition to win a Medicare contract and get paid a higher price even though their low bid reduced prices for all other suppliers in the competition area. CMS must use prices from urban DME competitions to inform fee schedule prices in rural areas, thereby undervaluing true costs in rural areas and threatening access to care. Effective CY 2024, this proposal changes the way Medicare pays for DME under the competitive bidding program, from a single payment amount based on the maximum winning bid to each winning suppliers' own bid amounts. As a result, Medicare payment to low bidders will equal their low bid amount. It also expands competitive bidding to additional geographic areas, including rural areas, and includes inhalation drugs as a service category for the first time. To reduce burden on suppliers, this proposal also removes the surety bid bond, which requires all suppliers to secure a surety bond for every competition. In the event that fewer than two suppliers submit bids in a rural area, CMS will base prices on information from similar rural areas. Expanding competitive bidding will allow CMS to base prices for DME items and services in rural areas on competitions in those areas rather than setting fee schedule prices in rural areas based on competitions in urban areas. [$7,730 billion in Medicare savings and $435 million in Medicaid savings over 10 years]

Use Retail Price Information for Durable Medical Equipment Fee Schedule Rates

Medicare often pays much higher rates for DME than the retail price for these items in the open market. To update the DME fee schedule based on retail price information, CMS must conduct a complex and onerous inherent reasonableness process, making it administratively burdensome for CMS to update DME prices even as the market or technology changes. This proposal allows CMS to annually update DME prices based on retail prices through rulemaking, without using the inherent reasonableness process. This change will allow Medicare prices to adapt to rapidly changing and often cheaper technology, and reduce Medicare costs as DME prices drop in the retail market. [$1.6 billion in Medicare savings and $85 million in Medicaid savings over 10 years]

BRING VALUE TO HEALTHCARE

Pay for Outcomes

CMS is committed to paying for outcomes in order to ensure a focus on outcomes and patient health rather than for procedures. The Budget includes several proposals that advance HHS's efforts to shift toward paying for patient outcomes in Medicare and to expand Accountable Care Organizations (ACOs).

Expand Basis for Beneficiary Assignment for Accountable Care Organizations

In addition to physicians, Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists furnish primary care to Medicare beneficiaries, but ACOs cannot use non-physician primary care providers for patient assignment. Effective CY 2020, this proposal allows the Secretary to base beneficiary assignment on a broader set of primary care providers. This option broadens the scope of ACOs to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries. [$80 million in savings over 10 years]

Create a Consolidated Hospital Quality Payment Program

Medicare requires inpatient hospitals to participate in four quality reporting programs: the Inpatient Quality Reporting Program, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Readmissions Reduction Program. This proposal establishes a new consolidated hospital quality payment program that combines and streamlines these four existing programs. All hospitals would have a five percent reduction in payments, and could earn back some percentage of that reduction based on performance. Additionally, given the importance of monitoring patient safety, this proposal would require hospitals, as a Medicare Condition of Participation, to accurately report hospital acquired infections data to the CDC's National Health Safety Network. These streamlined requirements drive quality improvement, lower healthcare costs, achieve transparency by publicly reporting performance information, and make value-based incentive payment adjustments. [Budget Neutral]

Extend and Enhance Medicare Independence at Home Demonstration

The Independence at Home Demonstration is a statutory patient-centered model that supports providers in caring for chronically ill patients in their own home. CMS implemented this successful model starting in 2012. This proposal extends the demonstration for an additional five years, lifts current restrictions on the number of beneficiaries that can enroll in the model, and provides HHS the flexibility to modify the demonstration design to ensure Medicare savings. Extending this demonstration will give certainty to existing participants, and the modifications will provide CMS the tools necessary to fully test the effectiveness of this demonstration in reducing costs and increasing quality of care. [Budget impact not available]

Implement Value-Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers

Medicare has value-based purchasing programs in place for inpatient hospital services and several other settings, but not for outpatient hospital services and ambulatory surgical centers. Beginning in CY 2021, CMS will implement a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers, offering incentives to improve quality and health outcomes. This proposal would link two percent of payments to performance on quality and outcome measures. Total rewards and adjustments will be budget neutral. [Budget Neutral]

Improve the Medicare Shared Savings Program Beneficiary Incentive Enhancements

Accountable Care Organizations (ACOs) in a risk bearing arrangement in the Medicare Shared Savings Program can offer their assigned beneficiaries an incentive

payment of up to $20 for receiving one or more qualifying primary care services. The low-cost incentive payment promotes primary care utilization to improve health outcomes and prevent costly acute care over time. ACOs are not using this incentive payment option because, under current law, they cannot target the payment toward specific primary care services or beneficiaries that would most benefit from the investment. This proposal allows ACOs to apply the incentive payment on a subset of primary care services or beneficiaries to incentivize specific care utilization, such as flu shots or chronic care treatment for beneficiaries with diabetes. Providing ACOs the flexibility to target the incentive payment will increase its use, and promote preventive services that improve care coordination and quality and reduce Medicare costs. [Budget impact not available]

Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments

Under current law, Medicare bases payments for services furnished at outpatient hospital and ambulatory surgical centers on the setting of care rather than patient acuity. This proposal will risk adjust payments to these facilities based on the severity of patients' diagnoses, in a budget neutral manner. This proposal will promote site neutrality in payments for similar services and similar patient characteristics at these facilities. [Budget Neutral]

Reprioritize Primary and Preventive Care in Medicare

Medicare's physician fee schedule does not adequately pay for primary care relative to specialty care due, at least in part, to challenges in reflecting clinician time and resources spent evaluating and coordinating ongoing patient care. Beginning in 2021, this proposal creates a risk-adjusted monthly Medicare Priority Care payment for providers who are eligible to bill for evaluation and management services and who provide ongoing primary care to Medicare beneficiaries. A five percent annual reduction to the valuations of all non-primary care services and procedures, as determined by the Secretary, under the Physician Fee Schedule will pay for the cost of these payments. [Budget Neutral]

Provide Price and Quality Transparency

HHS is committed to making healthcare prices and quality more transparent, laying the foundation for a patient-driven and value-based health system. The Budget includes a series of proposals that increase transparency in Medicare by increasing access to price and quality information and clarifying Medicare coverage and payment processes.

Eliminate Beneficiary Coinsurance for Screening Colonoscopies with Polyp Removal

Under current law, Medicare beneficiaries are not subject to the Part B deductible and coinsurance for most preventive and screening services, including screening colonoscopies. However, if a screening colonoscopy results in removal of a polyp, ablation, or other procedure, beneficiaries are subject to 20 percent coinsurance. This proposal eliminates beneficiary coinsurance under Part B for screening colonoscopies that result in removal of a polyp. Medicare beneficiaries eligible for a screening colonoscopy would benefit by not paying coinsurance or copayments on a screening colonoscopy. The proposal also shields beneficiaries from unexpected coinsurance costs for a service they anticipate is not subject to out-of-pocket costs. [$4.8 billion in costs over 10 years]

Enhance Quality Improvement Oversight of Post-Acute Care Facilities and Hospice Providers

When a hospice or inpatient rehabilitation facility has a serious deficiency, CMS's only recourse is the drastic step of terminating them from Medicare. This proposal allows the Secretary to implement intermediate remedies on hospices and other post-acute care facilities, such as levying civil monetary penalties. This proposal also redirects from the general fund to the Medicare Trust Fund penalties currently levied against skilled nursing facilities and home health agencies, as well as penalties proposed for other post-acute care providers under this proposal. These changes will give CMS more tools to address poor performance and quality of care concerns. [Budget impact not available]

Improve the Inpatient Hospital Wage Index

Medicare's current wage index system for inpatient hospitals perpetuates and exacerbates disparities between high and low wage index hospitals. This proposal creates a statutory demonstration to test comprehensive wage index reform. The demonstration redefines the labor market area to commuting data by zip code, identifies an alternative source for wage data, repeals the rural floor and other reclassifications and special payment adjustment (e.g., out-migration adjustment), and provides civil monetary penalty authority to penalize hospitals that submit inaccurate or incomplete data. The demonstration aims to

improve hospital wage index accuracy, reduce sharp differences in the wage index and Medicare payments between nearby hospitals, address the divergence between low wage and high wage hospitals, and protect access to healthcare in rural areas. [Budget Neutral]

Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations

Accreditation organizations currently do not make their survey reports and accompanying Plans of Corrections publicly available, and the Secretary is prohibited from disclosing the results of accreditation surveys that are not home health agency surveys or related to an enforcement action. This proposal would provide CMS with the authority to publish survey results for all accredited facilities, including hospitals, hospices, ambulatory surgical centers, outpatient physical therapy and speech language pathology services, and rural health clinics. This change will increase transparency and accelerate value. [Budget Neutral]

Support Certified Nurse Aide Staffing

Adequate staffing in nursing homes plays a critical role in safety and health of residents, and current oversight requirements can remove nursing homes' ability to hire, train, and certify these aides when necessary. This proposal increases flexibility for CMS to waive a disapproval of nursing home's Nurse Aid Training, Competency, and Evaluation Program. States can certify nursing homes to operate this training program, and therefore, certify their own nursing aides. However, nursing homes may lose their training certification due to non-compliance with a state survey regardless of whether the compliance issue related to the nursing home's competency in training their staff. Letting CMS more easily waive their disapproval of the training certification will allow nursing homes to improve their staffing while achieving overall compliance with state requirements. [Budget Neutral]

Remove Regulatory Burdens

HHS has made it a priority to ensure that providers can spend more time with patients instead of adhering to burdensome federal regulations. The Budget proposes to reduce regulatory burden in Medicare by eliminating unnecessary and onerous billing and oversight requirements.

Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models

Under the current structure of the Quality Payment Program, some clinicians who participate in advanced Alternative Payment Models may not be eligible for five percent incentive payments because they do not meet arbitrary thresholds. Effective CY 2021, the five percent bonus for clinicians in advanced Alternative Payment Models would be paid based on physician fee schedule revenues received through Models in which they participate rather than all Medicare physician fee schedule payments. This change directly rewards clinicians along a continuum based on their level of participation in advanced Alternative Payment Models, without subjecting clinicians to arbitrary participation threshold levels. [$50 million in costs over 10 years]

Allow Beneficiaries to Opt-Out of Medicare Part A and Retain Social Security Benefits

Medicare beneficiaries cannot decline enrollment in Part A while retaining their monthly Social Security benefits. This proposal gives beneficiaries flexibility to opt out of Part A, without any impact to their Social

Security benefits, empowering them to choose the best health insurance coverage option for themselves. Opting out of Part A does not surrender entitlement to the Part A benefit and would not affect assessment of any applicable late enrollment penalties for Parts B and D. The proposal creates an exception to the current prohibition on duplication of Medicare coverage and allow individuals who opt out of Part A to buy insurance in the private market. [Budget Neutral]

Eliminate Peer-Reviewed Journal Requirement under Merit-Based Incentive Payment System

Current law requires the Secretary to submit all proposed new measures for the Merit-based Incentive Payment System (MIPS) to a peer reviewed medical journal, but journals have been uninterested in publishing articles about the new measures. To support the goal of reducing administrative burden, this proposal eliminates the resource-intensive requirement to submit new MIPS proposed quality measures to peer reviewed journals. [Budget Neutral]

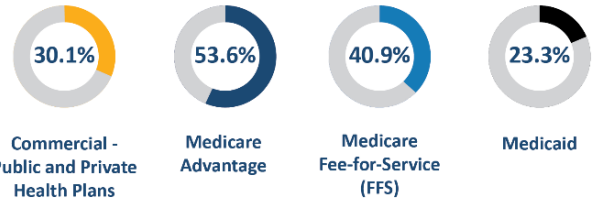
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment

Physicians must document a beneficiary's face-to-face encounter with a physician or a non-physician practitioner as a condition for Medicare payment for a DME order. This proposal allows CMS flexibility in the enforcement of the face-to-face requirement, eliminating this overly burdensome requirement for most Medicare providers and beneficiaries. [Budget Neutral]

MEDICARE EXCEEDS COMMERCIAL ALTERNATIVE PAYMENT MODELS (APM) PARTICIPATION IN 2018

In 2018, 35.8% of U.S. health care payments flowed through payment models with shared savings or more advanced value-based care approaches.

In each market, these payment methodologies accounted for:



Source: APM Health Care Payment Learning and Action Network (https://hcp-lan.org/2018-apm-measurement/2018-infographic).

Encourage Meaningful Measures for the End-Stage Renal Disease Quality Incentive Program

Current law prescribes which measures to include in the End-Stage Renal Disease Quality Incentive Program. This proposal provides the Secretary with broad authority to add and remove measures to the ESRD Quality Incentive Program through rulemaking. CMS will submit all new measures to the designated pre-rulemaking entity as currently specified in statute. This change will align the ESRD Quality Incentive Program with CMS's Meaningful Measures initiative, which seeks greater flexibility and less burden regarding the quality measures Medicare uses in its value-based payment systems. [Budget Neutral]

Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization

The Department and the regulated industry find that the physician self-referral law (commonly referred to as the "Stark Law") can be an impediment to care coordination, participation in alternative payment models, and the establishment of novel financial arrangements that further the goals of a value-based system. Effective CY 2022, this proposal establishes a new process for physicians to self-report inadvertent, technical non-compliance violations of the law and excludes physician-owned distributors from the indirect compensation exception, if physician owners generate more than 40 percent of the physician-owned distributor's business. [Budget impact not available]

Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission

Under current law, physicians must certify that all patients at critical access hospitals (CAHs) are reasonably expected to be discharged or transferred within 96 hours of admission. The CAH is still eligible for Medicare payment if an individual patient's stay exceeds 96 hours, so long as the CAH maintains an annual average length of stay of 96 hours or less, which is a Medicare Condition of Participation. This proposal removes the 96-hour physician certification requirement, thereby eliminating the burden of this unnecessary requirement. [Budget impact not available]

Remove Timeframe for Initial Surveys for End-Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018

The Bipartisan Budget Act of 2018 established a time frame by which compliance surveys should be initiated for new dialysis facilities seeking their initial certification, but did not specify whether the requirement applied to facilities participating in Medicare through accreditation. The proposal clarifies that the time frame is only applicable to surveys conducted by state survey agencies on behalf of CMS. Therefore, the statutory time frame would not be applicable to any End-Stage Renal Disease treatment facility choosing to be accredited by a CMS-approved accreditation organization, clarifying the current ambiguity over whether state survey agencies are required to survey these providers. [Budget Neutral]

Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System

The Merit-based Incentive Payment System (MIPS) is burdensome and overly complex, consisting of physician and other clinical level measures that are often not meaningful to clinicians who report them and do not help improve patient care. Effective CY 2023, this proposal alters the MIPS program by adopting a uniform set of broader claims calculated and beneficiary survey measures to assess performance at the group practice level instead of the individual clinician level during the performance period to reduce burden and provide meaningful and comparable results to clinicians and patients. This proposal uses the budget-neutral payment adjustments under the current statute to fund the incentive pool during the corresponding payment year and retains $500 million in annual additional performance bonus payments for top performers. [Budget Neutral]

Accelerate Drug and Device Approval and Reimbursement

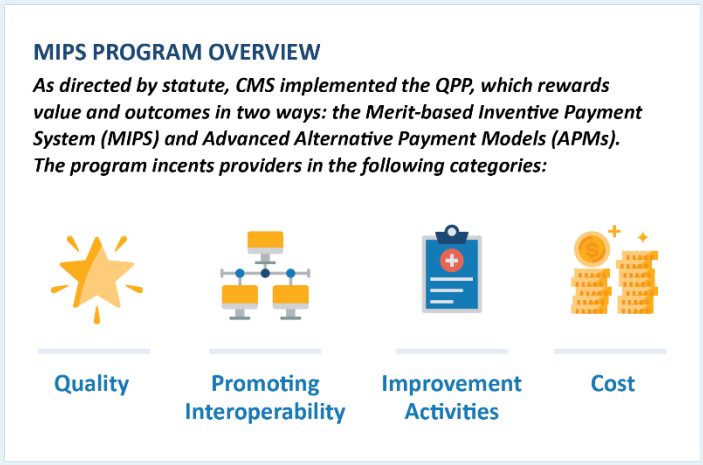
HHS is accelerating the development and review of transformative new drugs and devices that are intended to treat serious or life-threatening diseases, or conditions for which there are unmet medical needs. The Budget contains several legislative and administrative proposals aimed at accelerating drug and device approval and reimbursement.

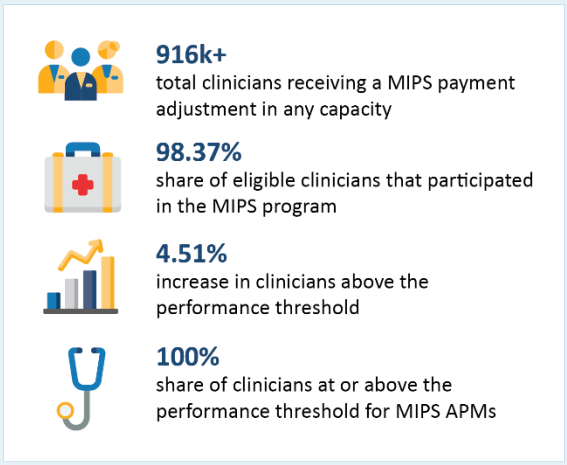
Accelerate Access to Non-Egg-Based Influenza Vaccines in Medicare

The current domestic enterprise for manufacturing influenza vaccines has shortcomings, including slow development and innovation, which can limit the ability to respond to a pandemic. This proposal supports the *Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health* by giving the HHS Secretary authority to establish higher Medicare payment amounts for cell-based and recombinant influenza vaccines than for egg-based vaccines. This will encourage the use and development of these vaccine types, which have faster development timelines and thus can be stockpiled for pandemics, among other benefits. This proposal is designed to be budget

QUALITY PAYMENT PROGRAM (QPP)

Promoting value-based care by integrating payment and outcomes





neutral, with the increased payments offset through corresponding decreases to egg-based vaccine payment rates. [Budget impact not available]

Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes

Medicare DME coverage excludes non-durable alternatives to DME. This proposal allows Medicare coverage for innovative non-durable medical equipment alternatives to treat and manage diabetes. Payment for these alternative items would be subject to competitive bidding and capped at the payment rate for their DME counterpart. Allowing access to these alternatives makes it possible for beneficiaries to choose items and services that better suit their medical needs. [Budget Neutral]

PROTECT LIFE AND LIVES

Advancing American Kidney Health

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. Medicare legislative proposals in the Budget advance the President's bold vision to bring kidney care into the 21st Century.

Extend Immunosuppressive Drug Coverage for Kidney Transplant Patients

Kidney transplant recipients not otherwise eligible for Medicare lose coverage of immunosuppressive drugs 3 years after transplantation. For patients without access to other healthcare coverage, the costs of continuing immunosuppressive drug therapy may be prohibitive. Without taking immunosuppressive drugs, the patient's body will reject the transplant and revert to having ESRD, requiring dialysis and possibly a subsequent transplant. The proposal creates a new federal program that provides lifetime coverage of immunosuppressive drugs for certain kidney transplant recipients until they are otherwise eligible for Medicare coverage. Coverage applies to kidney transplant recipients whose transplants were covered by Medicare and who are no longer ESRD patients or do not otherwise meet Medicare eligibility criteria. Eligible beneficiaries would be responsible for an income-adjusted monthly premium and 20 percent coinsurance. Extending coverage for immunosuppressive drugs will help ensure medication adherence, leading to long-term transplant success and preventing reversion to ESRD. [Budget impact not available]

Allow the Secretary to Determine the Appropriate Number of Organ Procurement Organizations

The statutory requirement related to the number of certified Organ Procurement Organizations (OPOs) does not provide the Secretary the flexibility to increase the number of OPOs should the Department determine that more localized procurement would be beneficial to increase the frequency of successful transplants. The proposal allows the Secretary to increase the number of Medicare-certified OPOs. This operational flexibility provides the Department with additional tools to increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate. [Budget Neutral]

Allow the Secretary to Determine the Appropriate Recertification Period for Organ Procurement Organizations

Current law prohibits recertification of OPOs from occurring more frequently than every four years. The proposal authorizes the Secretary to set the recertification interval to be at least every two years but not more than every four years. More frequent recertification results in greater oversight of OPOs, allowing CMS to survey poor performers more often and ensuring that quality deficiencies do not continue unexamined for extended periods. [Budget Neutral]

Reset and Increase End-Stage Renal Disease (ESRD) Networks Funding to Match Consumer Price Index

Currently, CMS funds ESRD Networks by withholding 50 cents from each treatment payment under the ESRD Prospective Payment System, unchanged since 1989. This proposal updates the amount from 50 cents to $1.50 and inflates that amount annually by the CPI-U to ensure funding is adequate for the networks to continue to carry out their work. [Budget Neutral]

Transforming Rural Health

The Administration is committed to transforming rural health for the more than 57 million Americans living in rural settings. The Budget supports this goal with Medicare proposals to build a sustainable rural health

model, prevent disease and mortality, increase access to rural healthcare, and leverage technology and innovation.

Modernize Payment for Rural Health Clinics

CMS has been limited to annual updates to the cap on Medicare payments to many rural health clinics based on increases in the Medicare Economic Index for many years, raising concerns that payments are inadequate. Rural health clinics subject to the cap are disproportionately likely to close compared to other clinics. This proposal establishes a new Medicare prospective payment system for rural health clinics with annual updates based on a market basket derived from cost report data and rebased periodically, similar to the recently-implemented payment system for Federally Qualified Health Centers. This new payment system would ensure equitable payment for these health clinics and help rural communities maintain access to these crucial services. [$1.8 billion in savings over 10 years]

Enhance Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics

Medicare only pays for telehealth services if furnished by physicians or certain non-physician practitioners as the distant site providers to the beneficiaries at certain originating sites located in certain geographic areas. This proposal allows Rural Health Clinics and Federally Qualified Health Centers to be distant site providers for Medicare telehealth and reimburses for these services at a composite rate similar to payment for comparable telehealth services under the Medicare Physician Fee Schedule. This proposal levels the playing field by allowing these critical healthcare facilities to participate in the existing Medicare telehealth program. It also increases beneficiary access to care in rural areas where these clinics and centers are often the only source of primary care. [Budget Neutral]

Extend Medicare Telehealth Services for IHS and Tribal Facilities

Medicare covers some types of telehealth services, but does not expressly cover telehealth services provided across state lines. In the Indian Health Service (IHS) system, telehealth practitioners are often located in a different state from the patient and are not licensed, registered, or subject to the law of the state where the patient is located and receiving such services. This IHS proposal allows all IHS and tribal facilities to bill Medicare for telehealth services as originating and distant sites under the Physician Fee Schedule, even if the facility does not meet the requirements for being located in certain rural or shortage areas, including coverage for telehealth services provided across state lines. Explicitly authorizing IHS and tribal health programs to receive Medicare payment as originating and distant sites for telehealth services will accommodate the unique structures and federal authorities that allow IHS and tribal health programs to operate across state lines and without regard to state licensure requirements. [Budget Neutral]

Modernize the Medicare Telehealth Benefit to Promote Value-Based Payment

Medicare payment for telehealth services is statutorily limited to circumstances where beneficiaries receive those services at particular healthcare settings, known as originating sites, and the originating site is located in a rural health professional shortage area or a federal telemedicine demonstration project. Medicare also limits the types of practitioners that can furnish telehealth services and pays for such services at the same rates as in-person services. This multifaceted proposal expands Medicare Fee-for-Service's telehealth benefit by removing existing barriers to telehealth services for providers participating in Medicare fee-for-service advanced Alternative Payments Models, which require more than nominal financial risk. This proposal would also require the Secretary to value telehealth services separately from similar services provided face-to-face for purposes of setting reimbursement rates in Medicare. This proposal broadens beneficiary access to Medicare telehealth services and addresses longstanding stakeholder concerns that the current statutory restrictions hinder beneficiary access, while ensuring Medicare is paying for value over volume. [Budget Neutral]

Preserve Access to Rural Emergency Hospitals

Medicare pays Critical Access Hospitals at 101 percent of costs but conditions eligibility for this higher payment on the hospital maintaining inpatient hospital beds. This proposal allows Critical Access Hospitals to voluntarily convert to an emergency hospital that does not maintain inpatient beds. This new facility type would receive the same Medicare payment rates as other emergency departments paid under the outpatient prospective payment system, plus an additional payment to assist with capital costs. The capital cost adjustment equals 10 percent of the 5-year average of the facility's payment. [Budget impact not available]

IMPROVE THE MEDICARE APPEALS SYSTEM

The Budget improves the Medicare appeals process across all four levels: two at CMS, the Office of Medicare Hearings and Appeals (the third level of appeal), and the Departmental Appeals Board (the fourth level of appeals). Legislative proposals accelerate the elimination of the backlog of appeals at the Office of Medicare Hearings and Appeals by the end of FY 2022 and will prevent a resurgence of appeals at all levels into the future.

Change the Medicare Appeal Council's Standard of Review

Currently, when a party files a request for review of an Administrative Law Judge decision, the Departmental Appeals Board's Medicare Appeal Council must review the decision *de novo*, from the beginning. This proposal changes the Council's standard of review from a *de novo* to an *appellate-level* standard of review. Changing the Departmental Appeals Board's standard of review will increase adjudication capacity by up to 30 percent and further distinguish the Council's role as an administrative appellate body. [Budget Neutral]

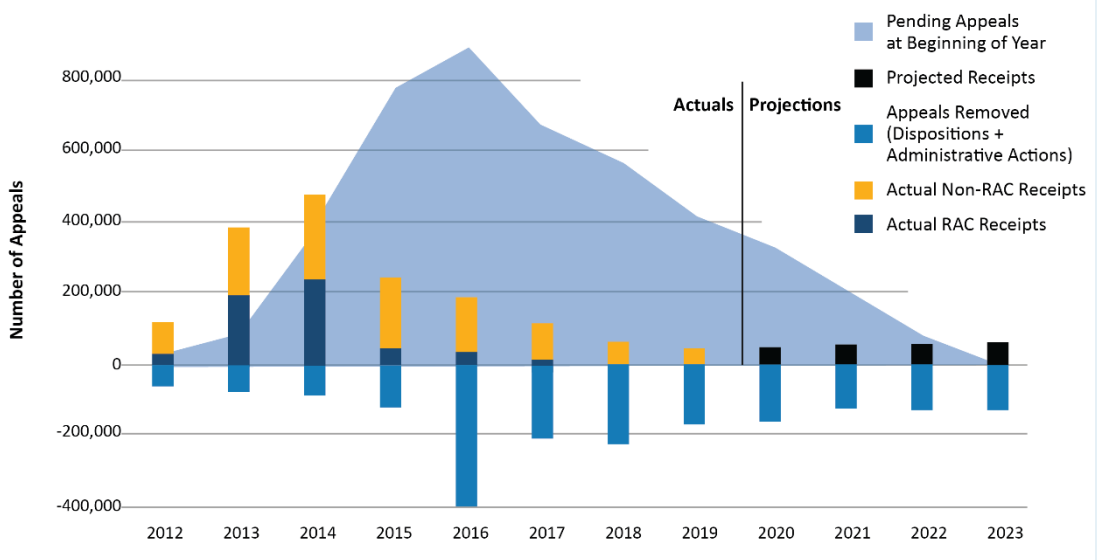
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals

Currently, there are no administrative fees charged for filing a Medicare appeal, which has in some cases resulted in appellant's filing non-meritorious appeals. This proposal establishes a post-adjudication user fee for all Medicare appeals, other than beneficiary appeals, which are denied, or otherwise receive unfavorable disposition, by the Office of Medicare Hearings and Appeals and the Departmental Appeals Board. The user fee supports 10 percent of the administrative costs required to adjudicate appeals and encourage those appellants who frequently file to more carefully assess their appeals before filing. [User fee revenue of $20.4 million over 10 years]

Expedite Procedures for Claims with No Material Fact in Dispute

Appellants have an option to bypass the Administrative Law Judge (ALJ) hearing at the third level of Medicare appeals by requesting expedited access to judicial review if specific conditions are met. This proposal allows the Office of Medicare Hearings and Appeals to issue decisions on the record without holding a hearing if there is no material fact in dispute. These cases include appeals, for example, in which Medicare does not cover the cost of a particular drug or the ALJ cannot find in favor of an appellant due to binding limits on authority. This proposal increases the efficiency of the Medicare appeals system and results in faster adjudications of pending appeals at the ALJ level of appeal. [Budget Neutral]

RISE AND PROJECTED FALL OF MEDICARE APPEALS BACKLOG AT OMHA FY 2012-2023



Note: Data reported in appeals, as of 9/30/2019.

Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal increases the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is $1,670in calendar year 2020 and updated annually. This adjustment will allow the amount at issue to better align with the amount spent to adjudicate the claim. Appeals not reaching the minimum amount in controversy will be adjudicated by a Medicare magistrate. [Budget Neutral]

Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal allows the Office of Medicare Hearings and Appeals to use Medicare magistrates for appealed claims below the Federal District Court amount in controversy threshold, which is $1,670 in calendar year 2020 and updated annually. This policy enables Administrative Law Judges to focus on more complex and higher amount in controversy appeals, while ensuring that all appealed claims are adjudicated. [Budget Neutral]

Limit Appeals When No Documentation is Submitted

Currently, appellants may pursue Medicare appeals when they have not submitted any documentation. This proposal limits the right for non-beneficiary appellants to appeal a redetermination of a claim denied because no documentation was submitted to support the items or services billed. This proposal does not apply to beneficiary appeals. Limiting the right to appeal when appellants do not submit documentation will incentivize providers and suppliers to submit documentation at the beginning of the appeals process so decisions can be made at the lowest, least costly level of appeal. [Budget Neutral]

Remand Appeals to the Redetermination Level with the Introduction of New Evidence

Currently, a party can submit new evidence at the second level of appeals or later in the administrative appeals process, decreasing the efficiency of the Medicare appeals system and contributing to the backlog of pending appeals at the third and fourth levels of appeal. This proposal permits the remand of an appeal to the first level of appeal when new documentary evidence is submitted into the administrative record at the second or later level of appeal. The proposal permits exceptions if evidence was provided to the lower level adjudicator but erroneously omitted from the record, or if an adjudicator denies an appeal on a new and different basis than earlier determinations. This proposal incentivizes appellants to include all evidence early in the appeals process and ensures the same record is reviewed and considered at subsequent levels of appeal. [Budget Neutral]

Require a Good-Faith Attestation on All Appeals

Currently, there are no statutory requirements that appellants consider the merits of their appeal before filing. This proposal requires all appellants to include in their initial appeal filing an attestation that they are submitting their appeal under a good-faith belief that they are entitled to receive Medicare reimbursement. This proposal also authorizes the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith. Requiring appellants to provide a good-faith attestation will reduce non-meritorious appeals and indiscriminate filing of appeals by high volume appellants. [Budget Neutral]

2021 ADMINISTRATIVE PROPOSALS

The Budget also includes four Medicare administrative proposals that the Department plans to implement in FY 2021 saving an estimated $116 billion over 10 years. These proposals support the Administration's priorities for Medicare and do not require Congressional action.

FACILITATE PATIENT-CENTERED MARKETS

Protect Medicare

Implement Medicare Advantage Risk Adjustment Model

Encounter data has been collected since 1998 and has been used as a source of risk adjustment data in Medicare Advantage since 2012. Encounter data reflects services rendered, rather than simply containing patient diagnoses. This proposal accelerates the phase-in of a new risk adjustment

model built on Medicare Advantage encounter data beginning in 2024, one year after the completed transition to using only diagnoses from encounter data for calculating risk scores. This new model will align risk adjustment in Medicare Advantage with the characteristics of beneficiaries in that program and improve payment accuracy by addressing excess payment adjustments driven by differences in documentation of health conditions rather than differences in costs of care for patients. [$40.6 billion in savings over 10 years]

BRING VALUE TO HEALTHCARE

Provide Price and Quality Transparency

Improve Clarity and Transparency of the Medicare Coverage Process

Many stakeholders find the process and standards for the Medicare coverage determination process lack clarity. This proposal requires CMS to issue additional guidance around the Medicare coverage process, including sub-regulatory guidance on the evidence standards that CMS utilizes in assessing coverage and the process to appeal coverage determinations, in an effort to improve clarity around Medicare coverage. [Budget Neutral]

Accelerate Drug and Device Approval and Reimbursement

Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations

It is currently not cost effective for providers to invest in some innovative technologies that could potentially save Medicare dollars over an episode of care. Under this proposal, the Center for Medicare & Medicaid Innovation would use existing authorities to identify bundled payment arrangements for certain high value devices. For example, these devices include technologies that could significantly reduce time and costs in a post-acute care setting but providers otherwise consider them impractical solely in the scope of Medicare payments to facilities. The proposal would require the device manufacturer to bear some or all of the risk. [Budget Neutral]

Strengthen the Parallel Review Process to Streamline Medicare Coverage

The Parallel Review program is a collaborative effort between the Food and Drug Administration (FDA) and CMS that reduces the time between FDA approval of a device and Medicare coverage of that item. This proposal strengthens the existing parallel review process to improve device manufacturer participation and increase transparency. [Budget Neutral]

FY 2021 Medicare Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Medicare Legislative Proposals			
Facilitate Patient-Centered Markets			
Protect Medicare			
Remove the Cap on Medicare Advantage Benchmarks and Remove the Doubling of the Medicare Advantage Quality Bonus Payments in Qualifying Counties	90	230	-1,200
Give Medicare Beneficiaries with High Deductible Health Plans the Option to Contribute to Health Savings Accounts and Medical Savings Accounts /1	--	--	--
Modify Reinsurance Arrangements for Medicare Advantage Plans	--	70	170
Modify Payments to Hospitals for Uncompensated Care /2	--	-65,470	-174,230
Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services	-4,200	-41,320	-117,200
Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care	-1,280	-28,290	-101,450
Reduce Medicare Coverage of Bad Debts	-410	-11,400	-33,600
Pay All Hospital-Owned Physician Offices Located Off-Campus at the Physician Office Rate	-1,800	-17,300	-47,240
Modify Payment for Hospice Care Provided to Beneficiaries in Skilled Nursing and Nursing Facilities	-310	-1,810	-4,520
Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria	-630	-4,030	-9,420
Reform and Expand Durable Medical Equipment Competitive Bidding	--	-1,570	-7,730
Use Retail Price Information for Durable Medical Equipment Fee Schedule Rates	-70	-620	-1,560
Bring Value to Healthcare			
Pay for Outcomes			
Expand Basis for Beneficiary Assignment for Accountable Care Organizations	--	-30	-80
Create a Consolidated Hospital Quality Payment Program	--	--	--
Extend and Enhance Medicare Independence at Home Demonstration	*	*	*
Implement Value-Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers	*	*	*
Improve the Medicare Shared Savings Program Beneficiary Incentive Enhancements	*	*	*
Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments	--	--	--
Reprioritize Primary and Preventive Care in Medicare	--	--	--
Provide Price and Quality Transparency			
Eliminate Beneficiary Coinsurance for Screening Colonoscopies with Polyp Removal	310	1,970	4,830
Enhance Quality Improvement Oversight of Post-Acute Care Facilities and Hospice Providers	*	*	*

FY 2021 Medicare Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Improve the Inpatient Hospital Wage Index	--	--	--
Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations	--	--	--
Support Certified Nurse Aide Staffing	--	--	--
Remove Regulatory Burden			
Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models	-170	-170	50
Allow Beneficiaries to Opt-Out of Medicare Part A and Retain Social Security Benefits	--	--	--
Eliminate Peer-Reviewed Journal Requirement under Merit-Based Incentive Payment System	--	--	--
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment	--	--	--
Encourage Meaningful Measures for the End-Stage Renal Disease Quality Incentive Program	--	--	--
Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization	*	*	*
Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission	*	*	*
Remove Timeframe for Initial Surveys for End-Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018	--	--	--
Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System	--	--	--
Accelerate Drug and Device Approval			
Accelerate Access to Non-Egg-Based Influenza Vaccines in Medicare	*	*	*
Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes	--	--	--
Protect Life and Lives			
Advancing American Kidney Health			
Extend Immunosuppressive Drug Coverage for Kidney Transplant Patients	*	*	*
Allow the Secretary to Determine the Appropriate Number of Organ Procurement Organizations	--	--	--
Allow the Secretary to Determine the Appropriate Recertification Period for Organ Procurement Organizations	--	--	--
Reset and Increase End-Stage Renal Disease (ESRD) Networks Funding to Match Consumer Price Index	--	--	--
Transforming Rural Health			
Modernize Payment for Rural Health Clinics	-20	-430	-1,790
Enhance Medicare Telehealth Services for Federally Qualified Health Centers and Rural Health Clinics	--	--	--
Extend Medicare Telehealth Services for IHS and Tribal Facilities	--	--	--

FY 2021 Medicare Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Modernize the Medicare Telehealth Benefit to Promote Value-Based Payment	--	--	--
Preserve Access to Rural Emergency Hospitals	*	*	*
Improve the Medicare Appeals System			
Change the Medicare Appeal Council's Standard of Review	--	--	--
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold	--	--	--
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals	--	--	--
Expedite Procedures for Claims with No Material Fact in Dispute	--	--	--
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review	--	--	--
Limit Appeals When No Documentation is Submitted	--	--	--
Remand Appeals to the Redetermination Level with the Introduction of New Evidence	--	--	--
Require a Good-Faith Attestation on All Appeals	--	--	--
Medicare Interactions			
Reduce Fraud, Waste, Abuse, and Improper Payments in Medicare	-752	-4,103	-13,892
Legislative Proposals for Medicare-Medicaid Enrollees /4	-20	-90	-230
Reform Graduate Medical Education Payments /3/5	-15,270	-92,990	-215,430
Rebase National Medicare & You Education Program User Fee /6	40	320	670
Reform Medical Liability	-78	-5,466	-27,119
Extend Sequester	--	--	-11,653
Part A Premium Interaction	235	2,694	7,066
Medicare Enrollment Extenders (ACL)	38	38	38
Subtotal Outlays, Medicare Legislative Proposals	**-24,297**	**-269,768**	**-755,521**
Medicare Administrative Proposals			
Facilitate Patient-Centered Markets			
Protect Medicare			
Implement Medicare Advantage Risk Adjustment Model	--	-1,700	-40,630
Bring Value to Healthcare			
Provide Price and Quality Transparency			
Improve Clarity and Transparency of the Medicare Coverage Process	--	--	--
Accelerate Drug and Device Approval and Reimbursement			

FY 2021 Medicare Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations	--	--	--
Strengthen the Parallel Review Process to Streamline Medicare Coverage	--	--	--
Medicare Interactions			
Reduce Fraud, Waste, and Abuse in Medicare	--	--	--
Target to Reduce Wasteful Spending in Medicare	-4,180	-45,300	-75,230
Subtotal, Medicare Administrative Proposals	**-4,180**	**-47,000**	**-115,860**

*Budget impact unavailable as of the publication date of the FY 2021 President's Budget.

1/ Memorandum A: Give Medicare Beneficiaries with High Deductible Health Plans the Option to Contribute to Health Savings Accounts and Medical Savings Accounts (non-add):

Medicare Impact	--	--	--
General Revenue Treasury Impact	--	6,222	16,275
Total Impact	**--**	**6,222**	**16,275**

2/ Memorandum B: Modify Medicare Payments to Hospitals for Uncompensated Care (non-add):

Medicare Impact	--	-65,470	-174,230
General Revenue Impact (CMS)	--	35,680	86,300
Total Impact	**--**	**-29,790**	**-87,930**

3/ Memorandum C: Reform Graduate Medical Education Payments - Government-Wide Impact (non-add):

Medicare Impact	-15,270	-92,990	-215,430
Medicaid Impact	-1,700	-9,570	-22,420
General Fund Impact	17,500	89,830	185,680
Total Impact	**530**	**-12,730**	**-52,170**

4/ See Medicaid chapter for proposal descriptions.

5/ Children's Hospital Graduate Medical Education is shown as $0 for FY 2021 and future years because this program is currently funded under a discretionary appropriation; in the FY 2021 Budget, HHS is no longer requesting funding for this program-specific appropriation. However, this proposal assumes that Children's teaching hospitals will continue to receive approximately the same amount of Graduate Medical Education funding from the General Fund as they do under current law in FY 2020 ($325 million).

6/ The proposal to Rebase National Medicare & You Education Program User Fee has a projected net positive revenue impact for the Medicare Trust Funds of $330 million over 10 years, comprised of $1.0 billion in additional user fees offset by $670 million in projected benefit spending. See proposal description in CMS Program Management chapter.

Program Integrity

	dollars in millions			2021 +/-
	2019	2020	2021	2020
Healthcare Fraud and Abuse Control Program				
Discretionary	765	786	813	+27
Mandatory /1	$1,330	$1,357	$1,427	+70
Subtotal, Healthcare Fraud and Abuse Control Program	**$2,095**	**$2,143**	**$2,240**	**+97**
Medicaid Integrity Program /1 /2	$82	$84	$91	+7
Total, Budget Authority	**$2,183**	**$2,227**	**$2,331**	**+104**

1/ The Fiscal Year (FY) 2019 and FY 2020 mandatory base and Medicaid Integrity Program include sequester reductions.
2/ Additional information on the Medicaid Integrity Program is included in the State Grants and Demonstrations chapter.

The Fiscal Year (FY) 2021 President's Budget (Budget) strengthens the integrity and sustainability of Medicare and Medicaid by investing in the prevention of fraud, waste, and abuse, protecting beneficiaries from unnecessary payments or harm, and eliminating wasteful spending. Two programs, the Healthcare Fraud and Abuse Control (HCFAC) Program and the Medicaid Integrity Program, comprise the largest portion of federal government investment in healthcare program integrity. The FY 2021 Budget provides $2.3 billion in total mandatory and discretionary investments for the HCFAC and Medicaid Integrity Programs.

HEALTHCARE FRAUD AND ABUSE CONTROL PROGRAM

The HCFAC Program, established in 1996, serves as the primary federal investment that addresses healthcare fraud and abuse through a coordinated effort between HHS and the Department of Justice (DOJ). It provides both discretionary and mandatory funding to address the full spectrum of healthcare fraud and abuse interventions, including identification and reduction of improper payments, prevention and detection, and investigation and prosecution of fraud

Discretionary Healthcare Fraud and Abuse Control

The Budget requests $813 million in discretionary HCFAC funding, $27 million above the FY 2020 level.

PROSECUTING HEALTH CARE FRAUD AND PROTECTING TAXPAYER DOLLARS

$4 returned for every $1 spent

NATIONWIDE MEDICARE BRACE SCAM

$1.2 billion in Medicare losses from telemedicine and neck, shoulder, and knee brace fraud scheme targeting seniors investigated.

24 Executives from DME and Telemedicine companies charged.

CMS took administrative action against **130** DME companies.

2019 APPALACHIAN OPIOID TAKEDOWNS

73 defendants charged for alleged health care fraud and participation in illegal prescribing and distribution of opioids and other narcotics.

24,000+ patients affected in April and September take downs.

350,000+ prescriptions and **35 million** pills involved.

In addition, in FY 2018 and 2019 HHS-OIG excluded **over 1,348 individuals** for conduct related to opioid diversion and abuse.

NATIONWIDE GENETIC TESTING FRAUD

Scammers targeted seniors offering "free" genetic testing to obtain personal information for fraudulent purposes.

35 defendants from telemedicine companies and cancer genetic testing labs charged.

CMS took administrative action against companies and individuals who billed **$2.1 billion** in Medicare claims.

This includes $317 million in base discretionary funds plus a discretionary cap adjustment of $496 million, consistent with the Budget Control Act of 2011.

Of the $813 million, CMS receives $628 million, DOJ receives $83 million, and the HHS Office of Inspector General (HHS OIG) receives $102 million.

The Budget also proposes to extend the discretionary cap adjustment, currently scheduled to end after FY 2021, through FY 2025 and then increase the FY 2025 levels for inflation though FY 2030.

Together CMS, DOJ, and HHS OIG will invest in innovative program integrity tools to fight fraud, waste, and abuse in a changing healthcare landscape. New advancements in predictive modeling and artificial intelligence will allow CMS to enhance existing efforts to reduce improper payments, prevent fraud, and target bad actors, while limiting burden. For example, CMS is exploring methods of using machine learning to conduct more rapid review of chart documentation to improve payment accuracy.

Investment in oversight and law enforcement will allow HHS OIG and DOJ to combat complex healthcare fraud, including illegal opioid prescriptions, and stay ahead of criminals who are armed with increasingly sophisticated tools and technologies. In April 2019, HHS and DOJ conducted a nationwide Medicare brace takedown of a complex fraud scheme between telemedicine and Durable Medical Equipment companies that demonstrates the importance of new fraud fighting techniques. HCFAC law enforcement partners will continue to invest in new technologies such as artificial intelligence and state-of-the-art data analytics to stay ahead of criminal actors who seek to harm taxpayers and patients.

In October 2019, CMS published two requests for information: "Future of Program Integrity" and "Using Advanced Technology in Program Integrity". CMS sought stakeholder input on how best to use emerging technologies to address fraud, waste, and abuse, and adapt program integrity efforts as a traditional fee-for-service system transforms to value-based payments. CMS received 1,843 comments from stakeholders on these two requests for information. Additionally, CMS conducted three in-person and one online listening sessions. CMS is using stakeholder feedback to develop a strategic plan for high impact, cost effective future investments in program integrity.

Mandatory Healthcare Fraud and Abuse Control

The Medicare Part A Trust Fund provides $1.4 billion in mandatory HCFAC resources for FY 2021, allocated to the Medicare Integrity Program and other HCFAC partners. This funding supports efforts across HHS, HHS OIG, DOJ, and the Federal Bureau of Investigation to combat healthcare fraud, waste, and abuse.

Return on Investment

Program integrity spending is a proven cost-effective investment. Medicare Integrity Program improper payment efforts have consistently yielded a savings of over $10 billion annually.

The three year rolling average return-on-investment for HCFAC law enforcement activities is $4 gained for every $1 spent. In FY 2018 alone, these activities returned $2.3 billion to the federal government or private individuals, including $1.2 billion to the Medicare Trust Funds and $550 million in federal Medicaid recoveries and audit disallowances to the United States Department of the Treasury.

CMS actuaries also assume that new spending on program integrity efforts will yield additional savings. Therefore, the additional $5.8 billion in discretionary spending from extending cap adjustment funding levels through 2030 will yield $6.1 billion in savings to the federal government over the 10-year window.

MEDICAID INTEGRITY PROGRAM

Using HCFAC as a model, the Deficit Reduction Act of 2005 established the Medicaid Integrity Program as the nation's first program integrity effort focused on Medicaid. The mandatory appropriation for the Medicaid Integrity Program adjusts annually for inflation and will total $91.2 million in FY 2021.

States are primarily responsible for combating fraud, waste, and abuse in the Medicaid program, and the Medicaid Integrity Program plays an important role supporting these efforts. Funded activities include reviews, audits, education activities, and technical support to states. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the HCFAC Program.

In FY 2018, CMS released a new strategy for Medicaid to address new program integrity challenges associated with the rapid Medicaid spending increase in the last

decade due in part to Medicaid expansion. The new initiatives in this strategy include:

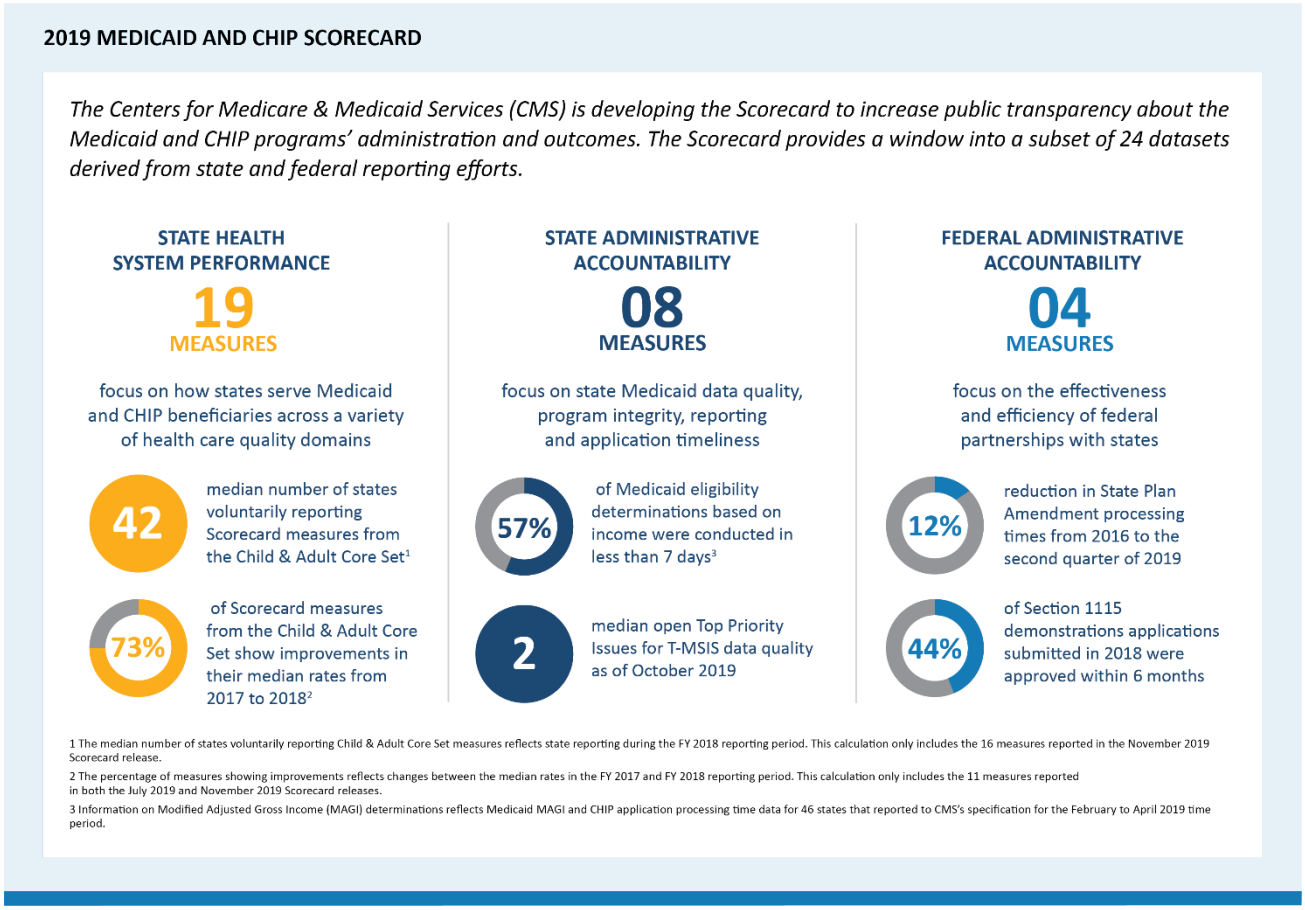
- New audits targeting improper claims for federal matching funds, managed care medical loss ratios, and rate setting. These audits address issues identified, in part, by the HHS OIG and the Government Accountability Office (GAO);
- New audits of state beneficiary eligibility determinations previously found to be high risk by the HHS OIG. These audits examine how states determine eligibility for groups that qualify for enhanced federal match; and
- Optimizing state-provided claims and provider data to both improve Medicaid eligibility and payment data and maximize their use for program integrity purposes.

In 2019, CMS updated guidance on expectations for states that implement Medicaid expansion to address concerns on how states determine Medicaid eligibility for the expansion population.

The Medicaid Financial Management and Oversight Project provides funding specialists, including accountants and financial analysts working with states to improve CMS's financial oversight of Medicaid and the Children's Health Insurance Program (CHIP). In 2018, these funding specialists partnered with states to avert or remove $1.5 billion in payments that states could not justify.

Combined with CMS program management and other accounts, Medicaid program integrity funding improves the Medicaid and CHIP Scorecard Initiative and critical Medicaid systems supporting program integrity. CMS released its first-ever Medicaid and CHIP Scorecard in June 2018 as part of a broader strategy to achieve a better balance in Medicaid between appropriate federal oversight and state flexibility, ensuring fiscal integrity, and promoting accountability for the quality of care provided to Medicaid beneficiaries.

The Scorecard is the public-facing federal dashboard of state health and administrative performance in the Medicaid and CHIP programs. It is designed to improve transparency and accountability for program outcomes through public reporting. In November 2019, sections



of the Scorecard were refreshed with updated data, an expanded set of measures, and enhanced functionality. The Scorecard includes a number of measures related to Medicaid program integrity, including state progress on T-MSIS and participation in the Healthcare Fraud Prevention and Partnership. The Scorecard is publicly available at Medicaid.gov.

Continued investments in CMS program operations and in Medicaid program integrity will ensure CMS can continue to enhance transparency through the Scorecard and will also fund critical updates to Medicaid information systems that support program integrity. These updates include investments in the Transformed-Medicaid Statistical Information System (T-MSIS), which is the nation's first accessible repository of Medicaid claims and encounter data. The GAO and HHS OIG both identified quality, functional T-MSIS data as a top priority for Medicaid program integrity. In 2019, CMS released research-ready data files for the first time. CMS is continuing to improve data quality and systems functionality to better enable stakeholder access to and use of this data, including for law enforcement, auditing, and other program integrity purposes. CMS is also modernizing its Medicaid drug reporting system, which is critical to support adequate oversight of the Medicaid drug rebate program.

2021 LEGISLATIVE PROPOSALS

The FY 2021 Budget includes a comprehensive package of program integrity legislative proposals, saving $31 billion over 10 years, that strengthen fiscal stewardship in Medicare and Medicaid by: improving payment accuracy; enhancing provider and program oversight; reducing improper payments; and supporting law enforcement.

Improving Payment Accuracy

Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste, and Abuse

Prior authorization can be an effective tool for healthcare payers to support payment accuracy and reduce unnecessary utilization, but current law allows Medicare to use this tool on only a few fee-for-service items and services. This proposal extends the narrow existing authority to all Medicare Fee-for-Service items and services, and CMS will target this authority toward items and services that are at high risk for fraud and abuse, such as inpatient rehabilitation facilities. By allowing prior authorization on additional items and services, CMS can reduce Medicare improper payments. [$13.7 billion in savings over 10 years]

Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation

Under current law, Medicare cannot hold a practitioner financially accountable for improperly documenting ordered items or services. This proposal allows the Secretary to assess an administrative penalty on practitioners for ordering high-risk, high-cost items or services without proper documentation, such as diagnosis or encounter data. The penalty would be $50 for Part B items/services and $100 for Part A services. [Budget Neutral]

Implement Targeted Risk-Adjustment Pre-Payment Review in Medicare Advantage

In FY 2019, Medicare Advantage had an improper payment rate of 7.87 percent and overpayments exceeded $9 billion. Beginning in CY 2022, this proposal would confirm diagnoses submitted by Medicare Advantage Organizations for risk-adjustment with the medical record prior to CMS making risk-adjusted payments. The Secretary would focus pre-payment review on plans, diagnosis, or beneficiaries at elevated risk of improper payments and would determine the threshold at which plans would be required to submit medical record documentation in support of the risk-adjustment. This proposal excludes certain types of plans. Confirming diagnoses before making risk-adjusted payments would improve payment accuracy in Medicare Advantage. [Budget Neutral]

Require Prior Authorization When Physicians Order Certain Services Excessively Relative to Their Peers

The Medicare Payment Advisory Commission and the GAO found certain in-office ancillary services are prone to inappropriate physician self-referral and overutilization. Effective calendar year 2022, this proposal establishes a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. Patients would be aligned to the physician who provided the majority of their in-office ancillary services during the given year. CMS will re-evaluate annually to determine which physicians would be subject to prior authorization in the coming calendar year. [Budget Impact not available]

Strengthen CMS's Ability to Recoup Medicaid Improper Payments

Recent audits identified instances of states enrolling individuals in Medicaid who did not meet eligibility requirements, resulting in overpayments to states, but current law and regulations restrict HHS's ability to recover these payments in most circumstances. This proposal gives HHS authority to collect overpayments from States that spend federal resources on ineligible or misclassified beneficiaries. Specifically, it would permit HHS to issue disallowances outside of the current improper payment rate measurement process and allow HHS and HHS OIG to issue disallowances extrapolated from findings based on a sample of beneficiary eligibility cases. It would also eliminate the current threshold that precludes HHS from issuing disallowances where states' eligibility-related improper payments are three percent or less of a sample. [$5.4 billion in savings over 10 years]

Enact Financial Penalties for States that are not Complying with Provider Screening, Enrollment, and Revalidation Requirements

To address state noncompliance with provider screening, enrollment, and revalidation requirements in Medicaid and CHIP for both managed care and fee-for-service, this proposal would give HHS authority to issue financial penalties to reduce administrative match rates until the states come into compliance. Specifically, this proposal would allow for a one percent reduction of the state's administrative match in FY 2021, a two percent reduction in FY 2022, a three percent reduction in 2023, and a four percent reduction thereafter. [Budget impact not available]

Strengthen CMS's Ability to Recover Medicaid and CHIP Overpayments Resulting from Noncompliance with Provider Screening and Enrollment Requirements

State noncompliance with provider screening, enrollment, identifier, and revalidation requirements is one of the largest drivers of Medicaid and CHIP improper payments. Compliance with existing regulations is essential to keeping bad actors out of the Medicaid and CHIP programs. This proposal would give HHS authority to issue disallowances for payments made as a result of noncompliance based on extrapolated improper payments findings in fee-for-service Medicaid and CHIP. [Budget impact not available]

Enhancing Provider and Program Oversight

Prevent Fraud by Applying Penalties on Providers and Suppliers who Fail to Update Enrollment Records

Medicare requires providers and suppliers to update enrollment records to remain compliant with program requirements. This proposal provides CMS the authority to implement civil monetary penalties for failure to report changes to information provided during enrollment or revalidation. Since outdated enrollment records can result in inaccurate information and make Medicare more susceptible to fraud, this proposal provides an additional incentive for providers and suppliers to update their enrollment records. [$32 million in collections over 10 years]

Extend Beneficiary Protection for Provider's Failure to Meet Procedural or Other Requirements

Currently, no provision in law prevents beneficiaries from being liable for payment if a provider or supplier fails to comply with procedural requirements for Medicare Part B services. This proposal would shield Medicare beneficiaries from financial liability when the provider fails to comply with Medicare requirements, resulting in a payment denial. Providers who inappropriately attempt to shift liability to the beneficiary would risk removal from Medicare. This proposal will align Medicare Part B beneficiary liability protections with Medicare Part A, and prevent beneficiaries from being inappropriately coerced into paying for Medicare services. [Budget impact not available]

Expand the Provisional Period of Enhanced Oversight Statutory Authority for New Providers and Suppliers to Further Stem Fraud, Waste, and Abuse

New Medicare providers and suppliers are subject to a provisional period of enhanced oversight, which allows CMS to increase scrutiny on a provider or supplier for up to one year after enrollment. Providers and suppliers can bypass the temporary period of enhanced scrutiny by delaying Medicare claims submissions until the period ends. This proposal provides CMS the authority to wait to initiate the enhanced oversight period until a provider or supplier submits its first claim rather than upon enrollment, and allows CMS to extend the enhanced oversight period for longer than one year. These changes close loopholes that bad actors leveraged to avoid the period of higher scrutiny on new providers and suppliers. [Budget impact not available]

Ensure Providers that Violate Medicare's Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Program

Under current law, the reasonable assurance period allows providers and suppliers terminated from Medicare participation for noncompliance with federal requirements to reenter the program after just a preliminary showing of compliance. This is allowed even under circumstances that conflict with Medicare's minimum reenrollment requirements and puts beneficiaries at an increased risk of harm. This proposal allows the Secretary to enforce an exception to Medicare's reasonable assurance period in cases of patient harm or neglect by removing providers from the program for a 1 to 3 year period. [Budget Neutral]

Reform Medicare Practitioner Opt- Out

Currently, most physicians and eligible non-physician practitioners who do not wish to enroll in the Medicare program may opt out of Medicare for two years and termination of the opt out is limited. This proposal would provide broader flexibility under the Medicare opt out rules. New flexibilities would include expanding opt out provisions to a broader range of physicians and non-physician practitioners (e.g., occupational therapists, chiropractors) and reducing the standard opt out period to one year, with exceptions for shorter periods based on the Secretary's discretion. This proposal is consistent with the Department's efforts aimed at administrative simplification and burden reduction. It would also reduce confusion among the provider community about the impact of opting out of Medicare. [Budget impact not available]

Require Reporting on Clearinghouses and Billing Agents when Medicare Providers and Suppliers Enroll in the Program

Providers and suppliers employ clearinghouses and billing agents to process their claims with CMS, yet CMS has no method for tracking these entities and their affiliations, which leaves the program vulnerable to entities that perpetrate abusive schemes. This proposal requires providers and suppliers to report clearinghouses and billing agents that act on behalf of Medicare providers and suppliers. It would allow CMS to obtain clearinghouse and billing agent organization information in support of CMS and law enforcement's efforts to track and address fraud and abuse. [Budget Neutral]

Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments

The HHS OIG reported that Medicaid personal care services claims are at a high risk for fraud and recommended CMS better screen such claims prior to payment. This proposal requires states to implement claims edits to enable better screening and automatically deny unusual personal care services claims, such as, duplicative services, services from a provider not meeting state qualification requirements, or services rendered to individuals no longer eligible for Medicaid. [$11.1 billion in savings over 10 years]

Consolidate Provider Enrollment Screening for Medicaid and CHIP

To protect Medicaid and CHIP against ineligible and fraudulent providers, states are required to screen providers enrolling in Medicaid or CHIP according to their risk for fraud, waste, and abuse; however, providers enrolling in multiple state Medicaid or CHIP programs and managed care plans often face unnecessary and duplicative screening by states, federal programs, and managed care plans. This proposal requires providers receiving federal funding and enrolling in Medicaid or CHIP to undergo centralized CMS screening. State Medicaid and CHIP agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening. [Budget Neutral]

Streamline the Medicaid Terminations Process

States do not always remove bad actors from their Medicaid programs as quickly as needed to avoid continued fraud, waste, and abuse. This proposal enhances the existing Medicaid provider terminations statute in three ways. First, it defines appeals periods such that state Medicaid agencies will report terminations to CMS after the first level of appeal rather than waiting until all appeals have been exhausted. Second, it establishes reporting requirements for rescissions and reinstatements of terminated Medicaid providers. Third, it requires that states check the centralized Termination Notification Database before enrolling providers. This proposal protects beneficiaries from bad actors who remain enrolled in Medicaid during the appeals period, reduces provider and state burden, and prevents unnecessary Medicaid spending, while ensuring that bad actors are not able to enroll in other state Medicaid programs. [Budget Neutral]

Extend Flexibility in Annual Open Payments Reporting Deadline

Many covered entities find the Open Payments reporting deadline burdensome with limited time for review and corrections before publication. The proposal removes the statutory June 30th publication date for Open Payments data and provides the Secretary discretion to establish an alternative annual publication date that does not extend beyond October 1st. This approach provides more time for impacted parties to review Open Payments data before release, ensuring reduced provider burden and improved accuracy of the data. [Budget Neutral]

Require Physician Owned Distributors to Report in Open Payments

Currently, Physician Owned Distributors often sell or distribute implantable medical devices to other entities with whom they have a financial interest but are not required to report in the Open Payments Program, making it difficult for patients to recognize potential conflicts of interests. Effective CY 2021, this proposal requires that all Physician Owned Distributors report and identify themselves in the Open Payments program. This approach promotes increased transparency in response to a primary criticism of Physician Owned Distributors, that ownership may affect physicians' clinical decision-making, influencing them to perform unnecessary surgeries or choose a medical device in which they have a financial interest over one more appropriate for the patient. [Budget Neutral]

Require Annual Certification of National Provider Identifier

National Provider Identifier data is used by the entire health industry as the definitive record to uniquely identify providers and process claims. Providers and suppliers are not required to certify and update their record at any regular interval. The result is an outdated, unreliable network of information, which forces Medicare Advantage plans, state Medicaid programs, private payers, and other organizations to independently collect and maintain their own provider directories. The proposal would require all healthcare providers and suppliers to annually recertify or update their record, if necessary. An updated, accurate record will support network accuracy, reduce burden on other organizations like Medicare Advantage plans, and bolster the development of interoperability. This proposal will also address program integrity by making these data systems better able to communicate with each other to track and address fraud, waste, and abuse. [Budget Neutral]

Supporting Oversight, Law Enforcement, and Fraud Reduction

Require Providers and Suppliers to Produce Part B Records to Support Part D Investigations or Audits

Currently, CMS lacks specific statutory authority to require records from Part B providers and suppliers in connection with an investigation or audit of drugs paid under Medicare Part D. The proposal allows CMS to demand Part B records and information in support of Part D investigations and audits. Access to Part B records and information would allow CMS to complete more comprehensive Part D abusive prescribing investigations. [Budget Neutral]

Address Patient Abuse or Neglect in Non-Institutional Settings

Medicaid Fraud Control Units receive cases of abuse and neglect in non-institutional settings they cannot pursue due to legal restrictions on federal matching funds for cases in non-institutional settings. These restrictions were established in 1978, at a time when Medicaid services were typically provided in institutional settings, and do not reflect the shift in delivery and payment for health services to home and community based settings. The Budget proposes to allow Medicaid Fraud Control Units to receive federal matching funds for the investigation or prosecution of abuse and neglect of a beneficiary in non-institutional settings, such as home-based care. [$63 million in non-PAYGO savings over 10 years]

Clarify Authority for the Healthcare Fraud Prevention Partnership

The Healthcare Fraud Prevention Partnership is a public/private partnership between federal and state officials, law enforcement, private plans, and associations with the goal to exchange information to fight healthcare fraud and abuse. Currently, the Partnership operates under the authority established by the HCFAC Program, which limits allowable fraud and abuse activities to data sharing. This proposal establishes explicit authority for the Partnership and expands the scope of allowable activities beyond data sharing. The new authorities would allow the Partnership to address the full spectrum of fraud and abuse in the healthcare sector, including efforts to examine large public health issues that have fraud,

waste, and abuse implications, such as addressing opioid misuse. [Budget Neutral]

Improve Effectiveness of HHS Program Integrity Efforts

Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor

CMS currently absorbs all fees charged by Treasury for most CMS overpayment collections. The proposal gives the Secretary authority to pass Treasury fees for CMS overpayment collections on to the debtor for certain programs. Specifically, CMS would increase the collection amounts to account for Treasury's recovery fee and ensure full repayment to the Medicare Trust Funds. [$200 million in savings over 10 years]

Improve Efficiency and Strengthen Program Integrity Efforts in Medicare Parts C and D

Despite their success in Fee-for-Service, Recovery Audit Contractors have found Medicare Parts C and D to be an unattractive business model because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. Additionally, Parts C and D Recovery Audit Program functions are currently being performed through other program integrity mechanisms. To more efficiently use program integrity resources, this proposal removes the requirement for CMS to expand the Recovery Audit Program to Medicare Parts C and D. The proposal also requires plan sponsors to report Parts C and D fraud and abuse incidents and corrective actions. This proposal creates programmatic and administrative efficiencies while strengthening fraud and abuse reporting. [Budget Neutral].

Allow States to Partner with the Treasury Offset Program to Recover Medicaid and CHIP Debts

States are only able to recover a portion of Medicaid and CHIP improper payments each year. This proposal would give states the option to partner with the State Reciprocal Program, which is a component of the Treasury Offset Program, to recover Medicaid and CHIP debts by offsetting those debts against state and federal payments, including federal tax returns. This would include provider and supplier debts, third party liability collections, and debts associated with enforcement of sponsor deeming and repayment requirements for certain immigrants. States would pass on fees to the debtor to cover Treasury's administrative costs. [$988 million in savings over 10 years]

Make the Medicaid Recovery Audit Contractor Program Optional for States

Recovery Audit Contractors have produced only modest returns for the Medicaid program, but states are currently required to contract with Medicaid Recovery Audit Contractors to recover fee-for-service improper payments. By making state participation optional, this proposal gives states the option to pursue more efficient and effective ways to recover improper payments. [Budget Neutral]

2021 ADMINISTRATIVE PROPOSALS

The FY 2021 Budget includes four administrative proposals, saving $220 million over 10 years, that strengthen fiscal stewardship in Medicare and Medicaid by improving payment accuracy; enhancing provider and program oversight; reducing improper payments; and supporting law enforcement.

Improving Payment Accuracy

Address Excessive Billing for Durable Medical Equipment that Require Refills on Serial Claims

In FY 2019, almost 31 percent of Medicare payments for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies were improper. By leveraging Medicare demonstration authority, this proposal tests whether using a benefits manager for serial durable medical equipment claims results in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring beneficiaries were receiving the correct quantity of supplies or services for the appropriate period. [Budget Neutral]

Address Improper Payments of Chiropractic Services through Targeted Medical Review

In an effort to reduce improper payments, recent legislation requires Medicare prior authorization for certain chiropractic services rendered by providers with aberrant billing patterns. CMS has determined that implementing the prior authorization program as specified in the legislation would cost more money to administer than it would save. Under this proposal, CMS would use Innovation Center authority to test whether more targeted medical review could effectively address improper payments in chiropractic services. [Budget Neutral]

Reduce Utilization of Low-Value Health Services through Prior Authorization Demonstrations

Medicare low-value health services currently pose risks of over-utilization or provision of care that is unlikely to improve health and can potentially harm patients. CMS will explore options within their current authority to test if applying prior authorization on low-value services can reduce Medicare costs by reducing unnecessary utilization. When implementing this proposal, CMS will consider patient access and other quality concerns, in an effort to reduce patient burden while ensuring appropriate provisions of healthcare. [Budget Neutral]

Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility

Current regulations restrict CMS's ability to issue disallowances related to beneficiary eligibility. This proposal will revise regulations relating to Medicaid improper payment rate measurement, empowering CMS to issue disallowances to states with a beneficiary eligibility improper payment rate above the statutory three percent threshold. This administrative action will expand the use of disallowances and will pave the way for the legislative proposal above to Strengthen CMS's Ability to Recoup Medicaid Improper Payments. [$220 million in savings over 10 years]

FY 2021 Program Integrity Budget Proposals

dollars in millions	2021	2021 -2025	2021 2030
Program Integrity Legislative Proposals			
Improving Payment Accuracy			
Medicare			
Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste, and Abuse	-730	-3,990	-13,660
Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation	--	--	--
Implement Targeted Risk-Adjustment Pre-Payment Review in Medicare Advantage	--	--	--
Require Prior Authorization When Physicians Order Certain Services Excessively Relative to Their Peers	*	*	*
Medicaid			
Strengthen CMS's Ability to Recoup Medicaid Improper Payments	--	-2,060	-5,410
Enact Financial Penalties for States that are not Complying with Provider Screening, Enrollment, and Revalidation Requirements	*	*	*
Strengthen CMS's Ability to Recover Medicaid and CHIP Overpayments Resulting from Noncompliance with Provider Screening and Enrollment Requirements	*	*	*
Enhancing Provider and Program Oversight			
Medicare			
Prevent Fraud by Applying Penalties on Providers and Suppliers who Fail to Update Enrollment Records	-2	-13	-32
Ensure Providers that Violate Medicare's Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Program	--	--	--
Expand the Provisional Period of Enhanced Oversight Statutory Authority for New Providers and Suppliers to Further Stem Fraud, Waste, and Abuse	*	*	*
Extend Beneficiary Protection for Provider's Failure to Meet Procedural or Other Requirements	*	*	*
Reform Medicare Practitioner Opt-Out	*	*	*
Require Reporting on Clearinghouses and Billing Agents when Medicare Providers and Suppliers Enroll in the Program	--	--	--
Medicaid			
Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments	-900	-4,930	-11,140
Consolidate Provider Enrollment Screening for Medicaid and CHIP	--	--	--
Streamline the Medicaid Terminations Process	--	--	--
Cross-cutting			
Require Annual Certification of National Provider Identifier	--	--	--
Require Physician Owned Distributors to Report in Open Payments	--	--	--
Extend Flexibility in Annual Open Payments Reporting Deadline	--	--	--
Supporting Oversight, Law Enforcement, and Fraud Reduction			
Medicare			

FY 2021 Program Integrity Budget Proposals

dollars in millions	2021	2021 -2025	2021 2030
Require Providers and Suppliers to Produce Part B Records to Support Part D Investigations or Audits	--	--	--
Medicaid			
Address Patient Abuse or Neglect in Non-Institutional Settings/1	-5	-27	-63
Cross-cutting			
Clarify Authority for the Healthcare Fraud Prevention Partnership	--	--	--
Improve Effectiveness of HHS Program Integrity Efforts			
Medicare			
Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor	-20	-100	-200
Improve Efficiency and Strengthen Program Integrity Efforts in Medicare Parts C and D	--	--	--
Medicaid			
Allow States to Partner with the Treasury Offset Program to Recover Medicaid and CHIP Debts	-75	-424	-988
Make the Medicaid Recovery Audit Contractor Program Optional for States	--	--	--
Subtotal Outlays, Program Integrity Legislative Proposals	**-1,727**	**-11,517**	**-31,430**
Subtotal, Medicare Impact	-752	-4,103	-13,892
Subtotal, Medicaid Impact	-975	-7,414	-17,538
Program Integrity Administrative Proposals			
Improving Payment Accuracy			
Medicare			
Address Excessive Billing for Durable Medical Equipment that Require Refills on Serial Claims	**--**	**--**	**--**
Address Improper Payments of Chiropractic Services through Targeted Medical Review	--	--	--
Reduce Utilization of Low-Value Health Services through Prior Authorization Demonstrations	--	--	--
Medicaid			
Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility	--	-80	-220
Subtotal, Program Integrity Administrative Proposals	**--**	**-80**	**-220**
Subtotal, Medicare Impact	--	--	--
Subtotal, Medicaid Impact	--	-80	-220
Non-PAYGO Savings/2			
Savings from Address Patient Abuse or Neglect in Non-Institutional Settings/1	-5	-27	-63
Savings from Social Security Program Integrity Investment	-279	-3,639	-14,624
Subtotal, Medicare and Medicaid Savings from Program Integrity Investment	**-284**	**-3,666**	**-14,687**

*Budget impact not available at the time of publication

1/ This proposal results in $63 million in non-PAYGO savings over 10 years. The Budget totals include this in PAYGO savings and will be corrected in Mid-Session Review.

2/ Includes non-PAYGO savings from increased program integrity investments in Medicaid Fraud Control Units and in Social Security disability reviews above savings assumed in current law.

Medicaid

	dollars in millions /2			2021 +/- 2020
	2019 /3	2020	2021	
Current Law				
Benefits /1	386,331	424,901	428,609	+3,708
State Administration	23,090	22,340	23,169	+829
Total Net Outlays, Current Law	**409,421**	**447,241**	**451,778**	**+4,537**
Proposed Law				
Legislative Proposals /4	--	--	-3,633	-3,633
Total Net Outlays, Proposed Law	**409,421**	**447,241**	**448,145**	**904**

1/ Includes outlays from the Vaccines for Children Program, administered by the Centers for Disease Control and Prevention. Also reflects administrative proposal outlay impacts assumed in the baseline.
2/ Totals may not add due to rounding.
3/ The Fiscal Year (FY) 2019 column reflects the initial levels (post Unaccompanied Alien Children transfer, disaster supplemental, and others).
4/ Legislative Proposals numbers include non-PAYGO savings from the proposal "Address Patient Abuse or Neglect in Non-Institutional Settings", which is described in the Program Integrity chapter.

Medicaid provides medical assistance to millions of low-income and disabled Americans. In FY 2020, nearly 74 million people on average in any given month received healthcare coverage through Medicaid. CMS predicts that enrollment will increase in the future due to factors such as population growth. Without reforms, CMS's Office of the Actuary estimates total federal and state Medicaid benefit spending will reach nearly $1.2 trillion by FY 2030, comprising 3.3 percent of United States gross domestic product.

CMS continues to usher in a new era of state flexibility in Medicaid program administration. CMS's vision is to reset and restore the federal-state relationship, while modernizing Medicaid to deliver better outcomes for the people it serves. Fostering state innovation and pairing it with enhanced accountability and integrity improves program sustainability for the long term. This commitment will help states achieve the flexibility they need to promote the health and well-being of their most vulnerable citizens and help them rise out of poverty.

HOW MEDICAID WORKS

States design, implement, and administer their own Medicaid programs based on federal guidelines. The federal government matches state expenditures using the Federal Medical Assistance Percentage (FMAP), which is based on state per capita income compared to the national average, and can be no lower than 50 percent. In FY 2020, the federal share of Medicaid outlays will be approximately $447 billion.

Medicaid beneficiaries include children; pregnant women; adults in families with dependent children; and the aged, blind, and/or disabled. Individuals must meet certain minimum categorical and financial eligibility standards. States have flexibility to extend coverage to higher income groups, including medically needy individuals, through waivers and amended state plans. Medically needy individuals do not meet the income standards of the above mentioned categorical eligibility groups but incur large medical expenses and would otherwise qualify for Medicaid.

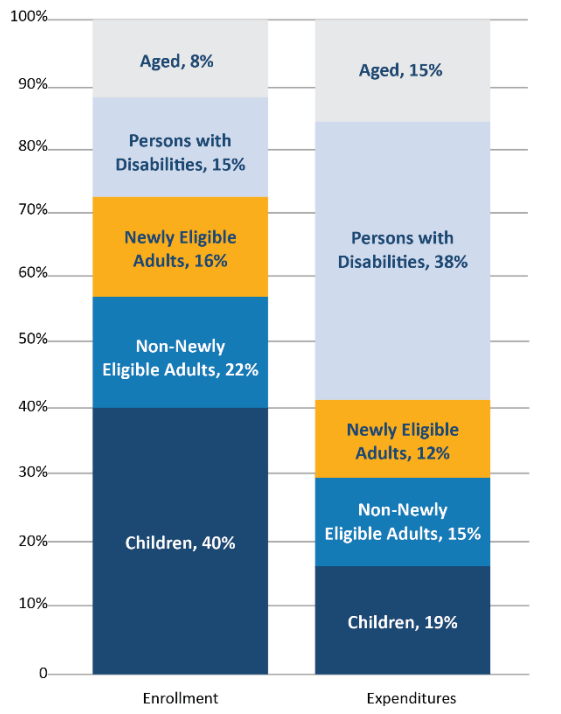
Under Medicaid, states must cover certain medical services and have the flexibility to offer additional benefits to beneficiaries. Medicaid covers most of the costs of providing long-term care services for beneficiaries.

ADMINISTRATION ACTIONS TO TRANSFORM MEDICAID

The key to building a better health system, and the President's promise, is to protect what works in our system and fix what is broken. The Administration's strategy to deliver this vision in Medicaid is to:

- Facilitate patient-centered markets by reforming how healthcare is financed and deriving better value from that care;

IN FY 2017, CHILDREN COMPRISED 40% OF TOTAL MEDICAID ENROLLMENT AND PERSONS WITH DISABILITIES COMPRISED 38% OF MEDICAID EXPENDITURES



Source: CMS Office of the Actuary
Note: Totals and components exclude Disproportionate Share Hospital expenditures, territorial enrollees and expenditures, and financial adjustments.
Note: Percentages may not add to 100% due to rounding.

- Protect life and lives by addressing impactable health challenges like maternal health and the opioid and methamphetamine crisis; and
- Promote independence by strengthening efforts to treat serious mental illness.

CMS is improving the Medicaid program in these areas to protect and improve the lives of Medicaid beneficiaries.

FACILITATE PATIENT-CENTERED MARKETS

CMS has already taken steps to ensure the program's financial health for future generations and preserve the safety net for those who truly need it. The following actions taken to date support the Administration's vision of patient-centered markets that bring value to healthcare, put Medicaid on a sustainable fiscal path, lower drug prices, and remove regulatory burdens.

Making Medicaid Fiscally Sustainable

On September 23, 2019, HHS finalized the Disproportionate Share Hospital (DSH) Health Reform Methodology, as required by statute, to implement annual DSH allotment reductions. In anticipation of lower uninsured rates and lower levels of hospital uncompensated care, the Patient Protection and Affordable Care Act (ACA) reduced Medicaid funding to hospitals that serve a disproportionate share of uninsured, low-income patients. The statute reduces state allotments by $44 billion for FY 2020 through FY 2025, increasing the fiscal sustainability of the program. However, the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) delays DSH reductions until May 23, 2020.

On August 22, 2018, CMS released guidance on budget neutrality for Medicaid demonstration projects authorized under Section 1115(a) of the Social Security Act. The guidance outlines CMS's budget neutrality policy for demonstration projects to strengthen fiscal accountability and prevent excessive federal expenditures under Section 1115 demonstrations.

Lowering Drug Prices

In alignment with President Trump and Secretary Azar's Blueprint to Lower Drugs Prices and Reduce Out-of-Pocket Costs, CMS approved seven states' value based supplemental rebate agreements that link payments of drugs to the drugs' effectiveness and outcomes for beneficiaries.

Additionally, the President recently signed into law two Administration FY 2020 Budget proposals. One excludes authorized generic drug sales from the calculation of the brand drug's average manufacturer price under the Medicaid program in order to prevent manufacturers from paying inappropriately low drug rebates to the Medicaid program. The other imposes greater penalties for manufacturers who knowingly misclassify drugs.

Removing Regulatory Burdens

On November 8, 2018, CMS published a proposed rule on Medicaid and the Children's Health Insurance Program (CHIP) managed care that seeks to further streamline the Medicaid and CHIP managed care regulations by reducing unnecessary and duplicative administrative burden. This proposed rule also seeks to further reduce federal regulatory barriers to help ensure state Medicaid and CHIP agencies are able to work efficiently and effectively to design, develop, and

implement Medicaid and CHIP managed care programs that best meet each state's local needs and populations. Specifically, the proposed rule aims to promote flexibility, strengthen accountability, and maintain and enhance program integrity.

PROTECT LIFE AND LIVES

HHS is giving state Medicaid programs the flexibility they need to advance interventions that protect the lives of beneficiaries by addressing impactable health challenges like the opioid and methamphetamine crisis, maternal health, and rural health.

Combating the Opioid and Methamphetamine Crisis

In November 2017, CMS published a State Medicaid Director (SMD) letter to extend a Section 1115 demonstration opportunity for states to receive federal financial participation for the continuum of services to treat addiction to opioids, meth, and other substances, including services in residential treatment facilities such as Institutions for Mental Diseases (IMD). Since the SMD letter, CMS has approved 22 demonstrations to address substance use disorder under Section 1115 waiver authority.

Currently, while pregnant and postpartum women may have access to various clinical services and social and community supports, those with a substance use disorder often face challenges accessing medication-assisted treatment and recovery supports like housing. The Center for Medicare and Medicaid Innovation's (Innovation Center) Maternal Opioid Misuse model encourages state Medicaid agencies, front-line providers, and healthcare systems to coordinate clinical care and integrate support services for pregnant and postpartum women with opioid use disorder and their infants.

Improving Maternal Health

Medicaid pays for nearly half of all births, with deliveries and newborn care accounting for 25 percent of total Medicaid inpatient spending. CMS is developing ways to amplify the existing solutions that show success and exploring every lever to improve maternal health outcomes.

Medicaid coverage for women after birth is limited to at least 60 days postpartum depending on a state's Medicaid plan. In December 2019, CMS approved a targeted eligibility expansion for pregnant women with a substance use disorder (SUD) diagnosis in South Carolina. States have implemented other initiatives to improve maternal health outcomes, including using evidence-based models to support the health of pregnant and postpartum women and mothers of young children. As of January 2020, CMS approved 10 waivers that include a family planning component, which expands access to family planning and related services for pregnant women.

APPROVED SUBSTANCE USE DISORDER SECTION 1115 DEMONSTRATIONS

State	Approval Date
Washington, D.C.	11/6/2019
Ohio	9/24/2019
Delaware	7/31/2019
Minnesota	6/28/2019
Nebraska	6/28/2019
Michigan	4/5/2019
Rhode Island	12/20/2018
Kansas	12/18/2018
New Mexico	12/14/2018
Alaska	11/21/2018
Wisconsin	10/31/2018
North Carolina	10/19/2018
Washington	7/17/2018
New Hampshire	7/10/2018
Pennsylvania	6/28/2018
Vermont	6/6/2018
Illinois	5/7/2018
Louisiana	2/1/2018
Indiana	2/1/2018
Kentucky	1/12/2018
New Jersey	10/31/2017
Utah	10/31/2017

*CMS approved West Virginia, Maryland, Virginia, Massachusetts, and California before November 2017

PROMOTE INDEPENDENCE

The President believes we have an obligation to give every American a shot at the American Dream, and to do that we must promote independence. This vision includes supporting older Americans and those with disabilities, who deserve the right to be able to live and receive care in their homes or communities rather than an institutional setting.

Treating Serious Mental Illness

In 2018, 47.6 million adults had a mental illness, of whom 11.3 million suffered from Serious Mental Illness (SMI), meaning their mental illness substantially interfered with or limited major life activities. More than one out of every three individuals with SMI does not receive mental healthcare and those that receive care encounter an often fragmented mental health system that is often fragmented. The Budget promotes methods of delivering care that improve outcomes for individuals with SMI. Finding ways to provide care for these individuals in the correct modalities is crucial to better outcomes and the most efficient use of federal and state dollars.

In November 2018, as required by the 21st Century Cures Act of 2016 (P.L. 114-255), CMS published a State Medicaid Director letter discussing strategies under existing authorities and new opportunities for states to implement innovative service delivery system reforms for adults with serious mental illness and children with serious emotional disturbance. These innovative reforms include improving availability of behavioral health screenings and mental health and substance use disorder services in schools to identify and engage children with serious emotional disturbance sooner. The letter also announced a Medicaid Section 1115 demonstration opportunity for states to receive federal financial support for treating Medicaid beneficiaries with these conditions during short-term acute care stays in psychiatric hospitals or in residential treatment facilities that qualify as an IMD. As of the end of FY 2019, CMS has approved these demonstrations in three states.

Requiring Community Engagement

In January 2018, the Administration announced its intention to test community engagement requirements through approval of Medicaid Section 1115 demonstrations. These demonstrations promote work or community engagement activities (e.g. volunteering, educational activities, and job training) for working-age, able-bodied adults to promote improved health and well-being, and empower beneficiaries to rise out of poverty.

To date, CMS has approved 11 community engagement programs and is actively reviewing an additional 9 proposals that link working-age, non-disabled adult beneficiaries with community, educational, and job opportunities. Well-designed community engagement incentives have great potential to promote better mental, physical, and emotional health, and target certain health determinants that may improve health outcomes.

2021 LEGISLATIVE PROPOSALS

The FY 2021 President's Budget (Budget) puts Medicaid on a path to fiscal sustainability by transforming Medicaid financing and reducing waste while still maintaining a healthcare safety net for those who need it. In total, the Budget includes net savings to Medicaid of $920 billion over 10 years. Proposals address impactable health challenges, such as the opioids and methamphetamine crisis, maternal health, and rural health. The Budget promotes independence by strengthening efforts to treat serious mental illness and through community engagement. As part of the President's Health Reform Vision, Medicaid spending will grow at a more sustainable rate by ending the financial bias that currently favors able-bodied working adults over the truly vulnerable and by permitting states to select between a per capita cap or a block grant. [See the CMS Overview chapter for more information]

FACILITATE PATIENT-CENTERED MARKETS

Making Medicaid Fiscally Sustainable

The Medicaid program has grown tremendously over recent years. Its open-ended financing structure makes it the number one or number two state budget item, consuming an average of 30 percent of total state budgets. The following proposals reflect HHS's commitment to protecting the fiscal health of Medicaid and ensuring it remains a safety net for generations to come.

Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations

Asset tests allow states to prioritize receipt of Medicaid for lower-income individuals by screening for assets

and resources, such as savings accounts or vehicles. The ACA's Modified Adjusted Gross Income (MAGI) eligibility rules eliminated asset tests for most children and able-bodied adults, leaving asset tests only for aged, blind, and disabled Medicaid beneficiaries. This proposal provides states the option to apply asset tests to populations determined financially eligible by the MAGI standard, such as able-bodied adults, so states can refocus Medicaid on the truly needy. This proposal also provides states with the option to apply asset tests to individuals eligible through the MAGI standard who are receiving long-term care. [$2.2 billion in savings over 10 years]

Clarify Medicaid Treatment of Third Party Payments for Disproportionate Share Hospital (DSH) Allotments

Medicaid regulations require states to include all third party payments for Medicaid beneficiaries when calculating uncompensated care costs under the Medicaid DSH limits. Some hospitals continue to receive duplicate uncompensated care payments from other payers, such as private insurance or Medicare. This proposal would codify existing regulations to remove ambiguity for states and hospitals. This strengthens CMS's ability to enforce existing federal regulations and prevent hospitals from being paid twice for the same care episode. [Budget Neutral]

Continue Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions

Current law reduces Medicaid DSH allotments between May 23, 2020 and FY 2025 to account for decreases in uncompensated care. This proposal continues the reduction through 2030, saving an additional $32.4 billion and increasing the fiscal sustainability of the program. [$32.4 billion in savings over 10 years]

Increase Limit on Medicaid Copayments for Non-Emergency Use of Emergency Department

State flexibility to charge copayments above the nominal statutory amounts for non-emergency use of the emergency department is limited to Section 1115 waiver requests, a burdensome and time-consuming process. The Budget proposes to provide states the option to use state plan authority to increase these copayments to encourage personal financial responsibility and proper use of healthcare resources. By providing state plan authority, states would have the option to charge higher copays for non-emergency use of the emergency department consistent with approvals to date under Section 1115. [$1.8 billion in savings over 10 years]

Prohibit Medicaid Payments to Public Providers in Excess of Costs

Medicaid payments for healthcare services are limited to what Medicare would have paid for the same service (referred to as the Upper Payment Limit), which in some cases may exceed a public provider's actual cost of providing care to Medicaid patients. This proposal limits Medicaid reimbursement for healthcare providers operated by a governmental entity to an amount not exceeding the actual cost of providing those services. This prevents states from using supplemental payments to public providers to circumvent Medicaid matching requirements. [Budget impact not available]

Require Documentation of Satisfactory Immigration Status before Receipt of Medicaid Benefits

Under current law, States must enroll individuals who claim they have, but cannot immediately provide documentation of citizenship or satisfactory immigration status. After a period, individuals must submit evidence of citizenship or satisfactory immigration status to maintain enrollment. This proposal requires individuals to prove Medicaid eligibility before receiving coverage. States may still elect to provide coverage during a reasonable opportunity period, but this proposal prohibits federal payments for medical assistance during this period. [$2.6 billion in savings over 10 years]

Reduce Maximum Allowable Home Equity for Medicaid Eligibility

Some states have set home equity limits so high, individuals with the means to pay for their own long-term care qualify for Medicaid payment for that care, transferring what should be an individual or family responsibility to taxpayers. This proposal removes states' authority to substitute a higher home equity limit than the statutory minimum which focuses long-term care coverage on lower-income individuals without significant assets that could liquidated to cover long-term care. [$34.3 billion in savings over 10 years]

Removing Regulatory Burdens

The following proposals reflect HHS's commitment to a Medicaid program that ensures state flexibility and simpler processes for states.

Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers

Many states have waivers for Medicaid managed care programs, yet they must submit paperwork for re-approval every 5 years for programs with dual-eligible individuals and every 2 years for all other Medicaid eligibility groups. This proposal eliminates the current 5-year time limit for Section 1915(b) waivers to give the Secretary flexibility to determine the appropriate approval timeframe for all Medicaid managed care enrolled populations, reducing unnecessary administrative burden for both CMS and states. [Budget Neutral]

Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers

States are required to submit unnecessary paperwork to renew managed care waivers that have been in place for years. This proposal reduces burdensome federal reviews by allowing states to grandfather managed care authorities in waivers and demonstration programs under their state plans if there are no substantive changes and the state renewed the waiver at least once. [Budget Neutral]

Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals

States may be forced to adjudicate duplicative appeals at the state Medicaid agency when another entity has already adjudicated the same case. This proposal reduces the burden on states by allowing them to meet the Medicaid fair hearing requirements for cases adjudicated by Exchange Appeal Entities or by HHS. Specifically, state Medicaid agencies would still provide the opportunity for a fair hearing, but state Medicaid agencies would be free to substitute a fair hearing before another state agency or HHS. [Budget Neutral]

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

On average, 130 Americans die each day of opioid-related drug overdoses. HHS is committed to ending the crisis of substance use disorder and overdose in America, and the following proposals reflect the Administration's commitment to improving addiction services for Medicaid beneficiaries.

Prohibit States from Terminating CHIP Coverage for Inmates

This proposal aligns Children's Health Insurance Program (CHIP) policies with existing Medicaid policies under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271) to suspend, rather than terminate, coverage for youth inmates of criminal institutions. (See the CHIP chapter for a full proposal description). [Budget Neutral]

Prohibit States from Terminating Medicaid Coverage for Inmates for Six Months

Many incarcerated individuals have a high prevalence of untreated, chronic healthcare conditions and substance use and mental health disorders. This proposal would prohibit states from terminating Medicaid coverage for the first six months of incarceration, complementing the SUPPORT for Patients and Communities Act. States would be required to suspend coverage for the first six months that the inmate is in custody, after which states may continue with the suspension or terminate coverage. If the state chooses to terminate coverage, it would be required to establish a process to re-enroll beneficiaries upon release. Facilitating enrollment in Medicaid and supporting access to services following incarceration has the potential to improve the health and ability to obtain health services for this population. Such enrollment will also help individuals with disabilities obtain critical community services to avoid crises and recidivism. [Budget Neutral]

Improving Maternal Health

The U.S. has the highest maternal mortality rate in the developed world, which disproportionately impacts low-income and minority communities. The following proposals contribute to the Administration's existing efforts by promoting adoption of best practices and addressing preventable risks.

Allow States to Extend Medicaid Coverage for Pregnant Women with Substance Use Disorders to One Year Postpartum

Substance use is strongly associated with significant adverse health impacts for both mothers and infants. Opioid use during pregnancy and incidents of neonatal abstinence syndrome have increased dramatically in recent years. This proposal would make it easier for states to provide full Medicaid benefits for one year postpartum for pregnant women diagnosed with a

substance use disorder. [$205 million in costs over 10 years]

PROMOTE INDEPENDENCE

Treating Serious Mental Illness

Americans with serious mental illness (SMI) too often end up homeless or in our prisons, when access to treatment could help them lead healthy lives. Medicaid is the largest payer for mental health services nationally and the Budget makes it a priority to expand access to evidence-based treatment for SMI. The following proposals align with the Administration's priority by improving Medicaid coverage and access to mental health services for beneficiaries with SMI and beneficiaries in foster care.

Modify the Institutions for Mental Diseases (IMD) Exclusion

In 2018, 4.6 percent of adults, or 11.4 million adults, were affected by SMI. To ensure access to care and effective treatment for this population, states have the option of receiving Medicaid reimbursement for covered services provided to adult beneficiaries with SMI aged 21-64 residing in IMDs. Under this option, states must meet certain criteria and requirements prior to receiving federal funding. [$5.4 billion in costs over 10 years]

Exempt Qualified Residential Treatment Programs from Medicaid IMD Payment Exclusion

The Family First Prevention Services Act (P.L. 115-123) allows title IV-E funding for placements in group foster care programs that provide treatment for serious emotional or behavioral conditions and meet certain quality standards, referred to as qualified residential treatment programs (QRTPs). However, on- and off-site services provided to foster children while residing in QRTPs may not be covered by Medicaid if those QRTPs qualify as IMDs under current law. In collaboration with the Administration for Children and Families, the Budget proposes a legislative fix to make QRTPs exempt from the IMD payment exclusion allowing children in IV-E foster care through age 18 or 21, depending on state law, to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD (see also the Administration for Children and Families Mandatory chapter). This change will not add costs to the Foster Care and Permanency Program. [$500 million in costs over 10 years]

Extend Community Mental Health Services Demonstration Program

On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), which extended this Medicaid demonstration until May 22, 2020. It provides enhanced federal medical assistance percentage (FMAP) to support states in improving the availability and quality of community-based, comprehensive treatment and recovery support services to individuals living with mental illness and SUD. Beginning in FY 2016, HHS awarded a total of $22.9 million in planning grants to support 24 states in planning to participate in the demonstration. In FY 2017, HHS selected eight states to participate in this demonstration program to provide community-based mental health and SUD treatment. Certified Community Behavioral Health Clinics (CCBHCs) provide a comprehensive, coordinated range of evidence-based behavioral health services certified by the state to meet six key aspects of improved care: staffing, organization authority, care coordination, scope of services, quality and other reports, and availability and accessibility of services. Under the demonstration, certified clinics may receive Medicaid payment through a daily or monthly prospective payment system rate that is clinic-specific and reimburses the expected cost of demonstration services. The Budget proposes to extend this demonstration for the current eight participating states through FY 2021. (See also the State Grants and Demonstrations chapter for a proposal description) [$906 million in costs over 10 years]

Incentivizing Community Engagement in Medicaid

Employment is tied to improved long-term health outcomes, and community engagement requirements promote employment for able-bodied Medicaid beneficiaries. The following proposal reflects the Administration's commitment to emphasize engagement as a key component of the Medicaid program.

Implement Medicaid Community Engagement Requirements

Traditionally, Medicaid enrollees have not been required to participate in community engagement activities to maintain Medicaid eligibility, unlike requirements in Temporary Assistance for Needy Families (TANF) and the Supplemental Nutrition Assistance Program (SNAP). The Budget improves consistency between requirements in federally-funded

public assistance programs, including Medicaid, TANF, and SNAP, by requiring able-bodied, working-age individuals to find employment, train for work, or volunteer (community service) to receive benefits. This would enhance service coordination for program participants and improve the financial well-being of those receiving assistance. [$152.4 billion in savings over 10 years]

Supporting Older Americans and Those with Disabilities Living in Their Homes or Communities and Those Who Are Dual-Eligibles

Home and community based services are cost-effective and enable beneficiaries to receive care in a home-based setting. The following proposals reflect the Administration's commitment to promoting independence through home and community based services.

Create New Money follows the Person (MFP) State Plan Option

In recent years, uncertainty about future availability of federal funding created challenges for states to budget for and carryout related activities under the MFP demonstration. The Budget gives states the option to establish an MFP program under the state plan with a time limited enhanced federal match for those activities. States that spent less than 50 percent of their long-term service and supports funding on home and community based services in the prior year would receive an enhanced match for the first five years they provide MFP services. (See the State Grants and Demonstrations chapter for a proposal description) [$91 million in savings over 10 years]

Allow CMS Flexibility to Determine the Frequency of PACE Program Audits

Current law requires a comprehensive review of a new Program of All-inclusive Care for the Elderly (PACE) organization's operations annually during the 3-year trial period, including on-site visits, and additional reviews as needed, after the trial period. This proposal provides flexibility to conduct one comprehensive review of a new PACE organization during the first year of the three year trial period, barring no significant noncompliance issues in the first year audit. It then allows for additional reviews in any year after the first year of the trial period on an as-needed basis. These flexibilities would decrease the large administrative and financial burdens on PACE organizations, CMS, and state administering agencies that participate in the PACE program reviews. [Budget Neutral]

Clarify PACE Organizations' Coverage of Inpatient Hospital Stays

When a PACE participant unenrolls during an inpatient stay and changes payer sources, the law fails to designate whether the PACE organization or a different payer is responsible for covering the entire inpatient stay through the discharge date. This issue has long created disputes regarding payment responsibilities. The Budget makes PACE organizations financially responsible for payment for services provided to a PACE participant during any inpatient hospital stay until the date of the participant's discharge, including for participants that unenroll from PACE during their hospital stay. This ensures a more seamless transition from PACE into other types of Medicare and Medicaid coverage, in addition to eliminating payment disputes, providing beneficiary protections, and reducing the administrative burden associated with appealing unpaid claims in an effort to resolve those disputes. [Budget Neutral]

Allow for Federal/State Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials

Marketing materials for Dual Eligible Special Needs Plans go through separate state and CMS review processes. This proposal allows for joint state and CMS review, which enhances a uniform message to beneficiaries. Providing CMS the ability to coordinate reviews with states based on a single submission of these marketing materials can improve the quality of products available to beneficiaries, while reducing the burden on health plans, states, and CMS. [Budget Neutral]

Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries

The Social Security Act requires CMS to maintain a continuous (monthly) Special Enrollment Period for full-benefit dually eligible beneficiaries to make changes to their Medicare Advantage and Medicare prescription drug coverage outside of the annual enrollment period. This has created unintended consequences, including aggressive targeting of dually eligible beneficiaries by enrollment agents, and decreased incentives for plans to invest in care coordination for this population. This proposal allows CMS to apply the same annual election process for both dually eligible and non-dually eligible beneficiaries, while preserving the ability for

full-benefit dually eligible beneficiaries to opt into integrated care programs or change plans following auto-assignment into a Part D plan. The proposal protects beneficiaries from aggressive marketing, improves incentives to invest in care coordination for high-cost, often vulnerable beneficiaries, and reduces the administrative burden on health plans from beneficiary fluctuations between plans. [No budget impact to Medicaid, $230 million in Medicare savings over 10 years]

2021 ADMINISTRATIVE PROPOSALS

The Budget also includes six Medicaid administrative proposals, saving an estimated $23.9 billion over 10 years. These proposals support the Administration's priorities for Medicaid and do not require Congressional action.

FACILITATE PATIENT-CENTERED MARKETS

Making Medicaid Fiscally Sustainable

Strengthen Medicaid Eligibility Process Program Integrity

Current regulations prohibit states from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on financial criteria. CMS will soon release the Proposed Rule "Strengthening the Program Integrity of the Medicaid Eligibility Determination Process" (CMS-2421-P) for public comment that will allow states the option to conduct more frequent eligibility redeterminations, amongst other reforms to improve the integrity of state eligibility determination and renewal processes.

Improve Transparency and Accountability of Medicaid Financing and Supplemental Payments

CMS does not currently have comprehensive provider-level data on Medicaid supplemental payments and state financing for those payments. Furthermore, in recent years some units of government, including states and localities, have acquired ownership of privately operated medical facilities. These newly public healthcare providers generate state and local Medicaid matching payments, while being held harmless for these donations by states through increased Medicaid supplemental payments. To improve the transparency and oversight of Medicaid supplemental payments and financing, the Budget supports finalization of a regulation requiring more complete and timely provider-level data on supplemental payments and clarifying financing terms to prevent gaming by government entities and private providers that transfer ownership from private to public for the sole purpose of maximizing Federal match. This approach provides CMS more data to assess whether state payments to Medicaid providers are economical, efficient, and fall within the Upper Payment Limit, as well as prevent states from inappropriately generating state share.

Reduce the Federal Match Rate for Medicaid Eligibility Workers

Medicaid regulations and related sub-regulatory guidance implementing the ACA increased the federal match rate for Medicaid eligibility workers to 75 percent by linking these costs to state system operation. This proposal phases down this match rate to 50 percent by FY 2024. This change will return federal reimbursement to historic levels and incentivize states to administer their Medicaid programs in a more efficient and fiscally responsible way.

Removing Regulatory Burdens

Make Medicaid Non-Emergency Medical Transportation Optional

Under current regulations, states must provide Non-Emergency Medical Transportation to all Medicaid beneficiaries. States requested additional flexibility from this requirement due to challenges containing these costs and addressing program integrity concerns. The Budget commits to using regulatory authority to change the provision of this benefit from mandatory to optional to provide greater flexibility to states.

PROTECT LIFE AND LIVES

Combating the Opioid and Methamphetamine Crisis

Require Minimum Standards in Medicaid State Drug Utilization Review Programs

The Medicaid statute requires each state to develop a Drug Utilization Review program to reduce clinical drug abuse and misuse, including opioids. CMS currently does not set minimum requirements for these programs, and there is substantial variation in state approaches. Under this proposal, HHS will set minimum standards for Drug Utilization Review programs, increasing oversight of opioid prescriptions and dispensing in Medicaid.

Improving Maternal Health

Improve Maternal Health Outcomes in Medicaid

Maternal morbidity and mortality is significantly higher in the United States than other developed nations. This proposal aims to work with state Medicaid programs to test interventions to reduce maternal mortality and morbidity.

FY 2021 Medicaid Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Medicaid Legislative Proposals			
Facilitate Patient-Centered Markets			
Making Medicaid Fiscally Sustainable			
Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations	-50	-830	-2,200
Clarify Medicaid Treatment of Third Party Payments for Disproportionate Share Hospital Allotments	--	--	--
Continue Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions	--	--	-32,360
Increase Limit on Medicaid Copayments for Non-Emergency Use of Emergency Department	-60	-600	-1,840
Prohibit Medicaid Payments to Public Providers in Excess of Costs	*	*	*
Require Documentation of Satisfactory Immigration Status Before Receipt of Medicaid Benefits	-210	-1,150	-2,610
Reduce Maximum Allowable Home Equity for Medicaid Eligibility	--	-12,950	-34,250
Removing Regulatory Burdens			
Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers	--	--	--
Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers	--	--	--
Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals	--	--	--
Protect Life and Lives			
Combating the Opioid and Methamphetamine Crisis			
Prohibit States from Terminating CHIP Coverage for Inmates	--	--	--
Prohibit States from Terminating Medicaid Coverage for Inmates for Six Months	--	--	--
Improving Maternal Health			
Allow States to Extend Coverage for Pregnant Women with Substance Use Disorders to One Year Postpartum	25	105	205
Promote Independence			
Treating Serious Mental Illness			
Exempt Qualified Residential Treatment Programs from Medicaid IMD Payment Exclusion	5	110	500
Modify the Institutions for Mental Diseases Exclusion	200	2,100	5,400
Extend Community Mental Health Services Demonstration Program	906	906	906
Incentivizing Community Engagement in Medicaid			
Implement Medicaid Community Engagement Requirement	-8,000	-62,900	-152,400
Supporting Older Americans and Those with Disabilities			
Create New Money Follows the Person (MFP) State Plan Option	--	174	-91
Allow CMS Flexibility to Determine the Frequency of PACE Program Audits	--	--	--
Clarify PACE Organizations Coverage of Inpatient Hospital Stays	--	--	--

FY 2021 Medicaid Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030
Allow for Federal/State Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials	--	--	--
Legislative Proposals in Other Chapters Impacting Medicaid			
Expand Access to the National Directory of New Hires /1	--	--	--
President's Health Reform Vision Allowance (Medicaid Impact)	--	-204,000	-744,000
Reform Graduate Medical Education Payments (Medicaid Impact) /2	-1,700	-9,570	-22,420
Reform Medical Liability (Medicaid Impact) /2 /3	-52	-52	-52
Reduce Fraud, Waste, Abuse, and Improper Payments (Medicaid Impact) /4	-975	-7,414	-17,538
Non-PAYGO savings from Address Patient Abuse or Neglect in Non-Institutional Settings /4	-5	-27	-63
Reform and Expand Durable Medical Equipment Competitive Bidding (Medicaid Impact) /5	--	-85	-435
Use Retail Price Information for Durable Medical Equipment Fee Schedule Rates (Medicaid Impact) /5	-5	-35	-85
Extend Special Immigrant Visa Program (Medicaid Impact) /6	9	84	161
Extend Reduced Pension for Certain Veterans and Survivors Covered by Medicaid Plans (Medicaid Impact) /7	--	--	341
Subtotal Gross Outlays, Medicaid Legislative Proposals	-9,913	-296,134	-1,002,831
Net Effect of All Medicaid Interactions /8	6,280	39,294	83,287
Subtotal Net Outlays, Medicaid Legislative Proposals	-3,633	-256,840	-919,543
Medicaid Administrative Proposals			
Facilitate Patient-Centered Markets			
Making Medicaid Fiscally Sustainable			
Address Medicaid Program Integrity and Wasteful Spending	-710	-9,150	-21,350
Improve Transparency and Accountability of Medicaid Financing and Supplemental Payments	--	--	--
Reduce the Federal Match Rate for Medicaid Eligibility Workers	--	-1,270	-6,348
Removing Regulatory Burdens			
Make Medicaid Non-Emergency Medical Transportation Optional	--	--	--
Protect Life and Lives			
Combating the Opioid and Methamphetamine Crisis			
Require Minimum Standards in Medicaid State Drug Utilization Review Programs	-15	-90	-205
Improving Maternal Health			
Improve Maternal Health Outcomes in Medicaid	--	--	--
Administrative Proposal Interactions			
Program Integrity Administrative Proposal (Medicaid Impact) /4	--	-80	-220
Subtotal, Medicaid Administrative Proposal Interactions /9	-725	-10,590	-28,123

*Budget impact not available at the time of publishing

1/ See ACF chapter for a description of this proposal.

2/ See the CMS Overview chapter for a description of this proposal.

3/ Savings reduced to account for the interaction with the President's Health Reform Vision Allowance.

4/ See Program Integrity chapter for descriptions of these proposals. Legislative Proposals numbers include non-PAYGO savings from the program integrity proposal "Address Patient Abuse or Neglect in Non-Institutional Settings".

FY 2021 Medicaid Budget Proposals

dollars in millions	2021	2021 -2025	2021 -2030

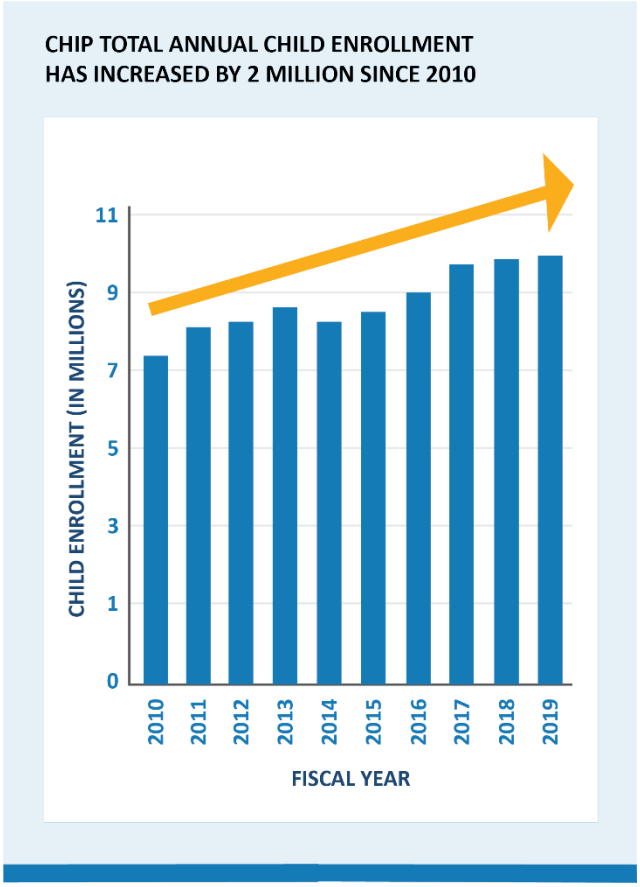
5/ See Medicare chapter for descriptions of these proposals.
6/ This proposal is included in the Department of State's FY 2021 Budget Request.
7/ This proposal is included in the Department of Veterans Affairs FY 2021 Budget Request.
8/ The gross Medicaid savings from all proposals in this package would be reduced when enacted in conjunction with other proposals. As such, due to these interactions, the net Medicaid savings proposed in the Budget is a subset of gross savings and is non-additive.
9/ These administrative actions are assumed to take effect in FY 2021 under current law.

Children's Health Insurance Program

	dollars in millions			2021 +/- 2020
	2019	2020	2021	
Current Law				
Children's Health Insurance Program	17,689	17,654	15,778	-1,876
Child Enrollment Contingency Fund	3	310	0	-310
Total Outlays, Current Law	**17,692**	**17,964**	**15,778**	**-2,186**
Proposed Law				
Children's Health Insurance Program Legislative Proposals	--	--	0	0
Total Outlays, Proposed Law	**17,692**	**17,964**	**15,778**	**-2,186**

BACKGROUND

Established by the Balanced Budget Act of 1997, the Children's Health Insurance Program (CHIP) provides health insurance coverage for children in households with incomes too high to qualify for Medicaid but too low to afford private health insurance. In Fiscal Year (FY) 2019, the CMS Office of the Actuary estimated that 9.7 million individuals received health insurance funded through CHIP allotments over the year. CHIP enrollment averaged approximately 7.1 million individuals per month in 2019.



Congress appropriated $24.8 billion to this program for FY 2021 in the HEALTHY KIDS Act of 2018 (P.L. 115-120). The Administration continues to support fiscally responsible reforms that would streamline funding sources and ensure flexibility in covering state shortfalls.

HOW CHIP WORKS

CHIP is a partnership between the federal government and states and territories to help provide children under age 19 from low- and moderate-income households with health insurance coverage and access to healthcare. Congress appropriates an annual capped funding amount for CHIP, which CMS then allocates to states and territories with approved CHIP plans according to a statutory formula. Since FY 2009, the amount of funding Congress appropriates for CHIP has exceeded the amount CMS can award states and territories according to the statutory formula. This statutory formula caps the annual CHIP allotment available to states resulting in possible funding shortfalls.

Congress grants states, the District of Columbia (D.C.), and territories flexibility in designing their CHIP programs. They may implement CHIP by expanding Medicaid, creating a separate program, or combining both approaches. CMS has approved a CHIP plan for every state, D.C., and territories. State plans include 14 Medicaid expansion programs, two separate programs, and 40 combination programs.

States use a Modified Adjusted Gross Income standard to determine eligibility for coverage under a state's CHIP program. The statute permits states to offer continuous eligibility for 12 months regardless of family income changes, and enroll children into CHIP who are eligible for family coverage under a state-employee health plan.

CHIP has several financing mechanisms to address potential state funding shortfalls. The Child Enrollment Contingency Fund supports states that predict a funding shortfall due to higher than expected enrollment. HHS invests the Contingency Fund in interest-bearing securities of the United States. Since its establishment in FY 2009, only four states have qualified for Contingency Fund payments totaling $422 million. Current law does not require states to spend Contingency Fund resources on CHIP activities.

In addition, CMS recoups unused state allotment funding to redistribute to states facing a funding shortfall. Since 2012, CMS has redistributed $2 billion to 32 states and territories. Current existing shortfall funding is limited and this amount may not address future needs.

The Children's Health Insurance Program Reauthorization Act of 2009 established a CHIP Performance Bonus Fund for FY 2009 through FY 2013 to provide payments to states that met five out of eight specific enrollment and retention activities. CMS's authority to make payments from the Performance Bonus Fund expired after FY 2013, leaving some funds unused.

RECENT PROGRAM DEVELOPMENTS

The HEALTHY KIDS Act and the Bipartisan Budget Act of 2018 (P.L. 115-123) extended CHIP funding and authorized the Child Enrollment Contingency Fund for 10 years through FY 2027. This 10-year extension is the longest period of CHIP funding and stability since CHIP's creation in 1997, and enables continued coverage of over 9 million children currently enrolled in CHIP.

CHIP also includes measures to improve child health quality in Medicaid and CHIP, strengthen the quality of access to children's healthcare, and conduct a national outreach and enrollment campaign to eligible children not enrolled in Medicaid and CHIP. Congress has appropriated a total of $168 million for the Outreach and Enrollment Program and $150 million for child health quality efforts for FY 2018 through FY 2027.

2021 LEGISLATIVE PROPOSALS

Strengthen the CHIP Safety Net for States

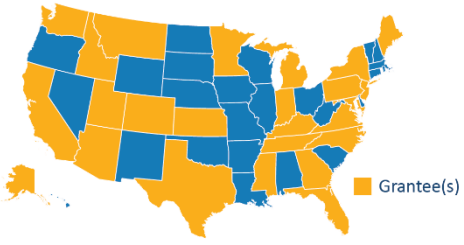
This reproposal seeks to strengthen the CHIP program by streamlining the funding mechanisms available to states experiencing a funding shortfall. The proposal establishes a Shortfall Fund comprised of unused annual appropriations that CMS may redistribute to states experiencing a shortfall and repeals the Performance Bonus Fund and Child Enrollment Contingency Fund beginning in FY 2022. CMS's authority to make payments from the Performance Bonus Fund expired after FY 2013, and few states meet the restrictive criteria to receive payments from the Child Enrollment Contingency Fund while experiencing a funding shortfall. By creating a single Shortfall fund

INCREASING OUTREACH AND ENROLLMENT TO ELIGIBLE CHILDREN

In FY 2019,
CMS announced $48 million in

OUTREACH AND ENROLLMENT

Grants to States, Tribal Providers,
and Community-Based Organizations



Note: Enrollment data for FY 2010 – FY 2019 taken from CMS Statistical Enrollment Data System (SEDS) Reporting

rather than a patchwork of funding mechanisms, CMS is making it easier for states and territories to access needed funding when facing CHIP funding shortfalls, and ensuring that shortfall funding is available to states and territories in the future. [Budget Neutral]

Prohibit States from Terminating CHIP Coverage for Inmates

Justice-involved individuals have a high prevalence of mental health and substance use disorders. Ensuring access to healthcare coverage for inmates upon release facilitates access to and continuity of treatment for youth to improve outcomes and avoid recidivism. The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (P.L. 115-271) requires states to suspend, rather than terminate, Medicaid coverage for beneficiaries under the age of 21 who become inmates, then restart coverage upon their release, but does not apply to CHIP beneficiaries. This proposal applies the concept of the SUPPORT for Patients and Communities Act to CHIP coverage, offering consistency across Medicaid and CHIP. The proposal does not change existing CHIP policy that precludes CHIP coverage during periods of incarceration. [Budget Neutral]

Children's Health Insurance Program

	dollars in millions		
	2021	2021-2025	2021-2030
Children's Health Insurance Program Proposals			
Strengthen the Children's Health Insurance Program Safety Net to States	--	--	--
Prohibit States from Terminating CHIP Coverage for Inmates	--	--	--
Total Outlays, Children's Health Insurance Program Proposals	0	0	0

State Grants and Demonstrations

	dollars in millions			
	2019	2020	2021	2021 +/- 2020
Current Law Budget Authority				
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	55	--	--	--
Money Follows the Person Demonstration /1	254	176	--	-176
Money Follows the Person Evaluation /1	1	--	--	--
Medicaid Integrity Program /2	82	84	91	**7**
Total, Current Law Budget Authority/6	**392**	**260**	**91**	**-169**
Current Law Outlays				
Demonstration Programs to Improve Community Mental Health Services	--	1	1	--
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	--	22	14	-8
Money Follows the Person Demonstration /1	291	340	322	-18
Money Follows the Person Evaluation /1	--	1	--	-1
Medicaid Integrity Program /2	81	66	72	6
Children's Health Insurance Program Outreach and Enrollment Grants /3	5	7	20	13
Katrina Relief/ 4	2	--	--	--
Total, Current Law Outlays/5	**379**	**437**	**429**	**-8**

1/ The Further Continuing Appropriations Act, 2020 (P.L. 116-94) amends the Deficit Reduction Act to provide $176 million from January 1, 2020 – May 20, 2020 for states with approved Money Follows the Person (MFP) demonstrations to continue providing home and community-based long-term care services to individuals transitioning from institutions to community-based settings until FY 2021. The appropriated funds will remain available for grants to states which have approved MFP demonstration projects as of December 31, 2018 until September 30, 2021.
2/ Budget authority is adjusted annually by Consumer Price Index for All Urban Consumers. Outlays include some spending from prior year budget authority. This is also described in the Program Integrity chapter.
3/ See the Children's Health Insurance Program chapter for additional information about this program.
4/ Outlays are the result of a downward adjustment in FY 2018.
5/ Totals may not add due to rounding.

The Centers for Medicare & Medicaid Services (CMS) State Grants and Demonstrations account funds diverse activities including:

- Strengthening Medicaid program integrity;
- Increasing the treatment capacity of providers participating under a state plan or waiver to provide substance use disorder treatment or recovery services;
- Funding outreach activities to enroll children into Medicaid and the Children's Health Insurance Program (CHIP); and
- Providing grants to states to prevent chronic diseases.

EXCELLENCE IN MENTAL HEALTH ACT DEMONSTRATION

On December 20, 2019, President Trump signed the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) into law, which extended the Excellence Act Demonstration until May 22, 2020. This HHS demonstration provides an enhanced Medicaid federal medical assistance percentage (FMAP) reimbursement to support states in improving the availability and quality of community-based, comprehensive treatment and recovery support services to Medicaid beneficiaries living with mental illness and substance use disorders. In 2015, HHS awarded $22.9 million in one-year planning grants for Certified Community

Behavioral Health Clinics (CCBHCs) to support 24 states in their efforts to plan to participate in this demonstration program. In 2016, HHS selected eight states (of the original 24) to participate in this demonstration program.

Since the launch of the initial eight state demonstrations, HHS made available FY2018 expansion grant funding opportunities for all 24 planning states to expand the CCBHC model. The Substance Abuse and Mental Health Services Administration (SAMHSA) expansion grants seek to increase the number of CCBHCs by providing additional funds for states that are not officially a part of the demonstration. On January 10, 2020 SAMHSA announced a funding opportunity for its "CCBHCs Expansion Grants" program to all CCBHCs across the country. CCBHCs are now eligible to apply for the SAMHSA funds regardless of whether they received a planning grant under the HHS demonstration (Please refer to the SAMHSA chapter for additional information). States outside of the demonstration are able to participate in the CCBHC model without an enhanced FMAP through a Medicaid waiver or State Plan Amendment.

CCBHCs provide a comprehensive, coordinated range of evidence-based behavioral health services certified by the state to meet six key aspects of improved care: staffing, organization authority, care coordination, scope of services, quality and other reports, and availability and accessibility of services. Under the HHS demonstration, certified clinics may receive Medicaid payment through a daily or monthly prospective payment system rate that is clinic-specific and reimburses the expected cost of demonstration services. Results to date show CCBHCs are making services more convenient by introducing more frequent appointments, tailoring services offered to diverse populations (e.g., school-aged youth and veterans) and expanding access to care within their communities. Additionally, Pennsylvania focused on a case management model in urban and rural areas to provide substance use disorder treatment for individuals receiving medication-assisted treatment.

The Budget proposes to extend this HHS demonstration for the current eight participating states through FY 2021 (Please refer to the Medicaid chapter for additional information).

DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE DISORDER PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 (P.L. 115-271) includes a $55 million Medicaid demonstration project over 4.5 years.

Through this demonstration, CMS will encourage increased substance use provider capacity by providing an enhanced Medicaid FMAP for select states. CMS selected 15 states to receive planning grants to assess behavioral treatment and provider needs to improve provider networks treating substance use disorders. CMS may choose up to five of the 15 states (provided they meet specified criteria) to receive the enhanced FMAP and implement the following demonstration activities:

- Supporting ongoing analysis of state behavioral health treatment needs;
- Supporting recruitment, training, and providing technical assistance for providers offering substance use disorder treatment or recovery services;
- Improving reimbursement and expanding the amount of treatment capacity of participating providers authorized to dispense Food and Drug Administration-approved drugs; and
- Improving reimbursement and expanding the amount of participating providers' treatment capacity to address the treatment needs for certain populations enrolled under the state plan or waiver.

MONEY FOLLOWS THE PERSON DEMONSTRATION

Under this demonstration, 43 states and the District of Columbia that were awarded competitive grants receive an enhanced FMAP to help eligible individuals transition from a qualified institutional setting to a qualified home or community-based setting. States have demonstrated positive outcomes, including helping individuals in institutions return to the community, improving participant quality of life, and lowering the cost of care. Additionally, the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) appropriated $176 million for grants to states available until September 2021 with approved Money Follows the Person demonstration projects to continue providing home and community-based long-term care

services to individuals transitioning from institutions to community-based settings.

The Budget allows for a state plan option to establish a Money Follows the Person program under the state plan, with temporary enhanced funding. States spending less than 50 percent of their long-term service and supports funding on home and community-based services would receive an enhanced FMAP for the first five fiscal years they provide these services. Please refer to the Medicaid chapter for additional information.

MEDICAID INTEGRITY PROGRAM

The Deficit Reduction Act of 2005 established the Medicaid Integrity Program with $75 million of funding annually. Congress later increased appropriations for inflation beginning in FY 2011. While states have the primary responsibility for combating Medicaid fraud, waste, and abuse, the Medicaid Integrity Program plays an important role supporting state efforts. CMS uses these funds to provide technical support to states and contracts with eligible entities to execute activities such as agency reviews, audits, identification of overpayments, and education activities. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the Healthcare Fraud and Abuse Control Program.

Please refer to the Program Integrity chapter for additional information.

CHIP OUTREACH AND ENROLLMENT GRANTS

The Outreach and Enrollment Program uses grants and a national campaign to improve outreach to and enrollment of children eligible for Medicaid and CHIP, including American Indian or Alaska Native children. These grants support educating families about the availability of affordable health coverage under Medicaid and CHIP, identifying children likely to be eligible for these programs, and assisting families with the application and Renewal process. Of the $168 million available for outreach and enrollment grants through FY 2027, the Bipartisan Budget Act of 2018 (P.L. 115-123) requires that CMS set aside 10 percent of the funding from FY 2024 to FY 2027 for evaluations and technical assistance.

Please refer to the CHIP chapter for additional information.

MEDICAID IMPROVEMENT FUND

The Medicaid Improvement Fund, established under section 1941 of the Social Security Act, is "available to the Secretary to improve the management of the Medicaid program by the Centers for Medicare & Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects." To date, none of this funding has been available for obligation by CMS. The Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (P.L. 116-69) appropriated $1.96 billion to the Medicaid Improvement Fund, authorized for Medicaid administrative activities beginning in FY 2025. The Budget proposes to rescind the remaining $1.96 billion balance from the fund, which becomes available in FY 2025, and ensures the funding can be used in a more fiscally responsible manner. [$2.0 billion in savings over 10 years].

FY 2021 State Grants and Demonstrations Budget Proposal

dollars in millions	2021	2021 -2025	2021 -2030
State Grants and Demonstration Legislative Proposal			
Rescind the Remaining Balances from the Medicaid Improvement Fund	--	-1,960	-1,960
Subtotal, State Grants and Demonstration Proposal	--	-1,960	-1,960

Center for Medicare and Medicaid Innovation

	dollars in millions			2021 +/-
	2019	2020	2021	2020
Innovation Center Obligations /1	$808	$1,414	$1,243	-171

1/ Fiscal Year (FY) 2019 numbers are actuals. FY 2020 and FY 2021 are estimates.

The Center for Medicare and Medicaid Innovation (Innovation Center) tests innovative payment and service delivery models with the potential to preserve or enhance the quality of care and reduce Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) spending. Better health is the fundamental goal of President Trump's vision for our healthcare system, understanding the vital importance that health holds for every American. The Innovation Center supports the Administration's goal to improve health by reforming how care is financed, bringing value to healthcare, and protecting lives by addressing specific, impactful health challenges.

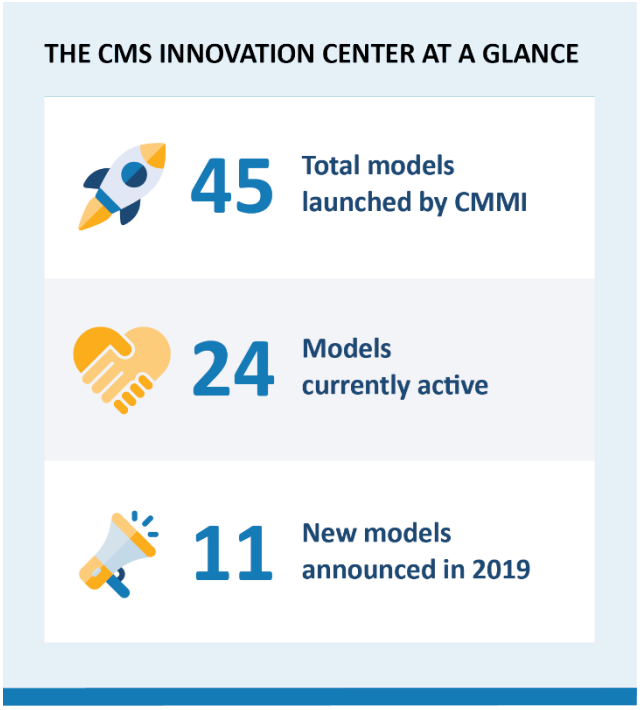
INNOVATION CENTER MODELS

Paying for outcomes and health versus procedures and sickness is the central premise of the Innovation Center's work. To date, the Innovation Center launched 51 models, including Accountable Care Organization models; episode-based payment models; primary care transformation; models focused on Medicaid, CHIP, and dually eligible populations; initiatives to accelerate development and testing of new payment and service delivery models; and initiatives to speed adoption of best practices. The Innovation Center also implements demonstrations established directly by Congress.

Model Evaluations and Results

The Innovation Center uses independent evaluators to routinely and rigorously assess the impact of each model on quality and expenditures. The evaluations include advanced statistical methods and generally include carefully selected comparison groups to determine model performance and success. Having a robust evaluation process allows the Innovation Center to determine on an ongoing basis and at the end of the testing period whether a model represented a high-value investment of taxpayer dollars. The Innovation Center shares evaluation results with the public as they become available.

In addition to evaluating results of individual model tests, the Innovation Center also systematically reviews and synthesizes evaluation results across multiple models, where appropriate. The Innovation Center submits a Report to Congress describing its entire portfolio of models and results to-date every 2 years. CMS will release the next Innovation Center Report to Congress in late 2020.



Expanded Models

Section 1115A of the Social Security Act provides the Secretary authority to expand the duration and scope of a model through rulemaking, including nationwide implementation. To exercise this authority, the Secretary, working with the Chief Actuary at CMS, must determine if expansion would reduce spending without reducing quality of care or improve quality of care without increasing spending. To date, the Innovation Center has certified two models for expansion: the Pioneer Accountable Care Organization Model, which supported experienced providers to coordinate care for patients across care settings, and the Medicare

Diabetes Prevention Program, which helps prevent the onset of type 2 diabetes among pre-diabetic Medicare beneficiaries. The Innovation Center also extended testing of the Medicare Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transport through December 1, 2020, after which nationwide expansion of the model may occur if the statutory criteria are met. Initial results for that model showed that prior authorization for repetitive, scheduled non-emergent ambulance transports can ensure these services are provided in compliance with applicable Medicare coverage, coding, and payment rules before rendering services and paying claims, thus saving money and preserving quality.

NEW AND PRIORITY INITIATIVES

Since January 2019, the Innovation Center has announced 11 bold, new models designed to provide better care at a lower cost and aligned with HHS's value-based transformation. In designing and implementing models, the Innovation Center carefully consults with a diverse group of stakeholders, including the Physician-Focused Payment Model Technical Advisory Committee, Congress, and beneficiaries.

Models that Advance Kidney Health

Kidney Care Choices Models

As part of the Administration's kidney health initiative, the Innovation Center announced the Kidney Care Choices Model, to test incentives for better kidney disease management. The model offers four voluntary payment options—Kidney Care First for nephrologists, and three Comprehensive Kidney Care Contracting options with distinct accountability frameworks for Kidney Contracting Entities comprised of nephrologists and nephrology practices, transplant providers, dialysis facilities, and other providers and suppliers.

These models will incentivize providers to prevent the progression of kidney disease and manage kidney patients' health. A nephrology practice or a group of healthcare providers will be responsible for a patient's kidney care from the late stage of chronic kidney disease through dialysis, kidney transplantation, and post-transplant care. In particular, providers will focus on delaying the progression of chronic kidney disease to end-stage renal disease, managing the transition onto dialysis, supporting beneficiaries through the transplant process, and keeping beneficiaries healthy post-transplant. The Innovation Center will test the model from CY 2020 through December 31, 2023 with the option for one or two additional Performance Years.

End-Stage Renal Disease Treatment Choices Model

This proposed model would give Medicare beneficiaries with End-Stage Renal Disease the freedom to choose a treatment approach that works best for them. Specifically, the model design encourages use of home dialysis and kidney transplants over facility-based dialysis treatment through two targeted payment adjustments. Both modalities have support among healthcare providers and patients as preferable alternatives to in-center hemodialysis, yet utilization in the United States has been far less than in other developed nations. For example, 82 percent of Americans receive center-based dialysis, whereas in Hong Kong, more than 80 percent receive home-based dialysis. This model would test whether shifting more patients to home-based care and increasing access to transplants will reduce Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries with End-Stage Renal Disease. The model would require about half of dialysis facilities across the country to participate.

Models to Combat the Opioid Crisis

Integrated Care for Kids Model

This model is one piece of the Administration's comprehensive strategy to combat the nation's opioid crisis. The model tests whether supporting coordination of state and local service delivery of integrated behavioral, physical, and complementary child health services will improve care for pediatric Medicaid and CHIP beneficiaries with significant health needs. As part of the model, states and local providers share accountability for cost and outcomes.
The Innovation Center issued eight cooperative agreements across seven states for this model, which began on January 1, 2020 and runs through December 31, 2026.

Maternal Opioid Misuse Model

This model is yet another part of the Administration's comprehensive strategy to combat the nation's opioid crisis. The model addresses fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder and aims to improve the quality of their care through state delivery system innovations. The model tests whether implementation of more sustainable coverage and payment strategies

that support the coordination of clinical care and the integration of health, wellbeing, and recovery services, and whether expanding access, service-delivery capacity, and infrastructure based on state-specific needs, can improve quality of care and reduce costs for mothers and infants. The Innovation Center awarded funding to 10 states for this model, which began on January 1, 2020 and runs through December 31, 2024.

Opioid Use Disorder Treatment Demonstration Program

The Innovation Center is working to implement Section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, which requires the Secretary to implement a demonstration program to increase access to opioid use disorder treatment services, improve physical and mental health outcomes, and to the extent possible, reduce Medicare expenditures. The demonstration will test whether paying eligible providers a care management fee for new opioid use disorder treatment services not otherwise covered by Medicare, along with a performance-based incentive payment adjustment, will achieve these goals. The statute requires that the demonstration be implemented no later than January 1, 2021 and run for 4 years.

Models that Address Social Determinants of Health

Accountable Health Communities Model

This model addresses a critical gap between clinical care and community services in the current healthcare delivery system. The model tests whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries' through screening, referral, and community navigation services will affect healthcare costs and reduce healthcare utilization. There are currently 30 community bridge organizations participating in the model. These organizations test promising approaches to link beneficiaries with community services that address their health-related social needs (i.e., housing instability, food insecurity, and transportation). The model's performance period is from May 1, 2017, through April 30, 2022.

Models that Bring Value to Healthcare

Radiation Oncology Model

This proposed model seeks to improve the quality of care for cancer patients receiving radiotherapy treatment, and to reduce provider burden by moving toward a simplified and predictable payment system. This patient-centered and provider-focused innovative payment model would test whether prospective episode-based payments to physician group practices, hospital outpatient departments, and freestanding radiation therapy centers for radiotherapy episodes of care reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. The proposed model would qualify as an Advanced Alternative Payment Model and a Merit-based Incentive Payment System Alternative Payment Model under the CMS Quality Payment Program.

Primary Care First Model

This model offers physicians a set of voluntary, innovative payment options that seek to reward value and quality, and support delivery of advanced primary care. The model will test whether prioritizing the doctor-patient relationship, enhancing care for patients with complex chronic needs and seriously ill patients, reducing administrative burden, and focusing financial rewards on improved health outcomes will reduce Medicare spending by preventing avoidable inpatient hospital admissions. The model will be tested over six performance years, with two staggered cohorts of participating practices, each participating for five performance years. One cohort will participate in the model from 2021 through 2025 and a second will participate from 2022 through 2026.

Direct Contracting Model

This model will test whether population based payment arrangements encourage better care and align financial incentives to reduce unnecessary use of high-cost settings and services in Medicare Fee-for-Service. The model offers two voluntary options that give participating organizations an opportunity to take on financial risk and earn rewards. Given the enhanced flexibilities for participants and focus on Medicare beneficiaries with complex chronic conditions, the model design targets a broad range of providers and organizations that have not participated in prior CMS models. The model builds on recent initiatives at CMS involving Accountable Care Organization programs and Medicare Advantage by incorporating features such as enhanced benefits, innovative risk-sharing arrangements, outcomes-based quality measures, and reduced administrative burden for practitioners. The Global and Professional model options will be tested from January 1, 2021, through December 31, 2025.

Artificial Intelligence Health Outcomes Challenge

This initiative is an opportunity for innovators to develop artificial intelligence solutions to predict unplanned hospital and skilled nursing facility admissions and adverse events. In partnership with the American Academy of Family Physicians and the Arnold Ventures, this challenge encourages innovators from any sector to develop AI solutions that help predict health outcomes to support innovative payment and service delivery models. The launch phase of the challenge, received more than 300 submissions and ran between March 27, 2019, and June 19, 2019. On October 30, 2019, CMS announced the 25 participants selected to advance to Stage 1, during which participants design and test their proposed solution using Medicare claims data. CMS will announce up to seven finalists in April 2020 to advance to Stage 2, during which participants will be able to request additional Medicare claims data and refine their solutions. The challenge will award up to $1 million to the grand prize winner.

INNOVATION CENTER DEMONSTRATIONS DISCUSSED IN OTHER CHAPTERS

The Budget also proposes new models to test innovations in program integrity and incentives for adopting high-value technology and devices. Please see the Medicare and Program Integrity chapters for proposal descriptions.

Program Management

	dollars in millions			2021
	2019	2020	2021	+/- 2020
Discretionary Administration				
Program Operations	2,816	2,825	2,479	-346
Federal Administration	733	733	773	+40
Survey and Certification	397	397	442	+45
Research /1	20	20	--	--
Subtotal, Discretionary Budget Authority	**3,966**	**3,975**	**3,694**	**-281**
Mandatory Administration /2				
Medicare Improvements for Patients and Providers Act	3	3	3	--
Protecting Access to Medicare Act (2014)	9	9	10	+1
Improving Medicare Post-Acute Care Transformation (2014)	17	5	6	-1
Medicare Access and CHIP Reauthorization Act	108	19	--	-19
SUPPORT Act	83	--	10	+10
Bipartisan Budget Act (2018)	21	--	--	--
Further Consolidated Appropriations Act (2020)	--	15	5	-10
Health Extenders Acts (2020)	**--**	3	**--**	**-3**
Subtotal, Mandatory Administration	**241**	**54**	**33**	**-21**
Reimbursable Administration /2				
Medicare and Medicaid Reimbursable Administration /3	553	609	758	+149
Exchange-Related Reimbursable Administration /4	1,824	1,752	1,526	-226
Subtotal, Reimbursable Administration	**2,377**	**2,361**	**2,284**	**-77**
Total Program Management Program Level, Current Law	**6,584**	**6,390**	**6,011**	**-379**
Proposed Law				
Survey and Certification Long Term Care Revisit Fee /5	--	--	--	--
Rebase National Medicare & You Education Program User Fee /5	--	--	--	--
Program Management Implementation Funds (mandatory)	--	--	200	+200
Subtotal, Proposed Law	**--**	**--**	**200**	**+200**
Total Program Management Program Level, Proposed Law	**6,584**	**6,390**	**6,211**	**-179**

1/ Research funding is requested as part of the Program Operations funding in Fiscal Year (FY) 2021.

2/ FY 2019 and FY 2020 amounts are net of sequester and pop-up authority. FY 2021 displays gross resources and estimated collections.

3/ Includes collections of the following user fees: Clinical Laboratory Improvement Amendments of 1988, sale of research data, coordination of benefits for the Medicare prescription drug program, MA/prescription drug program, and recovery audit contractors, and provider enrollment fees.

4/ Includes collections of user fees charged to issuers in Federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and Risk Adjustment.

5/ Collections from the proposed user fee proposals would begin in FY 2022.

The CMS Program Management budget provides administrative funding for CMS to operationalize the Administration's priorities to reform healthcare financing; deliver better value from that care; and improve the health and wellbeing of beneficiaries. The President's Fiscal Year (FY) 2021 discretionary Budget (Budget) requests $3.7 billion for CMS Program Management, enabling CMS to effectively administer Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Budget reflects CMS's priorities to: facilitate patient-centered markets; protect and improve Medicare for our seniors; lower drug prices; and strengthen the integrity and sustainability of Medicare, Medicaid, and CHIP by preventing fraud, waste, and abuse.

PROGRAM OPERATIONS

The Budget requests $2.5 billion for Program Operations to fund essential payment, information technology, and outreach activities for Medicare, Medicaid, CHIP, and private insurance programs. Priority activities for FY 2021 include:

Medicare Contractor Operations

Approximately 33 percent, or $826 million, of the FY 2021 Program Operations request supports ongoing Medicare contractor operations. This funding includes processing 1.3 billion Medicare Part A and B claims, enrolling providers in the Medicare program, paying providers and suppliers, processing 2.3 million first-level appeals, responding to inquiries from providers, educating providers about the program, and administering the participating physicians and supplier program. Contractor operations support allows CMS to process claims quickly, accurately, and in compliance with the law.

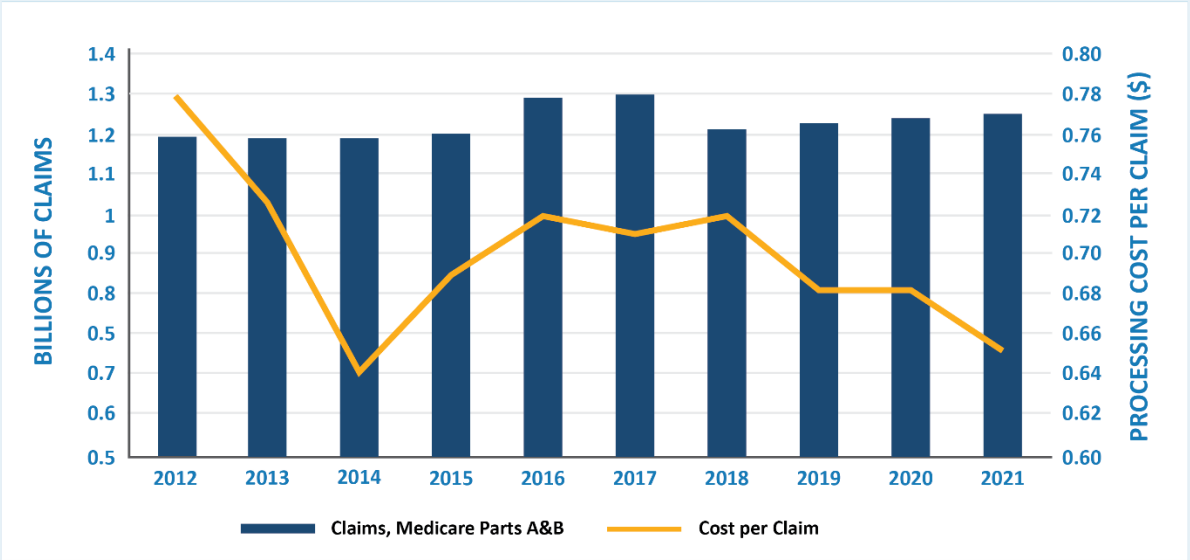
Medicare Appeals

The Budget includes $78 million to process approximately 273,000 second level appeals in a timely manner. CMS actively supports the Department's effort to improve the Medicare appeals process and address the pending backlog of appeals at the Office of Medicare Hearings and Appeals and Departmental Appeals Board levels. The Budget funds initiatives to reduce the number of appeals in the backlog. It also provides resources to meet increased workload while simultaneously supporting efforts to decrease the number of new appeals entering the system.

Information Technology Systems and Support

The Budget includes $450 million for information technology systems, including cybersecurity, allowing the agency to protect the valuable consumer health data of millions of Americans from outside threats. The Budget will continue investments to modernize fee-for-service claims processing systems, which will improve efficiency and reliability for CMS, health providers, and beneficiaries.

NUMBER OF MEDICARE CLAIMS PROCESSED HAS GRADUALLY INCREASED EVEN AS CMS'S COST TO PROCESS CLAIMS HAS TRENDED DOWNWARD



Medicaid and CHIP Operations

The Budget requests $126 million for administrative activities to improve Medicaid and CHIP program operations. This investment includes modernizing data systems and continuing development of the Medicaid and CHIP Scorecard, a searchable web-based platform reporting on health outcomes, quality of care, access to care, and administrative performance and efficiency. This scorecard increases transparency and accountability for states' progress on achieving tangible results that improve the lives of beneficiaries.

Exchanges

The Budget expands the use of Exchange user fees to cover all federal administrative expenses associated with operating the Exchanges. The program level for Exchanges totals $1.2 billion, all of which will be funded by Exchange user fees, with the exception of $25 million from the Healthcare Fraud and Abuse Control appropriation. Covering federal administrative expenses with user fees makes the Exchanges more financially self-sustaining.

Quality Payment Program

The Budget includes $40 million to implement the Quality Payment Program, which incentivizes clinicians to furnish high quality care, increase patient safety, promote patient outcomes, and improve coordination of care. In 2015, the Medicare Access and CHIP Reauthorization Act (MACRA) was signed into law and implemented this new value-based system for Medicare clinicians. Prior to 2021, MACRA provided temporary funding to support these activities.

FEDERAL ADMINISTRATION

The FY 2021 Budget requests $773 million for CMS federal administrative costs. At this level, CMS will maintain sufficient staffing necessary to support core Medicare, Medicaid, and CHIP operations.

SURVEY AND CERTIFICATION

The Budget requests $442 million for Survey and Certification. This level of investment will enable CMS to maintain non-statutory survey frequency levels in order to prevent serious violations of safety standards and avoid patient harm. Survey volume and cost have increased due to the growing number of participating facilities, higher levels of complaints, and increasing costs to conduct surveys.

CMS'S 5 PART STRATEGY TO ENHANCE SAFETY AND QUALITY IN NURSING HOMES

STRENGTHEN OVERSIGHT:

Provide revised guidance to ensure state survey agencies are fair and consistent in applying CMS rules.

ENHANCE ENFORCEMENT:

Hold nursing homes accountable, root out bad actors, and increase funding to respond to quality complaints.

INCREASE TRANSPARENCY:

Incorporate staffing data into Nursing Home Compare and Five Star Quality Rating System. Publish more quality and deficiency data.

IMPROVE QUALITY:

Develop new quality measures based on outcomes and link them to payment. Reinvest civil monetary penalties in quality improvement efforts.

PUT PATIENTS OVER PAPERWORK:

Ensure CMS requirements put patients first while removing unnecessary burdens on providers that create staffing challenges and increase cost without increasing quality.

Approximately 90 percent of the request for Survey & Certification will go directly to State Survey Agencies to perform health and safety oversight of Medicare certified providers. CMS expects states to complete over 25,000 initial surveys and re-certifications and over 65,000 visits in response to complaints in FY 2021. Surveys include mandated federal inspections of long-term care facilities (i.e., nursing homes), home health agencies, hospices, and federal inspections of other key facilities. All facilities participating in the Medicare and Medicaid programs must undergo inspection when entering the program and on a regular basis thereafter. CMS is implementing a new five-part strategy to ensure care provided in America's nursing homes is both safe and at the highest possible quality. This includes survey and certification improvements such as enhanced oversight of the State Survey Agencies that perform nursing home surveys, timely response to patient quality complaints, greater

transparency about nursing home performance, and development of outcomes-based quality measures.

The Budget requests two year budget authority for the Survey and Certification program. This approach increases administrative flexibility, enhances oversight and quality of care, and ensures funds are available early enough in the state FY to enable more effective planning, staffing, and funding of survey agencies to accomplish required survey workloads. This approach is particularly important since many states operate on FYs that are different from the federal FY. This proposal will further facilitate CMS's existing ability to reallocate funding between states when appropriate.

MEDICARE QUALITY IMPROVEMENT AND VALUE-BASED TRANSFORMATION

The Budget includes a total of $155 million across discretionary Program Management to support Medicare quality improvement, measurement, and select value-based activities to increase patient safety, make communities healthier, better coordinate post-hospital care, and improve clinical quality. These activities support the Administration's priorities to enhance quality transparency and foster value-based healthcare transformation.

NATIONAL MEDICARE EDUCATION PROGRAM

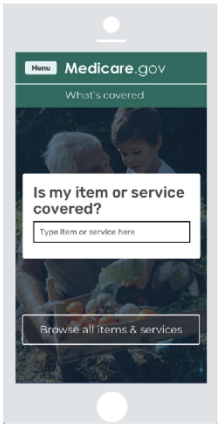
The Budget funds the National Medicare Education Program at $391 million, including $276 million in budget authority. CMS is committed to ensuring beneficiaries have access to the educational materials and tools needed to find accurate and up-to-date information on coverage options and available benefits. The Budget continues to support investments in personalized beneficiary tools (please see following graphic) to improve the customer experience. In 2019 CMS launched an updated Medicare Plan Finder with new functionalities. These functionalities are intended to supplement and not replace private sector enrollment options where innovation is most likely to occur.

The Budget provides $265 million, including $181 million in budget authority, to support the 1-800-MEDICARE call center, which provides beneficiaries access to customer service representatives trained to answer questions about the Medicare program. The request will support an estimated 23 million calls with an average-speed-to-answer of approximately 5 or fewer minutes. Beneficiaries can also use 1-800-MEDICARE to report instances of possible fraud or abuse.

The Budget includes $53 million, including $23 million in budget authority, for beneficiary materials, the majority of which goes to the printing and distribution of the *Medicare & You* Handbook.

MODERNIZING MEDICARE AND EMPOWERING PATIENTS

In 2019, CMS released the new "Whats Covered" app for people with Original Medicare and caregivers to quickly see whether Medicare covers a specific medical item.



2021 LEGISLATIVE PROPOSALS

The Department proposes several legislative changes to modernize and improve the efficiency of the administration of Medicare, Medicaid, and CHIP.

Rebase National Medicare Education Program User Fee

Despite growing enrollment in Medicare Advantage and Part D plans, the amount of user fees these plans pay to support beneficiary outreach and enrollment assistance through the National Medicare Education Program has not kept pace due to an outdated statutory cap. Starting in FY 2021, this proposal allows CMS to increase Medicare Advantage and Part D plan user fees to more equitably support outreach and enrollment assistance activities. [$1.1 billion in additional user fees over 10 years]

Modernize Medicare Beneficiary Education Requirements

CMS is required to mail Medicare education materials to beneficiaries annually. This proposal provides the Secretary with increased flexibility to determine how to most efficiently and effectively communicate Medicare benefits information included in the *Medicare & You* Handbook with beneficiaries including, in some cases, through electronic means. Offering digital alternatives will improve the efficiency of CMS Beneficiary Education activities and give beneficiaries communication options standard in most industries and settings. [No mandatory budget impact]

NATIONAL MEDICARE EDUCATION PROGRAM
FY 2021 PROGRAM LEVEL (DOLLARS IN MILLIONS)

Activity	2020	2021
Beneficiary Materials (e.g., Handbook)	64.4	53.4
1-800-MEDICARE and Beneficiary Claims Contact Center	233.8	265.1
Internet	46.5	42.1
Community-Based Outreach	5.4	5.4
Program Support Services/National Ad Campaign	25.0	24.7
Total NMEP Program Level	**390.2**	**399.6**

Note: Includes funding from Program Management and user fees.

Tailor the Frequency of Skilled Nursing Facility Surveys to More Efficiently Use Resources and Alleviate Burden for Top Performing Nursing Homes

State Survey Agencies must survey all skilled nursing facilities every 12 months, with no greater than 15 months between surveys, regardless of a facility's Five Star Quality Rating. Effective FY 2021, this proposal gives the Secretary authority to adjust statutorily-required survey frequencies for top-performing skilled nursing facilities and reinvest resources to strengthen oversight and quality improvement for poor performing facilities. This approach bases the frequency of nursing home surveys on risk to health and safety, which reduces burden on high-performing facilities. [Budget Neutral]

Charge Long Term Care Facilities Fees for Revisit Surveys

CMS, through State Survey Agencies, performs annual surveys of long-term care facilities to ensure compliance with Medicare guidelines and standards. This oversight provides an essential quality of care function, ensures safety of long-term care residents, and serves as an effective gatekeeper to participation in the Medicare program. When the state identifies serious deficiencies, it conducts a revisit survey to verify that the facility has corrected the deficiencies. This proposal allows CMS to collect a fee from the deficient long-term care facility for the cost of the revisit survey. Enactment of this fee will foster greater accountability for these facilities by creating an incentive to correct deficiencies and ensure compliance with Medicare Conditions of Participation. The fee will provide resources to support and enhance the CMS Survey and Certification quality assurance functions that improve patient health and safety. [User fee revenue of $270 million over 10 years]

Provide Mandatory Resources for Implementation

The Budget includes a comprehensive package of CMS legislative proposals to carry out Administration reforms to the Medicare, Medicaid, and CHIP programs. This proposal provides $200 million in mandatory Program Management funding to implement these legislative proposals.

Administration for Children and Families: Overview

	dollars in millions			2021 +/-
	2019 /1	2020	2021	2020
Mandatory				
Budget Authority	35,347	36,769	34,778	-1,991
Discretionary				
Budget Authority	26,389	24,444	20,198	-4,245
Total Administration for Children and Families Budget Authority	61,735	61,213	54,976	-6,237

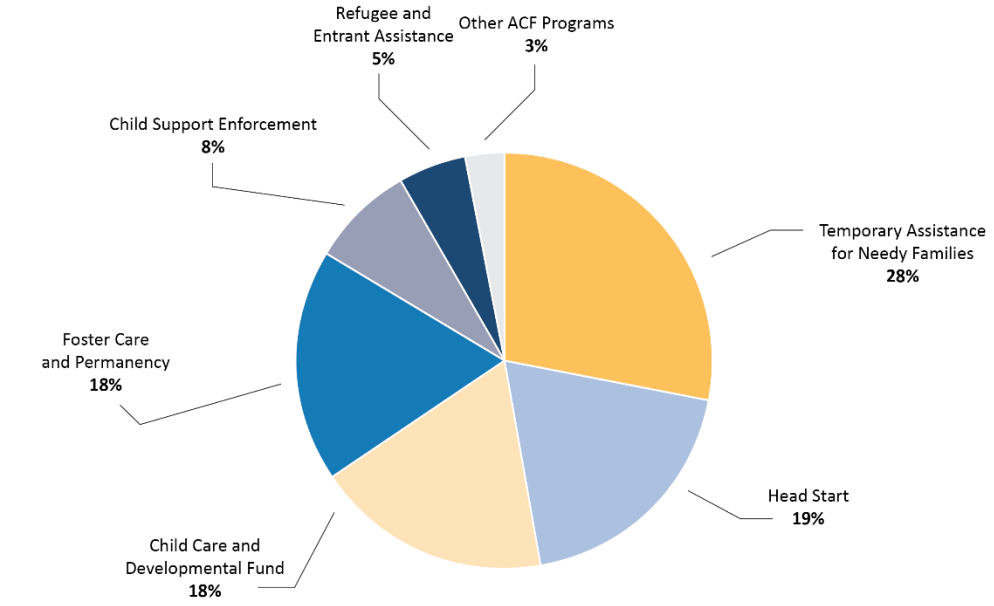
1/ Reflects FY 2019 Enacted, post required and permissive transfers and rescissions.
Note: Totals may not add due to rounding.

The mission of the Administration for Children and Families is to foster health and well-being by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services.

The Administration for Children and Families (ACF) works in partnership with states, tribes, and communities to provide critical assistance to help ensure that foster children, youth, families, and communities are resilient, safe, healthy, and economically secure. The President's Fiscal Year (FY) 2021 Budget (Budget) requests $55 billion for ACF.

The Budget supports working families and promotes upward economic mobility through programs such as Head Start, the Child Care and Development Fund, Child Support Enforcement, and Temporary Assistance for Needy Families (TANF). These programs promote personal responsibility, economic independence,

ACF FY 2021 BUDGET AUTHORITY, PROPOSED



Note: Totals may not add up to 100% due to rounding.

productivity, and well-being by helping parents enter the workforce, care for their children, and form strong social networks and family bonds. ACF's child welfare programs promote safety, well-being, and permanency through foster care, reunification, adoption, and efforts to prevent child maltreatment.

In this booming economy, there are more opportunities than ever for human services programs to connect Americans to self-sufficiency and independence. 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 increasing the investment in child care, an important support service that helps families increase their economic independence and productivity. The Administration is working to implement policies that increase access to high-quality, affordable child care. Putting parents first is fundamental to these reforms. Parents play the leading role in choosing the care that is best suited to their child's needs, their own values, culture, work schedules, and budget.

Through additional reforms proposed in the Budget, the Administration continues to promote independence for those relying on public safety net programs. The Budget's initiatives return TANF to its initial focus of promoting work, marriage, and family. The Budget's child welfare reforms increase support for the prevention of child maltreatment, foster care, and key services and partnerships that help to ensure children and youth have a stable and nurturing home with parents or kin, or through adoption. In FY 2018, the number of children in foster care declined for the first time in nearly 10 years, and the number of children adopted with public child welfare agency involvement reached a record high of over 63,000. While this represents progress, much remains to do – which is the focus of ACF's adoption initiative.

Administration for Children and Families: Discretionary

	dollars in millions			
	2019/1	2020	2021	2021 +/- 2020
Early Childhood Programs				
Head Start/2	10,083	10,613	10,613	--
Child Care Block Grant (discretionary)/2	5,288	5,826	5,826	--
Subtotal, Early Childhood Programs	**15,371**	**16,439**	**16,439**	**--**
Programs for Vulnerable Populations				
Runaway and Homeless Youth	127	132	132	--
Child Abuse Programs	158	181	197	+16
Child Welfare Programs/2	330	329	332	+3
Adoption Incentives	75	75	75	--
Chafee Education and Training Vouchers	43	43	43	--
Native Americans	54	56	57	+1
Family Violence Prevention and Services Programs	174	187	187	--
Promoting Safe and Stable Families (discretionary)	100	93	60	-33
Subtotal, Programs for Vulnerable Populations	**1,060**	**1,096**	**1,083**	**-13**
Refugee Programs				
Unaccompanied Alien Children/2	4,466	1,303	1,983	+680
Transitional and Medical Services	354	354	279	-75
Refugee Support Services	207	207	151	-56
Survivors of Torture	14	16	16	--
Victims of Trafficking (Foreign and Domestic)	27	28	28	--
Subtotal, Refugee Programs	**5,068**	**1,908**	**2,456**	**+548**
Discontinued Programs				
Low Income Home Energy Assistance Program	3,653	3,740	--	-3,740
Community Services Block Grant/2	743	740	--	-740
Preschool Development Grants	248	275	--	-275
Other Community Services Programs	29	30	--	-30
Subtotal, Discontinued Programs	**4,672**	**4,786**	**--**	**-4,786**
Other ACF Programs				
Social Services Research and Demonstration	6	7	6.5	-0.5
Disaster Human Services Case Management	2	2	4	+2
Federal Administration/2	209	206	209	+3
Subtotal, Other Programs	**218**	**215**	**220**	**+5**
Total Discretionary Budget Authority	**26,389**	**24,444**	**20,198**	**-4,245**
Total Program Level	**26,389**	**24,444**	**20,198**	**-4,245**
Full-Time Equivalents	1,284	1,443	1,445	+2

1/ Reflects FY 2019 Enacted, post required and permissive transfers and rescissions.

2/ In FY 2019, includes $3 billion from Emergency Supplementals of which $2.9 billion is for unaccompanied alien children.

The mission of the Administration for Children and Families is to foster health and well-being by providing federal leadership, partnership, and resources for the compassionate and effective delivery of human services.

The Administration for Children and Families (ACF) promotes economic and social well-being of communities, families, and children by providing services through states, tribes, and local governments, as well as non-profit, faith-based, and community-based organizations. HHS's overarching goal is to promote personal responsibility, and self-sufficiency—to help Americans lead flourishing, fulfilling, independent lives.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $20.2 billion for ACF programs. The Budget supports high-quality education and care for infants, toddlers, and preschoolers to help prepare America's children for success in life. Additional investments support programs that serve our nation's most vulnerable children and families, including child welfare research, child abuse prevention, adoption incentives, Native Americans, and unaccompanied alien children.

SUPPORT FOR WORKING FAMILIES

The Budget invests in programs that foster resilient, safe, healthy, and economically-secure families and communities, ensuring that more families can take full advantage of the opportunities that one of the strongest labor markets in history affords. These programs support working families, promoting economic opportunity for parents and enhancing their children's access to quality learning opportunities critical to their development and, ultimately, their success in school and in life.

Head Start

The Budget requests $10.6 billion, the same as FY 2020, to support Head Start ($7.26 billion) and Early Head Start ($2.97 billion), which includes the continued support for Early Head Start-Child Care Partnerships, and research, evaluation, training, technical assistance, and other program support ($370 million). This funding supports early learning programs that meet the highest standards of quality for preschoolers, infants, and toddlers. With this investment, Head Start will serve an estimated 857,627 children across the United States.

Head Start helps children from low-income families prepare to succeed in school through local programs. Head Start delivers programming to children in every state and territory through over 1,700 local agencies, and provides holistic, culturally competent services to promote growth and development in a positive learning environment. Head Start also aims to support the development of the whole child, from birth to the age of five, and enhances cognitive, social, and emotional development, and promotes kindergarten readiness.

Lastly, the Budget simplifies appropriations language that moves funding for Early Head Start Expansion and Early Head Start-Child Care Partnerships into the base Head Start appropriation to minimize administrative burden on grantees.

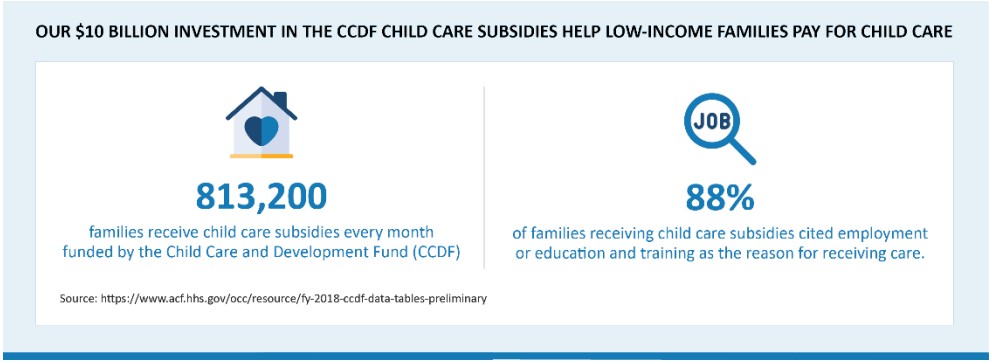
Child Care and Development Block Grant

The Budget provides $5.8 billion for the Child Care and Development Block Grant (CCDBG), and $4.2 billion in mandatory child care funding for a total investment of $10.0 billion.

CCDBG is the primary federal child care program that helps eligible, low-income, working families access child care and improves the quality of child care for all children. It 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 data is available, over 1.3 million children from about 813,000 low-income families received a monthly child care subsidy. The FY 2021 Budget will serve an estimated 1.9 million children.

Child care is an investment in both present and future generations of the workforce, but is also one of the biggest expenses a family faces and can be a barrier to work. The cost of center-based child care for two children exceeds home mortgage costs in 35 states and DC and annual median rent payments in every state. The Administration is engaging with stakeholders to identify promising innovations and new ideas from around the country to inform child care policy that better supports the success of working families.[3] The Budget reproposes a one-time mandatory $1 billion

[3] https://www.acf.hhs.gov/media/press/2019/public-input-sought-to-improve-child-care



fund for competitive grants to states to increase child care services for underserved populations and stimulate employer investment in child care.

The Budget also proposes a five-year reauthorization of the Child Care and Development Block Grant Act that builds upon the successful bipartisan reauthorization in 2014. This proposal strengthens program integrity, improves state flexibility to address local circumstances and special populations, ensures low-income working parents have equal access to the child care market, and enhances health and safety through improved background checks. The reauthorization also proposes new incentives for states to recover improper child care payments, and eliminates the requirement for a national child care hotline, as every state already maintains their own child care hotline.

SERVING VULNERABLE CHILDREN AND FAMILIES

ACF serves the needs of vulnerable children and families, including runaway and homeless youth and victims of child abuse and family violence, so they can live healthy, productive, violence-free lives.

Runaway and Homeless Youth

There are 4.2 million youth and young adults ages 13 to 25 who experienced a form of homelessness over a 12-month period.[4] The Budget includes $132 million for 646 programs across the country to provide comprehensive services to an estimated 63,401 homeless youth, who are more vulnerable to violence and substance abuse. ACF supports street outreach, emergency shelters, longer-term transitional living, and maternity group home programs to serve and protect these youth.

These programs provide positive alternatives for youth and families to ensure their safety, and offer them new opportunities. The Budget also proposes to create performance-based contracting demonstrations aimed at encouraging providers to focus more on outcomes in the design and delivery of their services.

Child Abuse Prevention

The Budget requests $197 million for grants to states, local government agencies, universities, and non-profit organizations. An additional $16 million is requested for demonstration projects to test the effectiveness of a multi-system approach to strengthen family capacity and to prevent child abuse and neglect before it occurs. Under a multi-system approach, partnerships – of public and private agencies, parents, community members, and others – will further develop centers that co-locate services to address risk factors for child maltreatment. Funds would also be used to improve child outcomes by expanding the evidence base and by ensuring that lessons learned are adopted by communities across the country, improve the investigation of child abuse, and train child protective service workers. Approximately 3.1 million children receive preventive services annually.

Promoting Child Welfare

The Budget requests $510 million for child welfare and adoption activities; within this total, an additional $3 million is requested to test models of improved interagency collaboration among child welfare, early care and education, and public health systems in approximately six sites. ACF supports at-risk families, enabling children to remain safely with their families or to safely reunify with their families in a timely manner. When children cannot remain safely with their families, ACF works to ensure that children, nevertheless, have "forever families" by removing barriers to adoption and providing incentive awards to states that increase the adoption of children from their foster care programs. ACF also supports programs to provide education and training vouchers to help foster care youth become self-supporting and achieve independence.

[4] Morton, M.H., Dworsky, A., & Samuels, G.M. (2017). Missed opportunities: Youth homelessness in America. National estimates. Chicago, IL: Chapin Hall at the University of Chicago.

Administration for Native Americans

The Administration for Native Americans supports Native American communities by providing financial assistance and capacity building, gathering and sharing data, and advocating for improved policies within HHS and across the federal government. ACF awards grants to federally recognized tribes, American Indian and Alaska Native organizations, Native Hawaiian communities, and Native populations in U.S. Pacific territories. ACF will issue competitive awards to such underserved communities to focus on prevention activities targeted to reduce the number of murdered and missing indigenous women and girls, opioid abuse, suicides, and tobacco/vaping use. The Budget includes $57 million, an increase of $1 million above the FY 2020 enacted level.

Family Violence Prevention and Services

ACF supports organizations and communities that work to end domestic violence. The Budget provides $187 million for Family Violence Prevention and Service Programs. This funding provides services to an estimated 1.3 million children and families to prevent family violence, domestic violence, and dating violence. It provides immediate shelter and support services for adult and youth victims. This total includes $12 million for the National Domestic Violence Hotline providing 24/7 crisis intervention, emotional support, counseling, safety planning, and resources to people experiencing family, domestic or dating violence.

REFUGEES, ENTRANTS, AND UNACCOMPANIED ALIEN CHILDREN

Unaccompanied Alien Children

ACF provides shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other law enforcement authorities. Unaccompanied alien children are particularly vulnerable to human trafficking, exploitation, and abuse. ACF provides care for these children and identifies suitable sponsors, usually parents or other relatives, to care for them while their immigration cases proceed. While in ACF's care, children receive physical and mental healthcare, education, and recreation. Children receive an individual counseling session and two group counseling sessions with a clinician every week. Additional mental health services are available as needed.

Most children receive care through a network of permanent facilities, which are state-licensed and operated by grantees under the close supervision of ACF staff. ACF has also operated temporary shelters in response to unpredictable but periodic rapid increases in the number of unaccompanied alien children requiring care.

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 $1.98 billion, and a 20 percent Secretary's transfer authority, to support capacity of 16,000 licensed permanent beds, depending on operational needs. It also includes a mandatory contingency fund to provide up to $2 billion in additional resources if needed.

Refugees and Other New Arrivals

Through networks of nonprofits and state and local governments, ACF assists refugees and other eligible new arrivals to become self-supporting and assimilate to life in the United States. Assistance includes financial support and medical services, English as a second language instruction, education, job training, case management, and counseling. New arrivals can receive up to eight months of financial support and medical assistance while looking for employment.

The FY 2021 assumption of eligible new arrivals is 91,000, including 18,000 refugees and 73,000 other new arrivals eligible for refugee benefits. The Budget includes $279 million for transitional and medical services, sufficient to maintain benefits for the estimated number of new arrivals and $151 million for refugee support services.

Victims of Trafficking

The Budget includes $28 million to screen and identify trafficking victims and provide services, including case management, emergency assistance, and medical services to an estimated 3,500 trafficking victims. ACF's National Human Trafficking Hotline provides 24-hour emergency counseling, referrals to services from a database of nearly 2,800 vetted social service programs, and tips to law enforcement on potential trafficking schemes.

HUMAN TRAFFICKING PREVENTION

Hotline activities have lead to increased prevention and law enforcement engagement

From FY 2016 to FY 2019, there have been increases for the following:

	FY 2016	FY 2019	Percent Increase
All Contacts (Calls, Texts, Chats, Online Tips, Emails)	54,823	124,293	125%
Contact with Individual Survivors	2,099	4,406	110%
Contacts from Potential Victims and Survivors	4,608	10,865	136%
Potential Trafficking Cases Identified	7,405	12,508	69%
Potential Cases Reported to Law Enforcement	2,120	3,817	80%

EVALUATION AND INNOVATION

Research and Demonstration

Program evaluation, and use of data and evidence, are critical for ACF and its partners to improve service delivery and increase program effectiveness. Social Services Research and Demonstration funding allows ACF to study programs that lack dedicated research and evaluation funds and to research areas that affect multiple programs. Topics of recent projects include employment and family self-sufficiency research; child poverty; studies of behavioral science interventions; examination of disparities in access to, and use of, ACF programs; and approaches to improving program efficiency and effectiveness, including efforts to improve the use of administrative data.

Disaster Human Services Case Management

In the wake of natural disasters, the ACF Disaster Human Services Case Management program connects individuals and families to critical local services to address disaster-caused unmet needs. The Budget invests an additional $2 million above FY 2020 to expand efforts to build out a standardized national response to disasters, which addresses the human services needs of individuals and families. Additionally, the investment will enhance collaboration between ACF and the HHS Assistant Secretary for Preparedness and Response National Disaster Medical System, ensuring an effective continuum of care for disaster survivors.

Federal Administration

Federal Administration funding pays for staff and administrative expenses necessary to effectively administer ACF programs that promote the economic and social well-being of families, children, individuals, and communities. Examples of administrative expenses include program management and required oversight, office space, and the development and maintenance of secure information technology systems. The Budget requests $209 million for federal administration. Additional funding is included to meet the requirements of the Family First Prevention Services Act. These include operation of the Title IV-E Prevention Services Clearinghouse, which rates programs and services intended to provide enhanced support to children and families and prevent foster care placements.

Administration for Children and Families: Mandatory

	dollars in millions			2021 +/-
	2019 /1	2020	2021	2020
Current Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	2,917	0
Child Support Enforcement and Family Support	4,322	4,402	4,439	+37
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,559	9,388	10,015	+627
Promoting Safe and Stable Families (mandatory only)/2	489	995	345	-650
Social Services Block Grant	1,680	1,685	1,700	+15
Temporary Assistance for Needy Families	16,737	16,739	16,739	0
Temporary Assistance for Needy Families Contingency Fund	608	608	608	0
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Budget Authority	35,347	36,769	36,801	+32
Proposed Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	4,212	+1,295
Child Support Enforcement and Family Support	4,322	4,402	4,458	+56
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,559	9,388	10,060	+672
Promoting Safe and Stable Families (mandatory only) /2	489	995	565	-430
Social Services Block Grant	1,680	1,685	0	-1,685
Temporary Assistance for Needy Families	16,737	16,739	15,245	-1,494
Temporary Assistance for Needy Families Contingency Fund	608	608	0	-608
Refugee and Entrant Assistance (mandatory only)	--	--	200	+200
Total, Proposed Law Budget Authority	35,347	36,769	34,778	-1,991

1/ Reflects Fiscal Year (FY) 2019 Enacted, post required and permissive transfers and rescissions.
2/ FY 2020 includes a one-time FY 2020 appropriation of $500 million for Family First Prevention Services Act implementation, to be used in FY 2020 and FY 2021.
Note: Totals may not add due to rounding.

The Administration for Children and Families (ACF) promotes the economic and social well-being of families, children, individuals, and communities through mandatory programs, including:

- Child Care Entitlement to States;
- Child Support Enforcement;
- Foster Care, Adoption Assistance and Guardianship Assistance;
- Promoting Safe and Stable Families; and
- Temporary Assistance for Needy Families (TANF).

PROMOTING INDEPENDENCE

In all human services work at HHS, the overarching goal is to promote well-being, independence, and self-sufficiency—to help Americans lead safe, 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, promote independence and personal responsibility, 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 support service that helps families achieve self-sufficiency. HHS also 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 President's Fiscal Year (FY) 2021 Budget (Budget) requests $34.8 billion in budget authority for ACF mandatory programs, with an estimated $34.6 billion in outlays. ACF's proposals reform welfare to promote work and economic independence, build strong family bonds to prevent children from entering foster care, promote strong social networks, and achieve efficiencies by reducing government waste and streamlining services.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

The TANF block grant provides states, territories, and eligible tribes the opportunity to design programs that help low-income families transition from welfare to self-sufficiency. The Budget includes $15.2 billion in budget authority for TANF in FY 2021, a decrease of $1.5 billion compared to FY 2020 current law.

The economy has added over 6.7 million jobs in the last 3 years—more than the combined populations of Wyoming, Vermont, Alaska, North Dakota, South Dakota, Delaware, Rhode Island, and Montana. This total is 4.8 million more jobs than the Congressional Budget Office projected for this period. A growing economy produces more jobs, yet our safety net programs are failing to move low-income families from welfare to sustained independence.

Legislative Proposals

Improve TANF by Strengthening Focus on Work and Families

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 created TANF on the principles that work and personal responsibility are key to reducing long-term government dependence and helping those in need achieve economic security. Over the last two decades, many states have lost sight of TANF's purpose, both in its focus on work and in targeting funds to the truly needy. The Budget strengthens TANF's focus on employment and the importance of work preparation by fundamentally changing the way TANF measures success. To fulfill Congress's vision of a program that reduces long-term government assistance, the Budget proposes comprehensive reforms to TANF, including:

- Phasing out the ineffective work participation rate and transitioning to outcome measures that focus on employment and the engagement of all work-eligible TANF recipients in meaningful work activities;
- Requiring a minimum investment from states in work activities and supports;
- Targeting funds to low-income families; and
- Requiring states to spend TANF funds on activities directly related to achieving one or more of the TANF statutory purposes, while phasing out the ability for states to use TANF funds for "activities authorized solely under prior law," an outdated expenditure category.

LEGISLATIVE PROPOSAL STRENGTHENS TANF'S FOCUS ON WORK AND FAMILIES

The proposal also reauthorizes TANF through FY 2025, re-proposes the 10 percent reduction to TANF state/territory grants, and reproposes the elimination of the TANF Contingency Fund from the FY 2020 President's Budget. These reductions, coupled with meaningful reform, refocus TANF funds on welfare-to-work activities, rather than the current broad set of activities that may not help individuals achieve independence. This proposal save $21.3 billion over 10 years.

Statutory limits on TANF reporting and significant differences between state TANF programs make it

impossible for HHS to report an improper payment rate as required by law. The Budget proposes to resolve this problem by giving ACF authority to collect quantitative and qualitative program integrity information from state TANF programs. This will enable the data collection efforts needed to provide information on states' improper payments.

Establish Opportunity and Economic Mobility Demonstrations

Leveraging state innovation to build best practices for helping low-income individuals achieve self-sufficiency, the Budget proposes to create Opportunity and Economic Mobility Demonstrations that will allow states to streamline welfare programs and tailor them to meet the specific needs of their populations. States would be held accountable for achieving targeted outcomes that focus on fostering employment, reducing welfare dependency, and promoting child and family well-being. The Budget provides $100 million in budget authority per year for five years to cover start-up costs, rigorous evaluations, and technical assistance related to these demonstrations.

Reauthorize Healthy Marriage and Responsible Fatherhood

TANF funding supports Healthy Marriage Promotion and Responsible Fatherhood Grants, which promote and encourage healthy marriages and relationships, positive father and family interactions, and other activities that foster social well-being and economic security. Participating fathers are more involved, nurturing, and steadily employed, compared to fathers not participating in the programs. Participating couples have increased levels of supportiveness and affection, have improved co-parenting relationships, are more likely to be married at the one-year follow-up, and have lower rates of severe intimate partner violence among women, compared to couples not receiving the programs. Funding for the grants expires in FY 2020. The Budget proposes a 5-year reauthorization with technical improvements to create greater flexibility in funding awards to eligible entities. This proposal is budget neutral.

CHILD CARE ENTITLEMENT TO STATES

Many Americans are joining the workforce as President Trump's policies continue to strengthen the economy and produce historically low unemployment rates. The Administration supports working families by increasing the investment in child care, an important support service that helps families increase their economic independence and productivity. The Administration is also working to implement policies that increase access to high-quality, affordable child care. ACF released a Request for Information in October 2019 seeking public input in identifying innovative practices to improve access to high-quality child care, as well as on policies that unnecessarily drive up the cost of care or limit child care choices available to parents. HHS also held a series of 10 roundtables around the country to hear about challenges and innovative solutions from the public and private sector, and from child care providers of all kinds. In December 2019, the White House hosted a summit on child care and paid family leave to discuss commonsense, practical reform ideas centered on the principle of putting parents first. These efforts seek to bring more Americans into the workforce and sustain economic growth into the future.

The federal government helps families access and afford child care through both the discretionary Child Care and Development Block Grant (CCDBG) and the Child Care Entitlement program. The Budget includes $4.2 billion in budget authority for the Child Care Entitlement in FY 2021, an increase of $1.3 billion in mandatory funding over FY 2020 enacted. The program provides funding to states and tribes for child care and requires states to spend at least 70 percent of funding on families receiving TANF, transitioning from TANF, or at risk of becoming eligible for TANF. In FY 2021, states must spend a minimum of nine percent of all child care funds, including the CCDBG, to improve the quality and availability of safe child care for all families.

Legislative Proposals

Increase the Child Care Entitlement to States

The Budget reproposes an increase in funding to the Child Care Entitlement program to maintain the federal government's investment in child care. This increase in child care spending offsets program changes to TANF and the elimination of the Social Services Block Grant (SSBG), as states currently spend a portion of TANF and SSBG funds on child care services. This proposal costs $221 million in FY 2021, an increase of $2.2 billion over 10 years.

Build the Supply of Child Care

Many parents struggle to find and afford quality child care, especially in rural areas and during non-traditional work hours. The Budget reproposes 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.

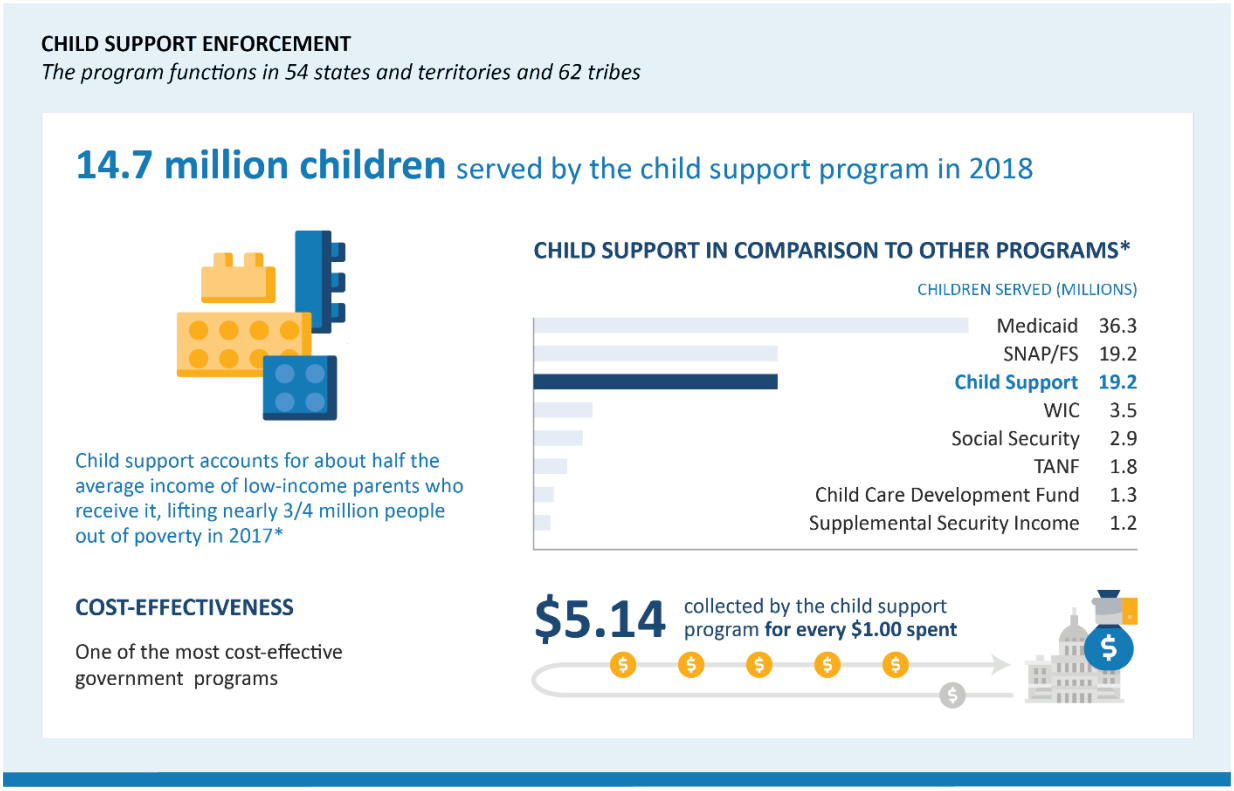
CHILD SUPPORT ENFORCEMENT AND FAMILY SUPPORT PROGRAMS

The Child Support Enforcement Program is a joint federal, state, tribal, and local partnership, operating under Title IV-D of the Social Security Act. The Budget includes $4.5 billion in budget authority for the Child Support Enforcement Program in FY 2021, an increase of $56 million compared to FY 2020 current law. The program allows children to rely on their parents for the financial, emotional, and medical support needed to be healthy and successful, even when parents live in separate households. The program functions in 54 states and territories, and 60 tribes. The Child Support Enforcement Program ensures economic and emotional support for children from both parents by locating noncustodial parents, establishing paternity, supporting access and visitation, and establishing and enforcing child support orders.

Legislative Proposals

Strengthen Child Support Order Establishment and Enforcement

The Budget promotes strong families and responsible parenting by engaging more parents in payment of child support, improving enforcement tools, and encouraging states to promote work programs for noncustodial parents. Currently, there are administrative and legal barriers that limit states, tribes, and federal agencies from coordinating, sharing data, and fully enforcing child support orders. The package of Child Support Enforcement proposals increases program efficiency and reduces burden on federal and state partners. For example, one proposal would authorize the Secretary to take administrative action on behalf of a state to freeze and seize assets in accounts in multistate financial institutions to satisfy child support obligations. Another proposal authorizes tribal child support programs to have direct access to the Federal Income Tax Refund Offset Program to increase child support collections in tribal communities. These proposals are estimated to result in $90 million in offsetting collections related to the TANF program and a combined savings of $354 million to the Supplemental Security Income Program and Supplemental Nutrition Assistance Program over 10 years.



Get Noncustodial Parents to Work

More than just a means of income, work creates opportunities for individual growth, instills personal responsibility and dignity, and provides low-income Americans with a clear pathway out of poverty to financial self-sufficiency and independence. Furthermore, when parents, custodial and noncustodial alike, are employed, they are able to fulfill a key parental responsibility by providing for their children. When noncustodial parents are out of the labor force, they suffer a decrease in life satisfaction and their families suffer from a lack of reliable child support payments.

As part of the Administration's commitment to promoting work and economic independence, the Budget includes a reproposal that allows states to use up to two percent of their child support expenditures to require work activities for all noncustodial parents who owe overdue child support. This proposal will increase regular child support collections, enable noncustodial parents to provide for their children through increased engagement in work activities, and offer families a pathway toward economic independence. This proposal has a net government-wide cost of $184 million over 10 years, including $353 million in HHS costs.

Fund States to Provide Parenting Time Services

Parenting time, or visitation, is time a noncustodial parent spends with the child. Research shows when noncustodial parents engage in their children's lives, they are more likely to meet their financial obligations. Several studies show that joint custody, and access and visitation programs, correlate with increased parent-child contact and child support payments. To improve parent-child relationships and outcomes for children, the Budget reproposes a $25 million increase in federal funding over 10 years for states to include parenting time provisions when establishing child support orders, at state option.

Increase the Repatriation Ceiling

The Child Support account includes the Repatriation program, which provides temporary assistance through service loans to eligible repatriates referred from the United States Department of State. Current law caps repatriation funding at $1 million annually. This amount has been insufficient to fully fund the need for temporary assistance during recent natural disasters. The Budget proposes to increase the annual ceiling on the amount of temporary assistance from $1 million to $10 million. This increase will improve responsiveness in the event of natural disasters or other circumstances when large numbers of Americans have to be repatriated unexpectedly and do not have resources for needs such as temporary housing, meals, healthcare, or transportation. This proposal costs $10 million over 10 years.

CHILDREN'S RESEARCH AND TECHNICAL ASSISTANCE

Children's Research and Technical Assistance supports training and technical assistance to states on child support enforcement activities and the operation of the Federal Parent Locator System (FPLS), which assists state child support agencies in locating noncustodial parents. The FPLS includes the National Directory of New Hires (NDNH), a national database of wage and employment information. The Budget includes $12 million for child support program training and technical assistance, an increase of $1 million over FY 2020. The Budget also includes $25 million to operate the Federal Parent Locator System, an increase of $1 million over FY 2020.

Legislative Proposals

Expand Access to the National Directory of New Hires

Federal and state agencies are increasingly using data matching to verify income and eligibility requirements, identify improper payments, and evaluate participation in certain programs. Currently, a new agency cannot access the new hire and wage data in the NDNH without legislative authorization from Congress.

The Budget includes a package of reproposals to provide access to NDNH for evidence-building and program integrity purposes, while ensuring privacy and security safeguards. Program integrity proposals include strengthening eligibility verification and reducing improper payments. Evidence-building proposals include providing access for statistical agencies and evaluation offices, as well as access for state agencies. If enacted, these proposals would eliminate duplicative efforts to collect the same employment and earnings data already in NDNH and improve government efficiencies. This proposal has no budget impact.

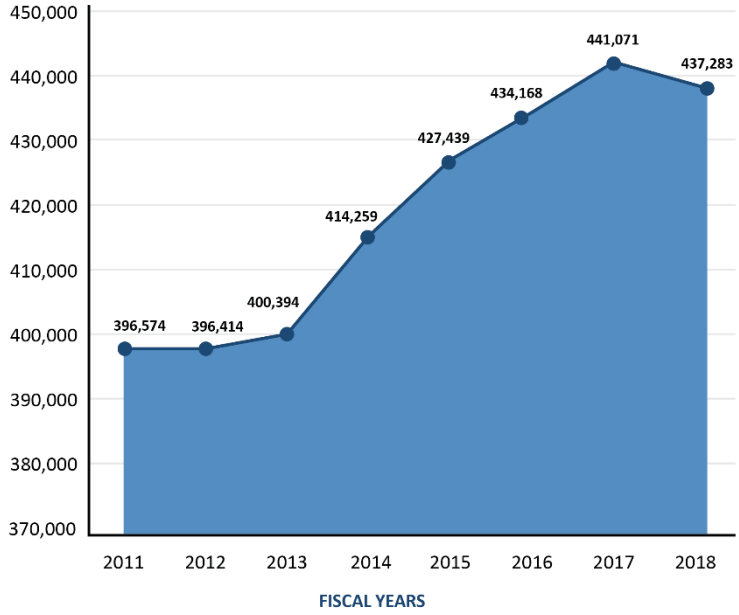
FOSTER CARE AND PERMANENCY

ACF's child welfare vision includes preventing maltreatment and the need for child welfare agency

involvement and foster care, prioritizing family and community, addressing the well-being of both children and their parents, providing services to build the capacity of families and communities to care for children, promoting adoption where reunification is not possible, and developing a healthy, skillful, and stable child welfare workforce.

Although the number of children in foster care is still very high, preliminary data show that the number decreased in FY 2018, for the first time since 2011, to 437,300, a decrease of almost one percent from FY 2017. The number of children entering foster care in FY 2018 decreased to 263,000, a 2.6 percent decrease from FY 2017. The number of children adopted with United States child welfare agency involvement increased for the fourth year in a row, to 63,100—a 6.1 percent increase from FY 2017 and the largest number of adoptions reported since data collection began.

NUMBER OF CHILDREN IN FOSTER CARE DECLINED FOR THE FIRST TIME SINCE 2011
Preliminary FY 2018 data



Source: U.S. Department of Health and Human Services, Administration for Children and Families, Administration on Children, Youth and Families, Children's Bureau Adoption and Foster Care Analysis and Reporting System (AFCARS) Data As Of August 22, 2019

The Foster Care, Adoption Assistance, Guardianship Assistance, Prevention Services, and John H. Chafee Program for Successful Transition to Adulthood programs provide safety and permanency for children separated from their families, support services to prevent child maltreatment and the need for foster care, and prepare older youth in foster care for independence. The Budget includes $10.1 billion for these programs, an increase of $672 million over FY 2020. Funding primarily supports partial reimbursement to states for board and care of eligible children in foster care; partial reimbursement to states for monthly funding to families to support adoption and guardianship; the Chafee Program for Successful Transition to Adulthood, which assists current and former foster youth up to age 23 in obtaining education, employment, and life skills for independence and self-sufficiency and successful transition to adulthood; and the additional services provided under the Family First Prevention Services Act (Family First Act). The additional funding will support the increased number of children participating in the Foster Care and Permanency programs, especially Adoption Assistance, and additional services under the Family First Act.

Increasing permanency for children through adoption, kinship placement, or reunification is a high priority for ACF, especially regarding the more than 125,000 children waiting for adoption and the 20,000 youth who age out of foster care each year without a permanent, forever family to help them grow into stable, responsible, and self-sufficient adults. ACF supports national recruitment and public awareness campaigns and partnerships with states and private, public, and faith-based groups to help find permanent homes for waiting children, especially older youth, sibling groups, and children and youth with disabilities.

Quality legal representation helps states reunify families and promote the well-being and safety of children and providing title IV-E funding for legal representation is within ACF's interpretive discretion. Therefore, in December 2018, ACF made title IV-E funding available for legal representation provided by states for the parents of children in foster care.

ACF plans to publish a final revision of the Adoption and Foster Care Analysis and Reporting System. The revised rule will significantly reduce the reporting burden for states and the Federal government, while

continuing to gather data to meet statutory requirements and program operations, oversight, or budgeting needs.

Family First Prevention Services Act

The Family First Act provides partial federal reimbursement to states for prevention services for children who are at risk of entering foster care, pregnant or parenting foster youth, and their parents or kin caregivers. Federal funding is not limited by whether the child meets title IV-E income eligibility standards. The funds can support mental health and substance abuse services, including opioid misuse, and in-home parent skill-based programs. Preventive services are an opportunity to make substantial improvements in the outcomes of children and families, shifting the mindset of child welfare to keeping families safely together and allowing communities the flexibility to meet the needs of their residents.

The Family First Act restricted federal funding for congregate foster care, often called group homes, in favor of family foster homes. When the Family First Act is fully implemented, federal funding will not be available for new congregate care placements after 14 days, except in limited circumstances with ongoing documentation and judicial review requirements. Twelve states have implemented the congregate care restrictions in the Family First Act, and all states will have fully implemented it by the end of FY 2021.

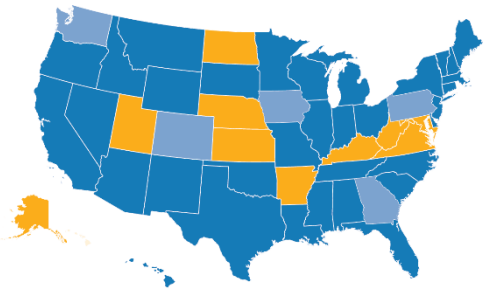
ACF is implementing the Family First Act to enhance child well-being, strengthen families and communities to prevent the need for foster care, safely reunify families, and provide permanency through adoption or guardianship when reunification is not possible. Under the Family First Act, ACF has approved 10 prevention services programs for federal funding, and is continuing to review additional programs. To speed implementation, ACF is allowing states to apply for and receive funding on a transitional basis for prevention services programs with documented evidence of effectiveness until ACF is able to complete its review and evaluation of such programs.

Legislative Proposals

Improvements to the Family First Prevention Services Act

The Family First Act directs ACF to operate a clearinghouse to review the effectiveness of prevention services programs. This clearinghouse requirement has limited the speed of Family First Act implementation because programs are not eligible for federal funding until the clearinghouse assesses the program as effective. The proposal allows ACF to approve all programs currently rated as evidence-based by the California Evidence-Based Clearinghouse and the HHS Home Visiting Evidence of Effectiveness Project, and modifies the review standard in the Family First Act to make it more similar to the standards utilized by the California Evidence-Based Clearinghouse. This change expedites review of programs to serve more children and families, which will increase spending by $1.2 billion over 10 years. The proposal also includes more flexibility for tribes in meeting title IV-E prevention services and funding eligibility requirements, reducing administrative burden for tribes and focusing child welfare programs on outcomes rather than bureaucracy.

IMPLEMENTATION OF PREVENTION SERVICES AND CONGREGATE CARE RESTRICTIONS IN THE FAMILY FIRST PREVENTION SERVICES ACT



Note: Puerto Rico and the U.S. Virgin Islands will implement in FY 2021.

Exempt Qualified Residential Treatment Programs from Medicaid IMD Payment Exclusion

The Family First Act allows title IV-E funding for placements in group foster care programs that provide treatment for serious emotional or behavioral

conditions and meet certain quality standards, referred to as qualified residential treatment programs (QRTPs). However, on and off-site services provided to foster children while residing in QRTPs may not be covered by Medicaid if those QRTPs qualify as institutions for mental diseases (IMDs) under current law. In collaboration with the Centers for Medicare & Medicaid Services, the Budget proposes a legislative fix to make QRTPs exempt from the IMD payment exclusion allowing children in IV-E foster care through age 18 or 21, depending on state law, to have Medicaid coverage in these placements even if a QRTP qualifies as an IMD (see the CMS Medicaid chapter for further discussion). This change is budget-neutral for the Foster Care and Permanency Program.

New Flexibilities and Support for Youth Who Age Out of Foster Care

Approximately 20,000 youth exit or "age out" of foster care each year. 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 by age 26. Youth who age out of foster care are also at increased risk of young parenthood, criminal justice system involvement, and other adverse outcomes.

ACF proposes to provide more flexibility in the John H. Chafee Foster Care Program for Successful Transition to Adulthood, lowering the age youth experienced foster care to 14 for eligibility for state education and employment services and housing assistance. This proposal allows a larger range of youth to access supports that can improve their successful transition to adulthood and ensures that older youth do not lose their eligibility for Chafee program benefits if adopted before age 16. The proposal also provides $12 million per year for competitive grants to research and develop improved strategies and effective services for youth in or transitioning out of foster care.

Promote Family Based Care

Many places around the country are struggling to recruit enough foster parents to provide family homes for children who have more complex behavioral, physical, or emotional needs. Under the Family First Act, congregate care placements require an assessed and documented need, meaning that more family homes are needed for children who are no longer eligible for congregate care, but need additional support. The Promote Family Based Care proposal will invest $251 million over 10 years to increase availability of family homes by allowing federal funding to reimburse states to pay salaries to foster parents who provide family homes for children with qualifying needs.

Create a Child Welfare Flexible Funding Option

Preventing entry into foster care is key to avoiding unnecessary trauma, disrupting intergenerational cycles of maltreatment, and achieving better outcomes for children and families. The proposal builds on the Family First Act by expanding resources available for the full spectrum of child welfare services, regardless of eligibility for foster care. Under current law, federal funds for foster care maintenance payments are only available for costs related to children who meet certain income qualifications, and expenses must be tracked for each child. The Flexible Funding Option allows federal funds to reimburse spending on any of the purposes or services authorized for child welfare spending under titles IV-E and IV-B of the Social Security Act in addition to the costs of foster care, adoption, guardianship, and for services authorized by the Family First Act.

This approach removes burdensome and prescriptive title IV-E eligibility reviews, refocusing the program and increasing the resources available to improve child and family outcomes and to prevent child maltreatment before it occurs. It empowers states to invest broadly in services that promote permanency and stability for children, tailored to each state's child welfare needs, such as addressing the impact of opioid misuse on families and children. The Federal Government would continue to monitor states' performance through Child and Family Services Reviews. This proposal is budget neutral.

Create Child and Family Services Review Incentives

Child and Family Services Reviews are a national assessment of state child welfare systems' outcomes and compliance, with penalties for poor performance. Performance on Child and Family Services Reviews has been poor, with no states in substantial conformity with all metrics. The Budget proposes a demonstration project to offer incentives to states to improve performance on Child and Family Services Reviews and to reinvest penalties for poor performance in child welfare improvement plans. This change will provide flexibility for states to invest in targeted performance improvements, and will keep child welfare funding focused on preventive services and other needs of

children and families. The incentives add a 10-year investment of $143 million.

PROMOTING SAFE AND STABLE FAMILIES

The Promoting Safe and Stable Families program provides formula grants to states for services to families to improve child safety at home. The grants also fund supportive services for reunifying and adoptive families, which promotes safety and permanency for children and families and avoids foster care. The Budget includes $415 million in mandatory funding for the program for FY 2021, an increase of $70 million over FY 2020 (excluding the FY 2020 appropriation of $500 million for Family First Act implementation, to be used in FY 2020 and FY 2021). Funding supports Court Improvement Program grants to state and tribal courts to improve the quality of child welfare proceedings and to transition to compliance with the Family First Act. Promoting Safe and Stable Families also includes Regional Partnership Grants, a competitive grant program that addresses the child welfare impact of substance abuse, including opioids. In recent years, parental substance abuse has grown as a circumstance associated with entry into foster care. The Regional Partnership Grant program helps to address this problem by supporting interagency collaboration and integration of programs to prevent the need for foster care and better serve children and families.

Legislative Proposals

Modernize and Expand the Court Improvement Program

The ongoing opioid crisis has required judges and court personnel to stay up-to-date on evidence-informed practices and to make timely and well-informed child welfare decisions. The Family First Act requires courts to review certain foster care placements under new rules. The Budget increases funding for the Court Improvement Program, already funded at $30 million per year, by an additional $30 million per year to help courts improve their practices and transition to compliance with the new requirements of the Family First Act, such as reviewing congregate care placements and providing training for judges, attorneys, and legal personnel working in child welfare cases.

Expand Regional Partnership Grants

Many communities are experiencing an increase in foster care and in child welfare cases involving substance abuse. The Budget increases funding to expand Regional Partnership Grants by $40 million per year to serve more communities, especially rural communities affected by substance use disorders including opioid misuse, and provides flexibility for a shorter planning period. These grants increase the well-being of, improve permanency for, and enhance the safety of children who are in, or at risk of, an out-of-home placement as a result of a parent's or caregiver's opioid or other substance abuse. Results from the first round of grants show that the majority of participating children at risk of removal remained in their parent's custody, most children in out-of-home placements achieved timely reunifications with their parent(s), and after returning home, very few re-entered foster care.

Reauthorize the Personal Responsibility Education Program and the Sexual Risk Avoidance Education Program

Promoting Safe and Stable Families includes the Personal Responsibility Education Program and the Sexual Risk Avoidance Education Program (formerly known as Abstinence Education). The Personal Responsibility Education Program provides formula grants to states, and competitive grants to tribes and local organizations, to educate adolescents on pregnancy prevention, sexually transmitted diseases, and adulthood preparation subjects such as healthy relationships and financial literacy. The Sexual Risk Avoidance Education Program provides formula grants to states and territories, and competitive grants to local organizations, for projects that educate youth on the health benefits of avoiding non-marital sexual activity. Programs focus on youth who are homeless, in foster care, live in rural areas or areas with high teen birth rates, or come from racial or ethnic minorities with disparities in teen birth rates. The Budget proposes a two-year reauthorization of each program at their current levels of $75 million each in mandatory funding per year, to continue promoting healthy choices, life skills, abstinence, and reduced teenage pregnancy.

SOCIAL SERVICES BLOCK GRANT

The Social Services Block Grant (SSBG) supports a broad array of social services for children and adults. The SSBG account also includes the Health Profession Opportunity Grants (HPOG) program. HPOG demonstration projects provide TANF recipients and other low-income individuals with education and training for occupations in the healthcare field. The Budget does not propose reauthorizing HPOG because there are other federal funding streams within the Department of Labor and TANF that can be utilized to help support employment and training opportunities, including apprenticeships.

Legislative Proposals

Discontinue Social Services Block Grant Funding to States and Territories

The Budget eliminates funding for SSBG. The Administration's goal is to support welfare programs that effectively help low-income families move to independence through paid employment, and to focus limited taxpayer dollars on program outcomes. A 2011 Government Accountability Office report noted that SSBG is fragmented, provides duplicative or overlapping services, and has limited accountability. The program lacks strong performance measures and has not demonstrated effectiveness in improving economic and social well-being. Recognizing grantees sometimes use SSBG to provide rapid and flexible funding for disaster relief, the Budget maintains the program's authorization for possible future use in emergencies.

REFUGEE AND ENTRANT ASSISTANCE

The Budget provides up to $2 billion in mandatory funding for an Unaccompanied Alien Children Contingency Fund. See the Unaccompanied Alien Children section of the ACF Discretionary chapter for a program description.

Administration for Children and Families: Mandatory

FY 2021 ACF Mandatory Outlays

	dollars in millions			2021 +/-
	2019 /1	2020	2021	2020
Current Law Outlays				
Child Care Entitlement to States	3,244	2,961	2,960	-1
Child Support Enforcement and Family Support	4,117	4,324	4,351	+27
Children's Research and Technical Assistance	36	33	38	+5
Foster Care and Permanency	8,599	9,389	9,910	+521
Promoting Safe and Stable Families (mandatory only)	421	607	779	+172
Social Services Block Grant	1,646	1,715	1,712	-3
Temporary Assistance for Needy Families	15,496	16,106	16,788	+682
Temporary Assistance for Needy Families Contingency Fund	600	608	608	0
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Outlays	34,159	35,743	37,146	+1,403
Proposed Law Outlays				
Child Care Entitlement to States	3,244	2,961	3,231	+270
Child Support Enforcement and Family Support	4,117	4,324	4,370	+46
Children's Research and Technical Assistance	36	33	38	+5
Foster Care and Permanency	8,599	9,389	9,955	+566
Promoting Safe and Stable Families (mandatory only)	421	607	801	+194
Social Services Block Grant	1,646	1,715	352	-1,363
Temporary Assistance for Needy Families	15,496	16,106	15,715	-391
Temporary Assistance for Needy Families Contingency Fund	600	608	0	-608
Refugee and Entrant Assistance (mandatory only)	--	--	130	+130
Total, Proposed Law Outlays	34,159	35,743	34,592	-1,151

1/ Reflects FY 2019 Enacted, post required and permissive transfers and rescissions.
Note: Totals may not add due to rounding.

Administration for Children and Families: Mandatory

FY 2021 ACF Mandatory Budget Proposals, Outlays

dollars in millions	2021	2021 -2025	2021 -2030
Proposed Law Outlays			
Promoting Independence			
Temporary Assistance for Needy Families (TANF)			
Improve TANF by Strengthening Focus on Work and Families	-1,703	-10,244	-21,309
Reduce the TANF Block Grant (non-add)	*-1,095*	*-7,204*	*-15,229*
Eliminate the TANF Contingency Fund (non-add)	*-608*	*-3,040*	*-6,080*
Provide for Alternative Improper Payments Reporting for TANF (non-add)	--	--	--
Remake the Safety Net Through Opportunity and Economic Mobility Demonstrations	22	300	500
Reauthorize Healthy Marriage and Responsible Fatherhood	--	--	--
Subtotal, TANF (non-add)	***-1,681***	***-9,944***	***-20,809***
Child Care Entitlement			
Increase the Child Care Entitlement to States	221	1,103	2,183
Build the Supply of Child Care	50	1,000	1,000
Subtotal, Child Care Entitlement (mandatory) (non-add)	***271***	***2,103***	***3,183***
Child Support Enforcement			
Strengthen Child Support Establishment and Enforcement (Child Support impact) /1	--	--	--
Get Noncustodial Parents to Work (Child Support impact) /2	17	125	353
Fund States to Provide Parenting Time Services	1	8	25
Increase the Repatriation Ceiling	1	5	10
Subtotal, Child Support Enforcement (non-add)	***19***	***138***	***389***
Children's Research and Technical Assistance (CRTA)			
Expand Access to National Directory of New Hires /3	--	--	--
Subtotal, CRTA (non-add)	***--***	***--***	***--***
Foster Care and Permanency			
Improve the Family First Prevention Services Act and Conforming Amendments	--	268	1,221
Exempt Qualified Residential Treatment Programs from Medicaid IMD Payment Exclusion (ACF Impact)	--	--	--
Create New Flexibilities and Support for Youth Who Age Out of Foster Care	12	60	120
Promote Family Based Care	8	112	251
Create Child Welfare Flexible Funding Option	--	--	--
Create Child and Family Services Review Incentives	7	50	143
Subtotal, Foster Care and Permanency (non-add)	***27***	***490***	***1,735***
Promoting Safe and Stable Families (PSSF)			
Modernize and Expand the Court Improvement Program	8	121	271
Expand Regional Partnership Grants	10	159	359
Reauthorize the Personal Responsibility Education Program	2	145	150

FY 2021 ACF Mandatory Budget Proposals, Outlays

dollars in millions	2021	2021 -2025	2021 -2030
Reauthorize Title V Sexual Risk Avoidance Education	2	140	150
Subtotal, PSSF (non-add)	***22***	***565***	***930***
Social Services Block Grant (SSBG)			
Discontinue Social Services Block Grant Funding to States and Territories	-1,360	-8,092	-16,592
Interaction with Discontinue Social Services Block Grant Funding to States and Territories and the Foster Care Account	18	114	239
Subtotal, SSBG (non-add)	***-1,342***	***-7,978***	***-16,353***
Refugee and Entrant Assistance			
Establish an Unaccompanied Alien Children Contingency Fund	130	199	200
Subtotal, Refugee and Entrant Assistance (non-add)	***130***	***199***	***200***
Total Outlays, ACF Mandatory Legislative Proposals	***-2,555***	***-14,428***	***-30,725***

1/ The Strengthen Child Support Establishment and Enforcement proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-$261 million over 10 years), the Supplemental Security Income program (-$93 million over 10 years), or the Federal Offsetting Collections related to recoveries to the TANF program (-$90 million over 10 years).
2/ The Get Noncustodial Parents to Work proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-$116 million over 10 years), the Supplemental Security Income program (-$15 million over 10 years), or the Federal Offsetting Collections related to recoveries to the TANF program (-$38 million over 10 years).
3/ This proposal does not incorporate savings to the U.S. Department of Agriculture (-$180 million over 10 years).

Administration for Community Living

	dollars in millions			2021
	2019/1	2020	2021	+/- 2020
Health and Independence				
Home and Community-Based Supportive Services	385	390	390	--
Nutrition Programs	906	937	937	--
Native American Nutrition and Supportive Services	34	35	35	--
Preventive Health Services	25	25	25	--
Chronic Disease Self-Management Education and Falls Prevention	13	13	--	-13
Aging Network Support Activities	16	12	12	-1
Subtotal, Health and Independence	**1,379**	**1,412**	**1,398**	**-14**
Caregiver Services				
Family Caregiver Support Services	181	186	151	-35
Native American Caregiver Support Services	10	10	10	--
Alzheimer's Disease Program	20	27	27	--
Lifespan Respite Care	4	6	3	-3
Subtotal, Caregiver Services	**215**	**229**	**191**	**-38**
Protection of Vulnerable Older Adults				
Long-Term Care Ombudsman Program	17	18	16	-2
Prevention of Elder Abuse and Neglect	5	5	5	--
Senior Medicare Patrol Program	18	18	18	--
Elder Rights Support Activities	16	16	18	+2
Subtotal, Protection of Vulnerable Older Adults	**55**	**57**	**57**	**--**
Disability Programs, Research, and Services:				
Intellectual and Developmental Disabilities Programs	169	173	128	-44
National Institute on Disability, Indep. Living, and Rehab Research	109	112	90	-22
Independent Living	116	116	114	-2
Traumatic Brain Injury	11	11	11	--
Limb Loss Resource Center	3	4	4	--
Paralysis Resource Center	9	10	10	--
Subtotal, Disability Programs, Research and Services	**417**	**426**	**357**	**-68**
Consumer Information, Access, and Outreach				
Voting Access for People With Disabilities	7	7	7	--
Assistive Technology	36	37	32	-5
Aging and Disability Resource Centers	8	8	6	-2
State Health Insurance Assistance Program	49	52	36	-16
Medicare Improvements for Patients and Providers Act Programs	38	38	38	--
Current Law Mandatory/2	*38*	*24*	*--*	*-24*
Proposed Law Mandatory	*--*	*14*	*38*	*+24*
Subtotal, Consumer Information, Access and Outreach	**138**	**142**	**119**	**-23**
Other Programs, Total and Less Funds From Other Sources				
ACL Program Administration	41	41	42	+1
Total, Program Level	**2,245**	**2,306**	**2,164**	**-143**
Less Funds from Other Sources	83	83	56	-28
Total, Budget Authority	**2,162**	**2,223**	**2,108**	**-115**
Full-Time Equivalents	180	189	195	+6

1/ Reflects FY 2019 Enacted, post required and permissive transfers and rescissions, except the NSIP transfer to USDA of $1.9 million.

2/ The FY 2020 appropriation extended the ACL MIPPA programs through May 22, 2020. The President's Budget extends funding for these programs at the annualized level through FY 2021.

The Administration for Community Living maximizes the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.

The Administration for Community Living (ACL) works to ensure that older adults and people of all ages with disabilities can live independently, with dignity, and participate fully in their communities. To that end, ACL invests in direct services, as well as research, training, and innovation. Community living is overwhelmingly preferred by Americans. It also is typically far less expensive than other options, such as skilled nursing facilities or residential facilities which usually are not covered by private insurance – costs for residential care are most often paid by Medicaid, followed by out-of-pocket payments by individuals and families.

IMPORTANCE OF COMMUNITY LIVING

WHAT IS COMMUNITY LIVING?

People with disabilities and older adults have the same opportunities as everyone else to:

- *Choose for themselves where to live*
- *Earn a living*
- *Lead the lives they want*
- *Make decisions about their lives*

HOW ACL SUPPORTS COMMUNITY LIVING

FUNDING *services that help people live independently*

INVESTMENTS *in research, innovation, training, and education*

ADVOCACY *for people with disabilities and older adults*

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $2.2 billion for ACL. This total includes $2.1 billion in discretionary budget authority and $56 million in mandatory funding. The Budget prioritizes funding for direct services, such as nutrition programs that help older adults maintain their health and live in their own homes; supports such as adult day care, personal care, and chore services; and initiatives to increase employment opportunities for people with disabilities.

PROMOTING HEALTH, SAFETY, AND COMMUNITY LIVING FOR OLDER AMERICANS

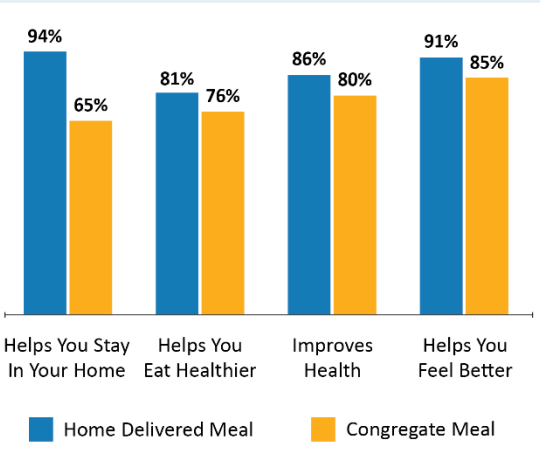
Between 2016 and 2025, the number of older adults in the United States ages 65 and older is projected to increase by 32 percent, from 49 million to over 65 million. This growth will increase the need for the direct service and community-based programs ACL provides, to ensure that older adults can thrive in their communities.

Nutrition Services Programs

Research indicates that good nutrition is vital to preventing common chronic conditions such as heart disease and diabetes. ACL's Congregate and Home-Delivered Nutrition Programs annually serve approximately 2.24 million older adults, many of whom are at high risk for hospitalization or entering nursing homes. The Budget provides $937 million for Senior Nutrition programs. This investment will enable states and communities to provide over 214 million meals, through home delivery and in congregate settings such as community centers, to 2.25 million older adults in FY 2021.

RESULTS OF NUTRITION PROGRAM RECIPIENTS SURVEY (%YES)

Depicts home-delivered and congregate meal feedback on ACL's Nutrition Programs



Home and Community-Based Supports

The Budget includes $425 million for Home and Community-Based Supportive Services and Native

American Nutrition and Supportive Services. These programs provide formula grants to 56 states and territories as well as 273 tribes to help older adults, with and without disabilities, live independently and avoid more expensive care settings. In FY 2021 this program is projected to provide 17.9 million rides to doctor's offices, 52.2 million hours of personal care and chore services, and 13.1 million hours of adult day care.

Meeting the highly varied needs of a rapidly growing older adult population and ensuring responsiveness to local needs requires innovative service delivery approaches. The Budget includes a new proposal to allow up to one percent of funds appropriated for the Home and Community Based Supportive Services program to be used to implement and evaluate such approaches. Investment opportunities include exploring the benefits of intergenerational programming for older adults, expanding the practical uses of technology in delivering services, and modernizing senior and community centers to better meet the needs of the local population.

ACL has effectively implemented a similar approach for the Senior Nutrition programs, which has resulted in innovative practices that are replicable across its network of grantees. These innovations include the use of in-home artificial intelligence technology to facilitate communication and food-ordering and increasing knowledge and self-management of certain chronic diseases to reduce hospitalizations.

Protection of Vulnerable Older Adults

Approximately 1 in 10 Americans age 60 and older are abused or neglected every year. Because research shows that elder abuse is widely under-reported to appropriate state systems, the actual prevalence is likely much higher. The Budget provides $39 million to protect vulnerable older adults, which includes $16 million to support the presence of ombudsmen in long-term care facilities in all states and $14 million to support ongoing development of state Adult Protective Service systems in 20 states. These investments also fund the National Center on Elder Abuse, Elder Justice Innovation Grants, and activities designed to raise awareness about elder abuse and enhance state systems to address it.

Research is starting to shed light on the disproportionate and growing impact of the opioid crisis on older adults. For example, a recent CDC study showed that from 2016-2017, adults 55 and older had a larger increase in emergency room visits due to suspected opioid overdose than those ages 25 to 34. States also have reported increases in the number of Adult Protective Services cases related to opioid use. In recognition of these trends, the Budget includes $6 million to support grants to five states and two tribes to identify gaps in their Adult Protective Service systems and propose solutions to quickly and adequately address cases of opioid-related abuse.

Preventing Medicare Fraud

The Budget provides $18 million for the Senior Medicare Patrol program, which supports nearly 7,000 Senior Medicare Patrol team members nationally, who serve as front-line resources for identifying and preventing Medicare fraud across the country. This investment will enable Senior Medicare Patrol programs to conduct education and outreach to over 1.7 million people across all 56 states and territories in FY 2021. In 2019, volunteers successfully alerted the HHS Office of the Inspector General about increased prevalence of genetic-testing schemes targeting Medicare beneficiaries. This alert led to an investigation that ultimately resulted in identification of over $2.1 billion in losses, as well as an increased outreach to prevent future losses.

Other Aging Programs

The Budget provides $36 million to help seniors through Preventive Health Services and Aging Network Support Activities. Aging Network Support Activities includes funding for the Holocaust Survivor's Assistance Fund which has provided trauma-informed services to over 13,000 Holocaust survivors since 2015.

The Budget consolidates the Falls Prevention Program and the Chronic Disease Self-Management Program into the Preventive Health Services Program, which prevents chronic disease and disability through formula grants to all 50 states, the District of Columbia and 5 territories for evidence-based interventions. This consolidation allows states to more effectively target resources to address local needs.

FAMILY CAREGIVER SUPPORT

An estimated 43 million caregivers provide care for an older adult or support for a family member with a disability each year in the United States. The economic value of this care is approximately $470 billion per year. These caregivers provide a critical source of support to older adults and people with disabilities,

many of whom would otherwise be at risk of institutionalization.

ACL serves caregivers through the Family Caregiver Support Services, Native American Caregiver Support Services, and Lifespan Respite Care programs. These programs provide critical services such as counseling, respite care, and training that enable caregivers to continue providing care to their loved one. The Budget provides $164 million for these programs to support both family and other informal caregivers.

In FY 2021, ACL's caregiver support programs will serve approximately 757,000 family caregivers. In addition to these efforts, ACL will continue to support the Recognize, Assist, Include, Support, and Engage (RAISE) Family Caregivers Act Advisory Council and the Supporting Grandparents Raising Grandchildren Act Advisory Council. These advisory councils will continue to provide recommendations to the Secretary of Health and Human Services on effective models of both family caregiving and support to family caregivers, as well as ways to improve coordination across federal government programs.

Alzheimer's Disease

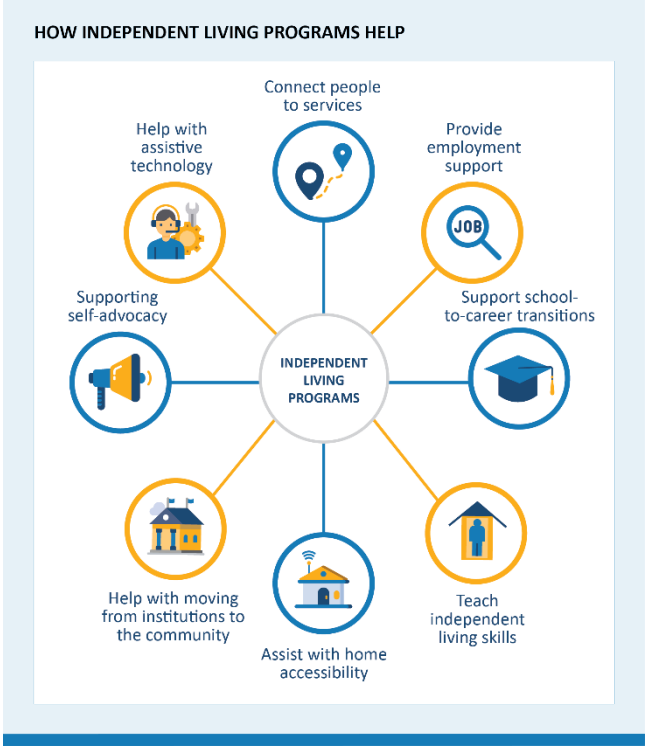
An estimated 5.8 million people are living with Alzheimer's disease and related dementias in the United States. In 2019, an estimated 16 million people provided over 18.5 billion hours of unpaid care to these individuals, who often have unique health needs. The Budget includes $27 million for ACL's Alzheimer's Disease Program to fund grants for states, tribes and community based organizations. This program works to address gaps in existing service-systems that support people with Alzheimer's disease and their caregivers, and operates the National Alzheimer's Call Center and the National Alzheimer's and Dementia Resource Center. These activities collectively increase the availability and effectiveness of dementia-capable services and supports for people with Alzheimer's and their caregivers.

EMPOWERING PEOPLE OF ALL AGES WITH DISABILITIES TO PARTICIPATE FULLY IN THEIR COMMUNITIES

Sixty-one million adults, or 26 percent of the adult population in the United States, have some type of disability. ACL works with states, territories, and community-based organizations to ensure that people with disabilities across the lifespan have access to the services and supports needed to thrive in their communities.

Independent Living

ACL's Independent Living programs are rooted in the belief that people with disabilities should be able to live independently in their communities, with the same opportunities as people without disabilities. These programs provide tools, resources, and supports, such as independent living skills training, assistance with transitioning from residential facilities to the community, and peer counseling. The Budget provides $114 million to support over 350 Centers for Independent Living and the operation of a State Council for Independent Living in each state and territory.



People with disabilities disproportionately face barriers to employment. In 2018, 19 percent of people with disabilities were employed, compared with 66 percent of the general population. Evidence overwhelmingly suggests that employment improves economic mobility as well as physical and mental health outcomes. The Budget includes $5 million within Centers for Independent Living funding to test evidence-based models of employment training and support that could be adopted by Centers for Independent Living to improve employment outcomes for people with disabilities.

Supporting Individuals with Limb Loss, Paralysis, and Traumatic Brain Injury

Across the United States, there are an estimated 2.1 million individuals living with limb loss and 5.4 million individuals living with paralysis. The Budget provides $4 million for the Limb Loss Resource Center and $10 million for the Paralysis Resource Center. These programs provide information, referral, education, outreach, and training services to individuals living with limb loss and paralysis.

Each year, approximately 2.5 million people are hospitalized due to traumatic brain injuries, which often result in long-term disabilities. The Budget includes $11 million for the Traumatic Brain Injury program to establish and strengthen coordinated, family-centered systems of care for individuals who sustain a traumatic brain injury. These individuals and their caregivers often need to access services that are fragmented across state systems. This funding helps states address this fragmentation, enhancing service delivery.

Intellectual and Developmental Disabilities Programs

The Budget invests $128 million in programs, research, and services that promote community living for people with intellectual and developmental disabilities. This includes State Councils on Developmental Disabilities ($56 million), Developmental Disabilities Protection and Advocacy ($39 million) programs, University Centers for Excellence in Developmental Disabilities ($33 million), and Projects of National Significance ($1 million). Collectively, these programs provide vital services to individuals with intellectual and developmental disabilities and their families, such as legal protection, systems advocacy, community education, research, and information dissemination.

Generating New Knowledge to Improve the Lives and Abilities of People with Disabilities

The Budget provides $90 million for the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), to invest in applied research that improves society's capacity to provide full opportunities and accommodations for people with disabilities. NIDILRR funds comprehensive research and related activities to maximize the full inclusion, social integration, employment and independent living of individuals with disabilities of all ages.

CONSUMER INFORMATION, ACCESS, AND OUTREACH

ACL's consumer information, access, and outreach programs provide older adults and people with disabilities with the information they need to make informed decisions and access appropriate supportive services.

Voting Access for People with Disabilities

Americans with disabilities have the same fundamental right to participate in the electoral process as those without disabilities. The Budget provides $7 million for grants to states and non-profit organizations to protect this right. This investment supports activities such as training election officials and poll workers on voting accessibility rights, conducting outreach to the disability community on accessible voting locations, and identifying and implementing modifications to make polling places more accessible.

State Health Insurance Assistance Programs

The Budget provides $36 million for State Health Insurance Assistance programs, which help Medicare beneficiaries understand, select, and access their benefits. In 2017, State Health Insurance Assistance programs provided 1.75 million hours of direct services to 3.5 million Medicare beneficiaries, and educated an additional 3 million people through public outreach events. Services help beneficiaries make informed health insurance decisions that optimize access to care and benefits, such as reducing costs on prescriptions, co-pays, deductibles and other benefit options. Grantees also assist beneficiaries with limited income and assets enroll in the Medicare Savings Program and Low Income Subsidy to reduce their Medicare out-of-pocket costs.

RESPONSIBLE STEWARDSHIP AND DELIVERY OF SERVICES

Program Administration

The Budget includes $42 million for program management and support activities. This funding supports critical investments in information technology and human capital necessary for ACL to responsibly administer programs and provide adequate oversight.

Office of the Secretary, General Departmental Management

	dollars in millions			
	2019	2020	2021	2021 +/- 2020
General Departmental Management				
Discretionary Budget Authority /1	484	480	347	-133
Public Health Service Evaluation Funds	65	65	74	+9
Total, Discretionary Program Level	**549**	**545**	**421**	**-124**
Full-Time Equivalents	976	1,019	995	-24

1/ FY 2019 reflects the 2019 Enacted level, post 2019 Secretary's Transfer from ACF and CMS.
2/ This table does not include funding of Full-Time Equivalents for the Pregnancy Assistance Fund, allocation for Healthcare Fraud and Abuse Control Program, or funding for the Physician-Focused Payment Model Technical Advisory Committee created by the Medicare Access and CHIP Reauthorization Act of 2015.

General Departmental Management supports the Secretary's role as chief policy officer and general manager of the Department.

LEADING THE NATION'S PUBLIC HEALTH ENTERPRISE

The U.S. Department of Health and Human Services (HHS) Secretary administers and oversees the largest cabinet Department, directing an annual budget of over $1 trillion that accounts for almost one out of every four federal dollars, and administers more grant dollars than all other federal agencies combined. The Secretary oversees HHS programs, policies, and operations to ensure effective stewardship of Department resources to enhance and protect the health and well-being of every American. The HHS Office of the Secretary's administrative budget is less than 0.02 percent of the total $1,428 billion HHS budget, and funds leadership, policy, legal, and administrative functions that help to support 11 Staff Divisions and provide management oversight for the Department as a whole.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests a program level of $421 million for General Departmental Management. The Budget ensures health policy and program coordination across the Department as well as supporting Administration priorities such as the *Ending the HIV Epidemic: A Plan for America* initiative.

PUBLIC HEALTH POLICY AND PROGRAM COORDINATION

The Office of the Assistant Secretary for Health (OASH) serves as the senior advisor to the Secretary for public health, science and medicine, and coordinates public health policy and programs across the HHS Operating and Staff Divisions. Additionally, the Assistant Secretary for Health (ASH) oversees the Office of the Surgeon General and the United States Public Health Service Commissioned Corps (Corps).

OASH oversees 11 core program offices, including the Office of Minority Health and the Office on Women's Health, that lead policy coordination across the Department, the government, and with nongovernmental partners. This coordination enables the Department to address a diverse range of public health challenges, including combatting the nation's opioid epidemic and ending the HIV epidemic in America. OASH focuses on supplying information and tools that empower individuals, communities, and health systems to emphasize health promotion and disease prevention.

MINORITY HIV/AIDS FUND

The Budget includes $54 million for the Minority HIV/AIDS Fund. These funds transform HIV prevention, care, and treatment for minority communities. To jumpstart implementation of the *Ending the HIV Epidemic: A Plan for America* initiative, the Budget leverages pilot programs started in FY 2019 in three jurisdictions (Baltimore City, MD; East Baton Rouge, LA; and DeKalb County, GA) and the Cherokee Nation in Oklahoma. The key strategies in the plan focus on increasing investments in geographic hotspots through effective new and existing programs, using data to

identify where HIV is spreading most rapidly to target treatment needs at the local level, and support jurisdictions to establish local teams committed to the success of the initiative.

OFFICE OF MINORITY HEALTH

The Budget includes $59 million for the Office of Minority Health. The Office of Minority Health leads, coordinates, and collaborates on minority health activities across the Department, including leadership in coordinating policies, programs, and resources to reduce healthcare disparities and advance health equity in America.

OFFICE ON WOMEN'S HEALTH

The Budget includes $34 million for the Office on Women's Health and funds prevention initiatives, addressing maternal mortality and health communication activities. The Office on Women's Health continues to support the advancement of women's health programs with other government organizations and consumer and health professional groups, with a special emphasis on maternal health.

OFFICE OF SURGEON GENERAL AND UNITED STATES PUBLIC HEALTH SERVICE COMMISSIONED CORPS

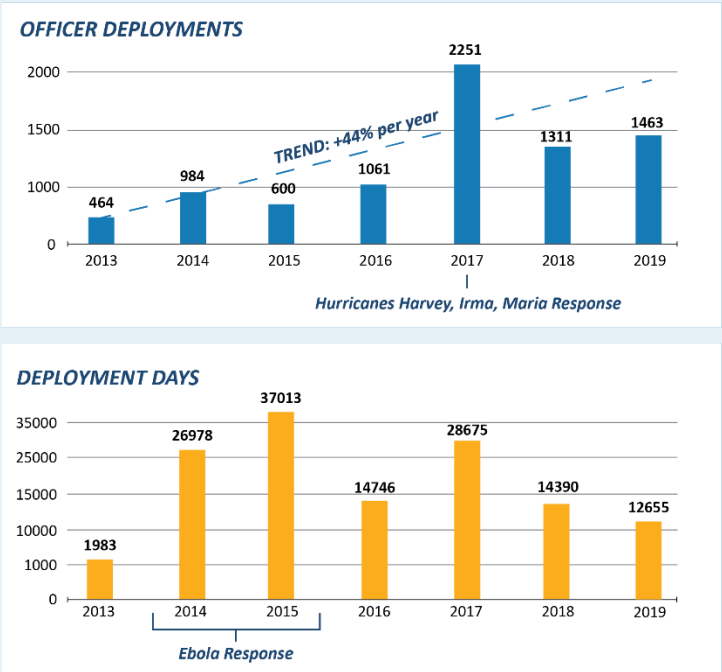
As the nation's doctor, the Surgeon General provides Americans with the best scientific information available on how to improve their health and reduce the risk of illness and injury. The Surgeon General manages the daily operations of the Corps, which consists of approximately 6,400 uniformed public health professionals who underpin the nation's response network for public health emergencies. Corps officers, including physicians, nurses, dentists, pharmacists, social workers, and engineers have supported the United States government's response to natural disasters and other public health emergencies.

Corps deployments increased an average of 44 percent annually over the past six years. Recent deployments include critical support to West Africa for the 2014-2015 Ebola response; public health support for displaced families during hurricanes Harvey, Irma, and Maria in 2017; medical screenings and primary care for migrant children and families at the southwestern border in 2018-2019, and other unexpected public health crises that the Corps mobilizes to address.

In FY 2019, the ASH completed a comprehensive self-assessment of the Corps, establishing a clearly defined strategy and mission for the 21st century. As part of reforming and improving the Corps, the ASH plans to establish the Ready Reserve to provide surge capacity for deployments in public health emergencies, and backfill critical positions left vacant during regular Corps deployments. The Budget provides $5 million within the Immediate Office of the ASH to continue implementation of the Ready Reserve.

The Budget also includes new funding of $11 million in the Public Health and Social Services Emergency Fund (PHSSEF) to support Corps officer training to prepare for additional and more complex missions and to support deployments to provide assistance to homeless individuals. See PHSSEF chapter for more details.

OFFICER DEPLOYMENTS AND DEPLOYMENT DAYS



OTHER GENERAL DEPARTMENTAL MANAGEMENT

The Budget includes $2 million for the Kidney Innovation Accelerator to catalyze innovation in the prevention, diagnosis, and treatment of kidney disease

in support of the President's Executive Order on Kidney Health.

The Budget includes $5 million to evaluate and oversee Department-wide investments in Artificial Intelligence in support of the President's Executive Order on Maintaining American Leadership in Artificial Intelligence.

The Budget includes $267 million for the remainder of the activities supported by General Departmental Management in the Office of the Secretary.

Office of the Secretary, Medicare Hearings and Appeals

	dollars in millions			2021 +/- 2020
	2019	2020	2021	
Office of Medicare Hearings and Appeals				
Medicare Appeals Adjudication	182	172	172	--
Proposed User Fee Collections	--	--	*2*	+2
Subtotal, Office of Medicare Hearings and Appeals Program Level	182	172	174	+2
Full-Time Equivalents	845	1,300	1,245	-55
Departmental Appeals Board – Medicare				
Medicare Appeals Adjudication	-	20	24	+4
Proposed User Fee Collections	-	-	*1*	*+1*
Subtotal, Departmental Appeals Board – Medicare Program Level	-	20	25	+5
Full-Time Equivalents	-	76	94	+18
Total, Medicare Hearings and Appeal Program Level	**-**	**192**	**199**	**+7**

1/ 2020 and 2021 funding levels for OMHA and DAB represent allocations from the overall appropriation and are subject to change based on actual incoming appeal receipt levels and statuses of appeal backlogs at each level.
2/ Reflects appropriated funding levels and does not include any transfers or carryforward balances.

The Office of Medicare Hearings and Appeals provides beneficiaries, providers, and suppliers an opportunity for a hearing on disputed Medicare claims. The Departmental Appeals Board for Medicare provides final administrative review of claims for Medicare entitlement, payment, and coverage at HHS.

Medicare Hearings and Appeals is an account created by Congress in FY 2020 to consolidate the costs of the adjudicative expenses associated with appeals of Medicare claims brought by beneficiaries and healthcare providers. The appeals process is overseen by administrative law and appeals judges at the Office of Medicare Hearings and Appeals (OMHA) and the Departmental Appeals Board (DAB), respectively.

Beginning in FY 2011, an aging population and unintended consequences from HHS's Medicare program integrity efforts led to a significant increase in Medicare claims denials. This increase resulted in more appeals than OMHA and DAB could process within the 90-day case adjudication time frame required by law. Despite best efforts, this resulted in a backlog of appeals pending adjudication at both OMHA and DAB.

THE APPEALS BACKLOG

While the Medicare appeals backlog remains significant, the Department has taken a number of administrative actions to reduce the pending appeals workload, including alternative dispute resolution and multiple settlement actions. OMHA reduced the backlog of cases by 65 percent to approximately 320,000 appeals (from a high of nearly 900,000 in FY 2015). DAB reduced the backlog of cases by 43 percent to approximately 17,500 (from a high of nearly 31,000 in FY 2017).

OFFICE OF MEDICARE HEARINGS AND APPEALS

OMHA administers the nationwide hearing process for appeals arising from Medicare coverage and payment claims for items and services furnished to beneficiaries.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $174 million for OMHA, $2 million above the projected FY 2020 operating level, which is subject to change. The FY 2021 Budget includes $2 million in proposed user fee collections that allows OMHA to recoup a partial amount of administrative costs resulting from unfavorable appeals. The Budget will

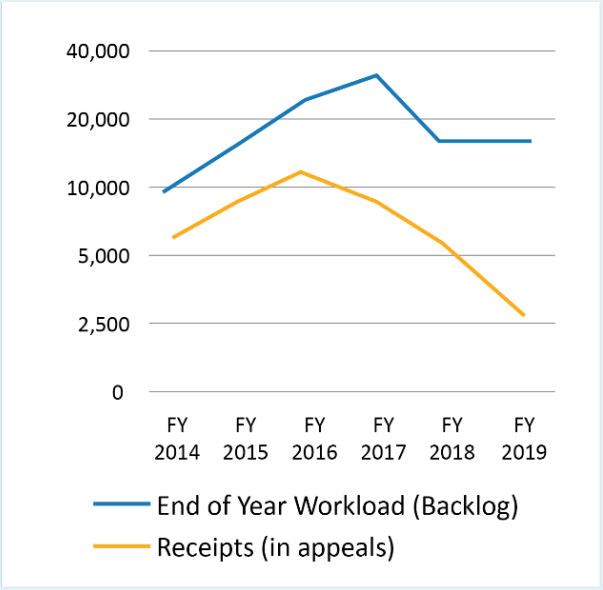
allow OMHA to support the number of full-time equivalent (FTE) staff necessary to manage the anticipated workload.

DEPARTMENTAL APPEALS BOARD

The Departmental Appeals Board (DAB) Medicare Appeals Council provides a final administrative review of claims for entitlement to Medicare, individual claims for Medicare coverage, and claims for payment filed by beneficiaries or healthcare providers and suppliers at HHS.

The FY 2021 Budget requests $25 million for DAB, $5 million above the projected FY 2020 operating level, which is subject to change. The FY 2021 Budget includes $1 million in proposed user fee collections. Starting in FY 2020, DAB's Medicare appeals adjudication costs are funded out of the same appropriation as OMHA. The Budget will allow DAB to increase FTE necessary to begin reducing the balance of its pending appeals backlog.

TO ADDRESS ITS BACKLOG OF 17,682 APPEALS, DAB NEEDS ADDITIONAL ADJUDICATORS



Office of the Secretary, Office of the National Coordinator for Health Information Technology

	dollars in millions			
	2019/1	2020	2021	2021+/- 2020
Office of the National Coordinator for Health Information Technology				
Total Discretionary Budget Authority	**60**	**60**	**51**	**-9**
Full-Time Equivalents	158	164	164	--

1/ Reflects FY 2019 final, post required and permissive transfers

The mission of the Office of the National Coordinator for Health Information Technology is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

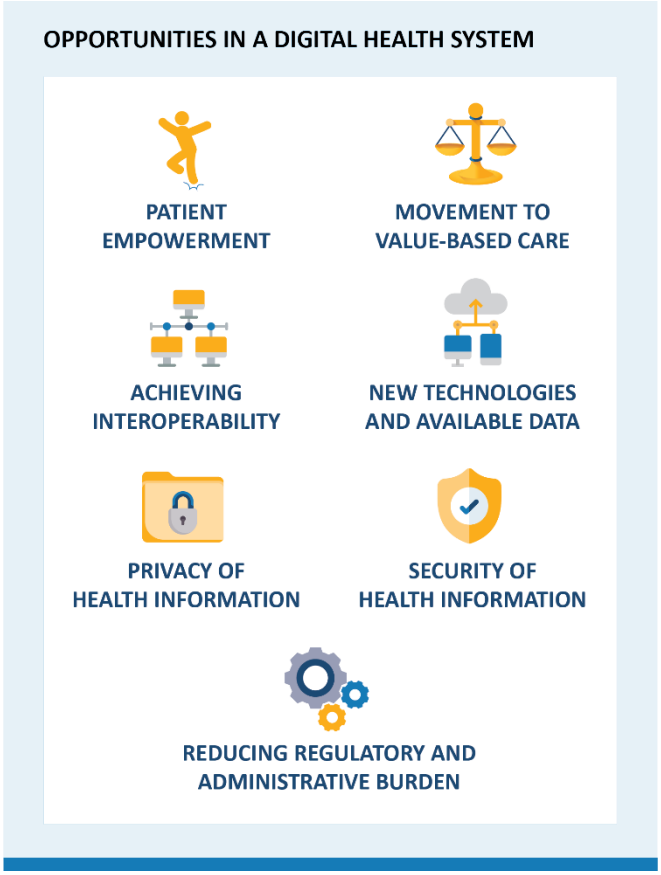
The Office of the National Coordinator for Health Information Technology (ONC) leads the nation's efforts to advance health information technology (IT). ONC supports the Administration's efforts to achieve interoperability, spur market competition in the health IT industry, and advance patient and provider experiences through product transparency.

The Fiscal Year (FY) 2021 Budget requests $51 million in discretionary budget authority for ONC. The Budget prioritizes funding to advance the interoperability and usability of health IT while reducing provider burden, combatting information blocking, and advancing standards development.

POLICY DEVELOPMENT AND COORDINATION

While ONC is a very small part of federal spending on healthcare, ONC's activities are central to promoting competition, transparency, and patient-centered care in the United States. ONC envisions an environment where a patient's right to access and control their medical records on their smartphones is operationalized and one where necessary price and quality information is available to healthcare providers to make decisions about the care.

Across the Federal Government, ONC coordinates the national health IT agenda through the Federal Health IT Coordinating Council (Council). Among its most recent efforts, the Council provided input to ONC to update the Federal Health IT Strategic Plan for FY 2020-2025, which will outline agency actions to use health IT. The draft plan was released for public comment in January 2020.



Health IT Advisory Committee

In FY 2021, ONC will continue to administer the Health IT Advisory Committee (HITAC), ONC's Federal Advisory Committee mandated by the Cures Act. Now in its

second year, the HITAC represents a broad and balanced spectrum of the healthcare system and provides recommendations to ONC on a variety of topics. To date, the HITAC has completed a Policy Framework, published the FY 2018 annual report, and provided recommendations on the draft Trust Exchange Framework and Common Agreement and the United States Core Data for Interoperability, among other topics.

Combatting Information Blocking

In 2019, ONC issued a proposed rule to implement and support seamless and secure access, exchange, and use of electronic health information. Once finalized, ONC will implement the rule through its programs and activities, including through the Health IT Certification Program.

First, the proposed rule sought to encourage competition in the healthcare delivery system by addressing the technical barriers and business practices that impede the secure and appropriate sharing of data. It also aims to facilitate patients' access to their electronic health information through their smartphone, allowing for patient and provider centered health IT economy through increased competition and price and product transparency. Finally, the proposed rule supports the data necessary to promote new business models of care and the clinical information and chart portability that patient's need to shop for their care. This will empower patients to use data to search for the lowest costs and highest quality care.

Promoting Trusted Exchange of Health Information

ONC is developing the Trusted Exchange Framework and Common Agreement to establish a set of shared principles, terms, and conditions to facilitate trust between health information networks. This approach will provide a single avenue to nationwide connectivity and advance technology so that information can securely follow patients where and when they need it.

In 2019, ONC selected The Sequoia Project, a private sector non-profit organization, to serve as the Recognized Coordinating Entity responsible for developing, updating, implementing, and maintaining the Common Agreement in collaboration with ONC. ONC will approve the baseline technical and legal requirements for networks to share electronic health information across the nation.

STANDARDS, INTEROPERABILITY AND CERTIFICATION

ONC leads standards and interoperability work to advance the technical infrastructure necessary to support price transparency and develop and implement strategies to make health information more readily available to patients. This will support better alignment between a patient's health information and its related cost information.

Health IT Certification Program

The FY 2021 Budget advances ONC nationwide health IT interoperability. ONC establishes conditions of certification for the health IT industry and coordinates standards development to ensure that the nation's health data is scalable, sustainable, and equitable.

ONC's Certification Program maintains test procedures and certification companion guides for approximately 60 certification criteria, used to standardize information across 21 distinct programs and initiatives taking place at CMS, the Department of Defense, the Veterans Health Administration, HRSA, and SAMHSA.

Congress charged ONC with enhancing its Health IT Certification Program to require modern standards-based application programming interfaces and in parallel preventing anti-competitive business practices related to health information exchange such as information blocking. The program aims to promote patient access to and control of their personal electronic health information. These strategies will allow patients to increase electronic control of their medical record to shop for care and simultaneously allow new business models for lower cost and better healthcare.

AGENCY WIDE SUPPORT

The Budget includes funding to provide executive, clinical, and scientific leadership to coordinate outreach between ONC and key federal stakeholders, allowing ONC to multiply and maximize their impact. This funding also maintains https://HealthIT.gov to promote federal health IT policy and ensures effective operations and management through an integrated operations function. In FY 2021, ONC will continue to seek operational and administrative efficiencies to reduce department controlled shared service costs.

Office of the Secretary, Office for Civil Rights

	dollars in millions			2021 +/- 2020
	2019	2020	2021	
Office for Civil Rights				
Discretionary Budget Authority	39	39	30	-9
Civil Monetary Settlement Funds	7	14	27	+13
Total, Program Level	46	53	57	+4
Full-Time Equivalents /1	139	157	156	-1

1/ Includes Full-Time Equivalents supported at the Program Level.

The Office for Civil Rights is the U.S. Department of Health and Human Services' primary enforcement and regulatory agency of civil rights, conscience and religious freedom, and health information privacy and security.

The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) ensures:

- Individuals receiving services from HHS-conducted or HHS-funded programs are not subject to unlawful discrimination;
- Individuals and entities can exercise their conscience and religious freedom rights while participating in HHS-funded programs; and
- People can trust the privacy, security, and availability of their health information.

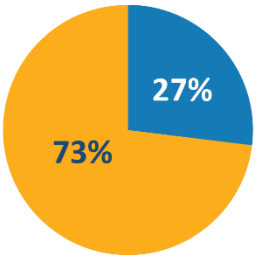
The Fiscal Year (FY) 2021 President's Budget (Budget) requests $30 million for OCR. OCR will utilize $9 million in civil monetary settlement funds to offset proposed reductions in discretionary appropriations that support Health Insurance Portability and Accountability Act (HIPAA) enforcement activities. The Budget supports OCR's role as the primary defender of the public's right to:

- Nondiscriminatory access to and receipt of HHS-funded health and human services;
- Conscience and religious freedom protections in HHS-funded programs; and
- Access to and privacy and security protections for personally identifiable health information.

To execute these functions, OCR investigates complaints, enforces rights, develops policy, promulgates regulations, and provides technical assistance and public education, to ensure understanding of, and compliance with, non-discrimination and privacy laws under its

OCR MAINTAINS HEALTH PRIVACY THROUGH WELL-MANAGED CASELOAD

OCR managed 36,591 cases in FY 2019.



OCR's workload shows 27% of their work is Civil Rights and 73% is HIPAA.

OCR received a 10.2% increase in their workload between 2018 and 2019.

OCR has aligned resources with their current workload so that there is no backlog.

jurisdiction.

HEALTH INFORMATION PRIVACY AND SECURITY

OCR administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules (HIPAA Rules). OCR seeks to ensure covered entities understand and comply with their obligations under the HIPAA Rules, and to increase individuals' awareness of their HIPAA rights and protections. OCR accomplishes these objectives by issuing regulations and guidance, conducting outreach, and providing technical assistance to the regulated community, in addition to pursuing investigations, settlement agreements, and civil monetary penalties.

OCR works to resolve substantial noncompliance with the HIPAA Rules. For example, in FY 2019 OCR settled with Anthem, Inc. for $16 million, constituting the largest healthcare data breach in American history and OCR's largest HIPAA settlement.

CIVIL RIGHTS

OCR enforces federal anti-discrimination laws with respect to race, color, national origin, disability, age, and sex in various programs that either receive financial assistance from, or are conducted by, HHS. For example, in FY 2019 OCR entered into a voluntary resolution agreement with Michigan State University (MSU) to resolve compliance issues after sexual misconduct violations. As a result, MSU agreed to:

- Designate a responsible official to take custody of, and improve processes for notifications, investigations, and resolutions of Title IX and Section 1557 complaints from students, student patients, faculty, and staff.
- Institute policies to ensure safety and privacy during sensitive examinations.
- Conduct all-staff trainings focused on the best practices that engender compliance, and ultimately better protect students and faculty.

HHS is committed to serving and protecting individuals with disabilities through all stages of life. HHS, including OCR, will use available enforcement and regulatory tools to enable access to life-saving healthcare without regard to disability. By way of example, OCR has favorably resolved several disability discrimination complaints, including when healthcare providers: denied a patient's placement on the United Network for Organ Sharing list on the basis of their intellectual disability, discharged a seriously ill patient from a facility upon learning the patient was HIV positive, failed to provide sign language interpreters and other auxiliary aids and services as required under disability law, and retaliated against an individual who filed a complaint of disability discrimination with OCR.

OCR will continue to address a broad range of critical civil rights matters that address compliance issues and are of paramount importance to the American people.

CONSCIENCE AND RELIGIOUS FREEDOM

OCR's Conscience and Religious Freedom Division continues to vigorously promote, implement, and enforce the healthcare conscience and religious freedom laws related to HHS programs and activities. OCR enforces, among other statutory conscience protections, the Religious Freedom Restoration Act of 1993, the Church, Coats-Snowe, and Weldon Amendments, and Section 1553 of the Affordable Care Act. The Division is actively engaged in outreach, enforcement, and policymaking. In FY 2019, OCR favorably resolved three matters of national significance involving five complaints, resulting in the enforcement of laws passed by Congress, the protection of the conscience rights of American citizens, and a heightened public awareness of the conscience and religious freedom rights and obligations in healthcare.

LEGISLATIVE PROPOSALS – DETERRENTS TO INDUSTRY NONCOMPLIANCE

Enhancing HIPAA Protections by Increasing Civil Monetary Penalty Caps and Authorizing Injunctive Relief

Current limits on civil money penalties are not a sufficient deterrent to industry noncompliance. Additionally, current statutory authority limits OCR's ability to obtain a proportional penalty for egregious violations. This proposal increases the monetary amount of civil monetary penalties and allows OCR to seek injunctive relief for HIPAA violations. These changes will strengthen OCR's enforcement at no additional cost to the taxpayer.

Enforcing Conscience and Protections Against Coercion in HHS Programs

The Weldon Amendment, one of several laws protecting conscience and prohibiting coercion in HHS programs, must be renewed annually by Congress in

the appropriations process. This proposal will make Weldon Amendment protections permanent, while ensuring that the scope of protected persons, entities, and beliefs are defined broadly. In addition, the proposal institutionalizes and expands OCR's regulatory and enforcement authority under these conscience protection laws, and aligns with other antidiscrimination laws that allow private parties to file claims in federal court. These changes enhance OCR's ability to enforce these laws, add certainty, and allow private actions to aid enforcement. This proposal will also strengthen, clarify, and further codify the prohibitions against governmental discrimination for healthcare entities that refuse to perform, refer for, participate in, pay for, or provide (or sponsor) coverage of abortion services.

Office of the Secretary,
Office of Inspector General

	dollars in millions			
	2019	2020	2021	2021 +/- 2020
Public Health and Human Services (PHHS) Oversight				
PHHS Oversight Discretionary	80	80	90	+10
Information Blocking (non-add)[1]	--	--	*5*	*+5*
FDA & NIH Transfers[2,3]	7	7	--	-7
Healthcare Fraud and Abuse Control (HCFAC) Oversight[4]				
HCFAC Program Discretionary	87	93	102	+9
HCFAC Mandatory	196	200	216	+16
HCFAC Collections	11	11	12	+1
Total, Program Level[5]	**381**	**391**	**419**	**+28**
Full-Time Equivalents	1,631	1,650	1,676	+26

[1] The funds for Information Blocking have been included under the PHHS Discretionary Oversight, however two-year funding is requested to fulfill this authority.
[2] FY 2019 Operating Level includes $1.5 million (rounded in the table display as $2 million), for the Food and Drug Administration Transfer and $5 million for the NIH Transfer in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill. FY 2019 Operating Level does not include supplemental appropriations ($6 million).
[3] FY 2020 Enacted table display includes $1.5 million (rounded in the table display as $2 million), for the Food and Drug Administration Transfer and $5 million for the NIH Transfer in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Bill.
[4] HCFAC Does not reflect estimated Sequester for FY 2021.
[5] Total Program Level display is rounded in table display and may vary slightly from description in narrative section.

The mission of the Office of Inspector General is to protect the integrity of the U.S. Department of Health and Human Services' programs, and the health and welfare of the people they serve.

The U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) is the largest inspector general's office in the federal government, with approximately 1,600 employees dedicated to combating fraud, waste, and abuse and improving the efficiency of HHS programs.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $419 million for OIG, a $28 million increase above FY 2020 Enacted. Funding enables OIG to provide independent oversight of HHS programs and operations through the development of new models and tools to support data-driven audits, evaluations, and inspections.

PRIORITY OUTCOMES

HHS is a complex agency with approximately 80,000 employees with a budget of approximately $1.3 trillion. OIG sets priority outcomes to achieve the greatest impact across HHS's diverse programs. OIG's priority outcome areas demonstrate the focus on strategically targeting oversight, driving measurable results, and achieving overarching performance goals. OIG develops strategies, actions, and measures to provide solutions and improve outcomes for HHS programs and beneficiaries.

PUBLIC HEALTH AND HUMAN SERVICES OVERSIGHT

The FY 2021 Budget requests $90 million in Public Health and Human Services (PHHS) Oversight budget authority, and increase of $10 million above the FY 2020 Enacted. The $10 million increase includes $4.7 million to enhance OIG's focus on the effective administration of grant programs for prevention and treatment of opioid addiction, substance abuse, and serious mental illness. Resources will support audits, evaluations, data analysis, and investigations into fraud schemes and vulnerabilities associated with effectively preventing, detecting, and treating substance abuse disorders.

INFORMATION BLOCKING

The FY 2021 PHHS Oversight request includes $5.3 million to execute new investigative and enforcement authorities related to information blocking. The 21st Century Cures Act (Cures Act), 2016 P.L. 114-255, Section 4004, authorizes OIG to execute new investigative and enforcement authorities related to the detrimental practice of information blocking. Information blocking is a practice that inappropriately impedes the flow or use of electronic health information. The availability and liquidity of electronic health information is a critical element of a high-functioning healthcare system. OIG will invest in hiring personnel, training, and investigative and enforcement litigation costs.

MEDICARE AND MEDICAID OVERSIGHT

OIG relies on prevention, detection, and enforcement to address fraud, waste, and abuse in Medicare and Medicaid programs. Two key focus areas are sound fiscal management and ensuring beneficiaries receive quality care.

The FY 2021 Budget for OIG includes $329 million for Medicare and Medicaid oversight, a $25 million increase over FY 2020 Enacted. The additional resources will support data-driven audits, evaluations, and inspections to target illegal prescription and distribution of opioids to Medicare and Medicaid beneficiaries, and to enhance oversight of critical programs furnishing treatment for substance abuse disorders and serious mental illness.

Public Health and Social Services Emergency Fund

	dollars in millions			
	2019 /1	2020 /5	2021	2021 +/- 2020
Assistant Secretary for Preparedness and Response				
Preparedness and Emergency Operations	25	25	27	+3
National Disaster Medical System	73	57	88	+31
Hospital Preparedness Program	265	276	258	-18
Medical Reserve Corps	6	6	4	-2
Preparedness and Response Innovation	--	--	15	+15
Biomedical Advanced Research and Development Authority	562	562	562	--
Project BioShield /2	735	735	535	-200
Strategic National Stockpile /3	604	705	705	--
Policy and Planning	15	15	20	+5
Operations	31	31	31	--
Subtotal, Assistant Secretary for Preparedness and Response	**2,315**	**2,411**	**2,245**	**-167**
Other Office of the Secretary				
Office of National Security /4	9	9	9	--
Cybersecurity /4	58	58	67	+9
Office of the Assistant Secretary for Health	--	--	11	+11
Subtotal, Other Office of the Secretary	**66**	**66**	**87**	**+21**
Pandemic Influenza				
No-Year Funding	225	225	275	+50
Annual Funding	35	35	35	--
Subtotal, Pandemic Influenza	**260**	**260**	**310**	**+50**
Total Discretionary Budget Authority	**2,625**	**2,737**	**2,641**	**-96**
Total Program Level	**2,641**	**2,737**	**2,641**	**-96**
Full-Time Equivalents	958	1,012	1,039	+27

1/ Reflects the FY 2019 Enacted Level, post required and permissive transfers and rescissions.
2/ In addition to BioShield funds, a total of $200 million from emergency supplemental Ebola funding appropriated in FY 2020 will be available to procure medical countermeasures in FY 2021.
3/ Transferred administratively from the Centers for Disease Control and Prevention (CDC) to the Assistant Secretary for Preparedness and Response in FY 2019. Reflects a FY 2019 Secretarial transfer of $6.1 million to CDC for transition costs.
4/ FY 2019 total reflects a realignment of $1.04 million from Cybersecurity to the Office of National Security to support cyber threat activities. FY 2020 total is comparably adjusted.
5/ FY 2020 total does not include supplemental appropriations for procurement of Ebola vaccines, therapeutics, and diagnostics ($535 million).

The Public Health and Social Services Emergency Fund's mission is to directly support the nation's ability to prepare for, respond to, and recover from, the health consequences of naturally occurring and man-made threats.

Within the Office of the Secretary, the Public Health and Social Services Emergency Fund (PHSSEF) supports biodefense, disaster response, and information security across HHS to improve the nation's preparedness and protect Americans from 21st century health security threats.

The Fiscal Year (FY) 2021 President's Budget (Budget) requests $2.6 billion for the PHSSEF and prioritizes emergency medical response capacity, pandemic influenza preparedness, and cybersecurity, and advances medical countermeasure development and stockpiling.

BIOTERRORISM AND EMERGENCY PREPAREDNESS

HHS prepares America for a range of natural and man-made health threats. The Budget prioritizes funding for medical response capacity, information security, and influenza preparedness to prepare the nation to respond to and recover from public health and medical emergencies. These activities support HHS's responsibilities under the National Response Framework to coordinate public health and medical services and provide emergency assistance when response and recovery needs exceed the state and local capability. PHSSEF agencies lead efforts across HHS in preparing for and responding to emergencies and disasters, including:

- Providing medical services and logistical support for federal responses to public health emergencies;
- Enhancing regional, state, and local disaster health response capabilities; and
- Developing, stockpiling, and deploying medical countermeasures.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The Assistant Secretary for Preparedness and Response (ASPR) fulfills HHS's responsibilities as the lead federal agency for public health emergency preparedness and response. ASPR strengthens public health systems across the nation; increases state and local governments' capacity to respond to public health threats; supports advanced development, procurement, and stockpiling of medical countermeasures; and provides operational leadership and policy development.

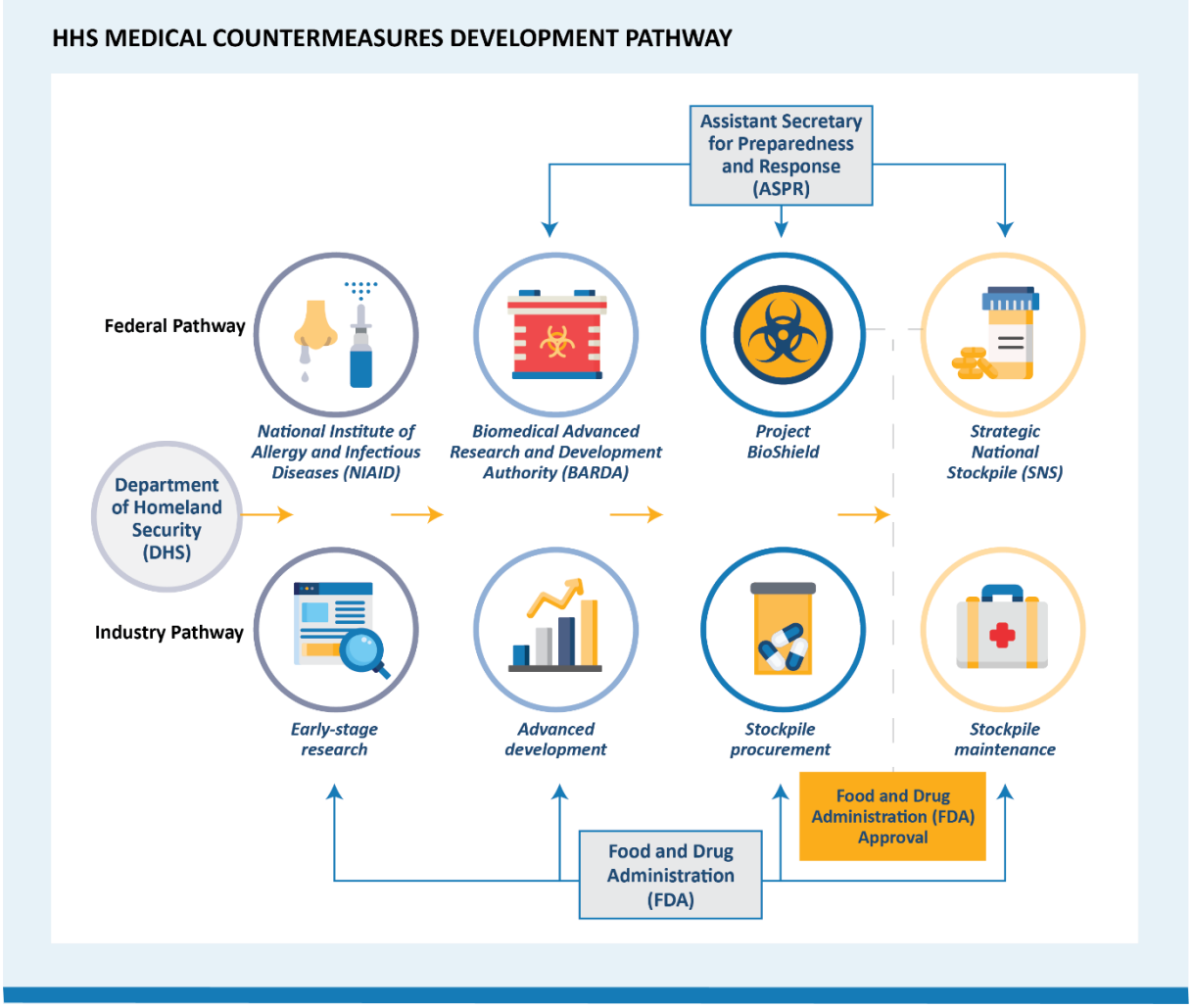
The FY 2021 Budget provides ASPR $2.6 billion to promote nationwide healthcare system readiness and response; deploy emergency resources and medical personnel; and develop and manufacture vaccines, drugs, diagnostics, and technologies to protect Americans from the impact of natural disasters, bioterrorism, and emerging infectious diseases including pandemic influenza.

Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority (BARDA) works with public and private sector partners to support advanced research, development, regulatory approval, and procurement of medical countermeasures to mitigate health effects of chemical, biological, radiological, and nuclear agents; pandemic influenza; and infectious diseases. Through these partnerships, BARDA collaborates with medical product developers to transition candidate drugs, vaccines, therapeutics, diagnostics, and medical devices from early development to advanced and late stage development and approval by the Food and Drug Administration (FDA). BARDA provides core support services and subject matter expertise to accelerate product development and FDA approval. Since 2006, BARDA's advanced research and development efforts have led to FDA licensure, approval, or clearance of 53 health security medical countermeasures, including ten in 2019 alone, the most in any year.

The Budget provides $562 million for BARDA to support the advanced development of new vaccines, antivirals, and therapeutics for anthrax, smallpox, and viral hemorrhagic fever viruses, broad-spectrum antimicrobials and diagnostics for biothreat pathogens, and treatments for chemical, radiological, and nuclear agents. The Budget also supports BARDA's Division of Research, Innovation, and Ventures, which invests in public-private partnerships to develop innovative products and technologies to solve systemic health security challenges, including preventing and treating sepsis and identifying early exposure to infectious disease.

The Budget provides $160 million within BARDA to support advanced development of broad-spectrum antimicrobials for drug-resistant biothreat pathogens, including vaccines, diagnostics, and novel antibiotic treatments. In FY 2021, BARDA will continue to



collaborate with the National Institutes of Health, academia, and private partners to sustain and expand the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X). CARB-X is a novel consortium approach to accelerate investment in early development of innovative medical countermeasures to fight antibiotic-resistant bacteria. Since its inception, CARB-X has accelerated the efforts of 47 companies, with six projects advancing to clinical evaluation.

Project BioShield

The Budget provides $535 million for Project BioShield to support late-stage development and procurement of medical countermeasures for the Strategic National Stockpile (SNS) that are sufficiently mature for use during a public health emergency. Late-stage development includes phase III clinical studies, pivotal non-clinical studies, and manufacturing process validation to achieve FDA approval. The Budget requests $200 million less in FY 2021, the amount planned for FY 2021, for procurement of Ebola vaccines, therapeutics, and diagnostics. A total of $200 million from emergency supplemental funding appropriated in FY 2020 will fund ASPR's FY 2021 procurement of Ebola medical countermeasures.

The Budget will also support the development and procurement of the highest priority countermeasures, including:

- A next generation anthrax vaccine;
- New antimicrobials to treat drug-resistant biothreat pathogens;
- A therapeutic to treat nerve agent-induced seizures;
- A smallpox vaccine and antiviral drug; and
- New countermeasures to detect and treat exposure to thermal and acute ionizing radiation.

ASPR's progress in advanced development strengthens the nation's health security and preparedness. Since 2004, BARDA has supported 27 unique medical

countermeasures under Project BioShield, procured 16 products for the SNS, and secured FDA approval for 11 products. These products counter chemical, biological, radiological, or nuclear threats, including a botulism antitoxin, anthrax and smallpox vaccines and therapeutics, and treatments for burn injuries, radiation exposure, and nerve agent-induced seizures. In FY 2021, BARDA will procure up to three new products and support additional FDA approvals and deliveries to the SNS.

Strategic National Stockpile

The SNS is a national repository of pharmaceuticals, medical supplies, and deployable healthcare facilities available for use in a public health emergency. When state, local, tribal, and territorial responders request federal assistance during an emergency, HHS deploys potentially life-saving medicines and supplies from the SNS. The Budget provides $705 million for the SNS to manage and sustain inventory, procure FDA approved products transitioned from Project BioShield, and train state and local responders nationwide for effective distribution and dispensing of stockpiled products. The Budget supports procurements of high-priority medical countermeasures, including smallpox vaccine, anthrax antibiotics and therapeutics, and pandemic influenza antivirals.

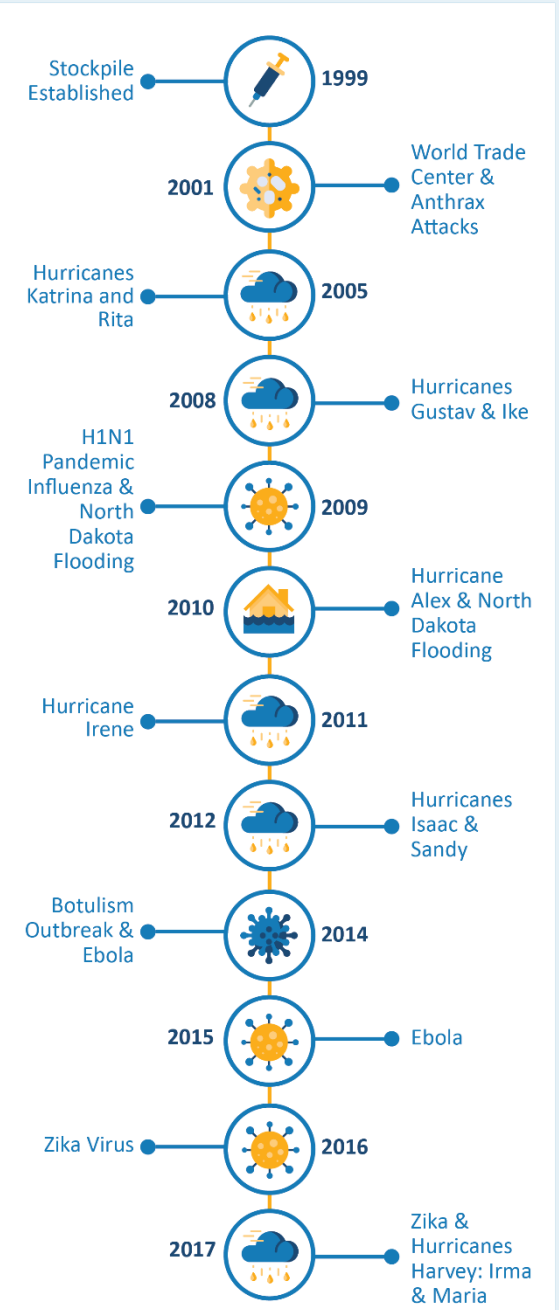
Hospital Preparedness Program

The Hospital Preparedness Program (HPP) supports hospitals and healthcare coalitions to prepare for emergency response. HPP improves patient outcomes, minimizes the need for supplemental state and federal resources during emergencies, and enables rapid recovery. ASPR supports Healthcare Coalitions to coordinate preparedness, response, and recovery activities among healthcare organizations and other local stakeholders. Over 44,000 member organizations, including over 5,000 acute care hospitals, participate in 357 healthcare coalitions nationwide. The Budget provides $258 million to fund 62 awardees, including all 50 states, eight United States territories and freely associated states, and four localities. ASPR will continue to prioritize efficiency and effectiveness by better incorporating risk into the funding formula.

National Disaster Medical System

The National Disaster Medical System (NDMS) is a nationwide partnership to deliver quality medical care to domestic disaster victims. This program provides state-of-the-art medical care under any conditions at a disaster site, in transit from the impacted area, and in participating hospitals. The FY 2021 Budget provides an additional $31 million, to a total of $88 million, for NDMS. Additional funding of $20 million will continue a Pediatric Disaster Care pilot program, $5 million to maintain a cache of 50 portable dialysis units, $5 million to train up to 6,700 staff on disaster medical field operations including highly infectious disease

STRATEGIC NATIONAL STOCKPILE RESPONSE HISTORY



Note: Not shown above: Frequent small-scale responses of unique medical countermeasures for anthrax, smallpox, and routine deployments of jointly-rotated vaccine stocks to supply Department of Defense requirements are also a part of stockpile deployments.

response and patient transport, and $1 million to support the emPOWER program, which provides datasets and tools to public health agencies to identify individuals who rely on electricity-dependent medical equipment and devices.

In June 2019, ASPR introduced the Pediatric Disaster Care Centers of Excellence pilot program to focus on children who represent 25 percent of the United States population and require specialized medical care due to their unique developmental and physiologic characteristics. The pilot helps identify gaps in pediatric care, develop best practices, and demonstrate the potential effectiveness and viability of a pediatric-focused approach. In FY 2021, ASPR will continue the pilot utilizing data from prior years to identify best practices and better focus activities to expand local and statewide capabilities to treat pediatric patients in disasters and public health emergencies, including supporting the National Disaster Pediatric Network, funding the Centers of Excellence, and procuring two mobile temporary shelters – one NDMS shelter and one SNS shelter.

Medical Reserve Corps

The Medical Reserve Corps is a national network of more than 850 volunteer groups that engage local communities to strengthen public health, reduce vulnerability, build resilience, and improve preparedness, response, and recovery capabilities. The Budget provides $4 million for the Medical Reserve Corps to provide technical assistance, coordination, communications, strategy and policy development, grants and contract oversight, training and other associated services.

Preparedness and Response Innovation

The Budget proposes $15 million for a new Preparedness and Response Innovation program to accelerate advanced research and development of emerging technologies beyond medical countermeasures. ASPR will emphasize revolutionary advancements in health security products, technologies, and innovations to improve response, recovery, and medical countermeasure manufacturing, deployment, and dispensing practices. In the first year, ASPR will focus on conducting research and development on next-generation portable dialysis units to ensure individuals with kidney failure have access to dialysis during a disaster. This project supports the 2019 Executive Order, "Advancing American Kidney Health", a new initiative to improve care for the estimated 37 million Americans with kidney disease. ASPR will also develop sterile saline on-demand technologies to ensure saline is produced and readily available at the point-of-need during a public health emergency.

PANDEMIC INFLUENZA

In 2019, President Trump signed an Executive Order, "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health," directing federal agencies to collaborate to improve the effectiveness, production, and supply of influenza vaccines to combat seasonal epidemics and pandemics. The Executive Order seeks to:

- Reduce the United States' reliance on egg-based influenza vaccine production;
- Expand domestic capacity of alternative vaccine production methods that allow a more agile and rapid response to evolving and emerging influenza viruses;
- Advance the development of new broadly protective and longer lasting influenza vaccines; and
- Promote increased influenza vaccine immunization across the population.

The Budget supports the Executive Order and provides an additional $50 million above FY 2020, a total of $310 million, for pandemic influenza preparedness activities carried out by ASPR and the Office of Global Affairs (OGA). ASPR will work with industry to expand manufacturing capacity and advance the development of a next generation influenza vaccine, alternative vaccine delivery technology and vaccine adjuvant formulations, and novel influenza diagnostics and

ASPR & OGA BUILD CAPACITY TO ADDRESS PANDEMIC INFLUENZA

antiviral drugs. OGA will lead global health diplomacy and policy coordination efforts for HHS to strengthen international pandemic preparedness. ASPR and OGA will build on previous investments to continue establishing a robust pandemic preparedness and response infrastructure that protects public health and ensures domestic and global health security.

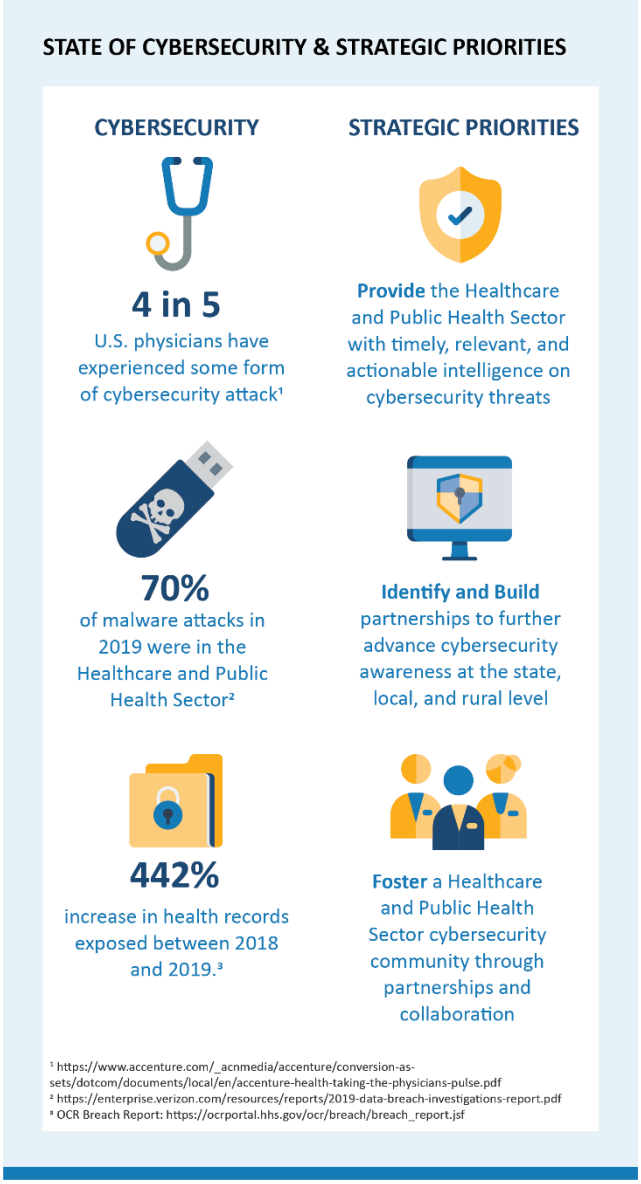
DEPARTMENT-WIDE INFORMATION SECURITY

Office of National Security

The Office of National Security (ONS) integrates intelligence and security information into HHS policy and operational decisions. ONS synthesizes intelligence and all-source information on public health, terrorism, national security, weapons of mass destruction, and homeland security for the Department. The Budget includes $9 million for ONS to expand activities to mitigate and respond to national security threats. ONS is the HHS point of contact for the intelligence community, and coordinates intelligence and national security support for the Secretary, senior policy-makers, and other consumers of intelligence across the Department. ONS's activities provide policymakers with early indicators and warnings of potential national security threats.

Cybersecurity

HHS's Cybersecurity program protects vital health information and enhances the Department's capacity to respond to new and emerging requirements, technologies, and cybersecurity threats. The FY 2021 Budget provides $67 million for the Cybersecurity program. These funds enable the Department to enhance cyber threat identification and management, which allows the program to best protect the HHS enterprise and translate threats into meaningful guidance provided to the Healthcare and Public Health sector through the Health Sector Cybersecurity Coordination Center (HC3). These funds also enable the Cybersecurity program to limit cyber event impacts through increased internal and external monitoring and active threat blocking. This funding supports enterprise-wide digital investigations and the supporting technology required for advanced forensic research as well as support for increased information sharing about cyber threat indicators.



ASSISTANT SECRETARY FOR HEALTH

United States Public Health Service Commissioned Corps

The United States Public Health Service Commissioned Corps (Corps) is a cadre of approximately 6,400 full-time uniformed officers that promote and advance public health and disease prevention programs, and fill essential public health, leadership, clinical and service roles across more than 21 federal agencies and programs. Corps officers maintain readiness to deploy and respond to public health crises, disease outbreaks, and humanitarian missions. Over the last six years there have been a number of public health emergency declarations, including: the Opioid crisis; Hurricane Dorian; Tropical Storm Barry; the California Wildfires; Typhoon Yutu; Hurricane Michael; Hurricane Florence;

Hurricane Harvey; Hurricane Irma; Hurricane Maria; the Zika virus outbreak; and Hurricane Sandy. With increasing numbers of public health emergencies, Commissioned Corps response efforts have concurrently increased to support the Department's public health and medical response. Corps deployments increased an average of 44 percent annually over the past six years.

The Budget provides $11 million to support increased training for the Commissioned Corps to prepare for complex missions both domestically and internationally, and to support deployments for the Commissioned Corps to provide services or assistance to homeless individuals. The Budget will allow the Commissioned Corps to meet leadership and readiness training requirements to ensure that officers are trained, equipped, and otherwise prepared to fulfill their public health emergency response roles. This training will develop a suite of trained Corps officers to support real-time medical, public health, and bio-threat capacity.

The Budget also supports a strategic initiative of the Administration to address the unsheltered homelessness and, separately, unsheltered veteran homelessness in the United States. Specifically, the Budget will support a Commissioned Corps led public health initiative inclusive of health assessments, treatment of acute and chronic illness, and medical stabilization for transitioning to long-term healthcare services – all of which would be coordinated with a larger program of human services including housing, nutrition, education, and training.

Abbreviations and Acronyms

A

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organization
AFM	Acute Flaccid Myelitis
AHRQ	Agency for Healthcare Research and Quality
AI	artificial intelligence
AIDS	Acquired Immune Deficiency Syndrome
AIM	Alliance for Innovation on Maternal Health
ALJ	Administrative Law Judge
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
AWARE	Advancing Wellness and Resiliency in Education

B

BA	budget authority
BARDA	Biomedical Advanced Research and Development Authority
BHWD	Behavioral Health Workforce Development Programs

C

CAH	critical access hospital
CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CCBHC	Certified Community Behavioral Health Clinic
CCDBG	Child Care and Development Block Grant
CDC	Centers for Disease Control and Prevention
CHAP	Community Health Aide Program
CHIP	Children's Health Insurance Program
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPI-U	Consumer Price Index for all Urban Consumers
CRTA	Children's Research and Technical Assistance
CY	Calendar Year

D

DAB	Departmental Appeals Board
DME	Durable Medical Equipment
DOJ	Department of Justice
DSH	Medicaid Disproportionate Share Hospital

E

EHR	electronic health record
ESRD	End-Stage Renal Disease

F

FDA	Food and Drug Administration
FMAP	Federal Medical Assistance Percentage
FPLS	Federal Parent Locator System
FTE	full-time equivalent
FY	Fiscal Year

G

GAO	Government Accountability Office
GDM	General Departmental Management

H

HCFAC	Healthcare Fraud and Abuse Control
HCV	Hepatitis C
HEAL	Helping to End Addiction Long-term
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITAC	Health Information Technology Advisory Committee
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
HPOG	Health Profession Opportunity Grants
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
HSA	Health Savings Accounts

I

IDeA	Institutional Development Award
IHS	Indian Health Service

IMD	institution for mental diseases
IPPS	Inpatient Prospective Payment System
IT	Information Technology

M

MACRA	Medicare Access and CHIP Reauthorization Act
MAGI	Modified Adjusted Gross Income
MEPS	Medical Expenditure Panel Survey
MIPS	Merit-based Incentive Payment System
MOM	Maternal Opioid Misuse
MSA	Medical Savings Accounts

N

NCI	National Cancer Institute
NDMS	National Disaster Medical System
NDNH	National Directory of New Hires
NIAID	National Institute of Allergy and Infectious Diseases
NIDILRR	National Institute on Disability, Independent Living, and Rehabilitation Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NIRSQ	National Institute for Research on Safety and Quality
NTAP	new technology add-on payment

O

OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights
OGA	Office of Global Affairs
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
ONS	Office of National Security
OPPS	Medicare Outpatient Prospective Payment System
OPO	Organ Procurement Organization

P

PACE	Program of All-inclusive Care for the Elderly
PHS	Public Health Service
PHSSEF	Public Health and Social Services Emergency Fund
PrEP	pre-exposure prophylaxis

Q

QRTP	Qualified Residential Treatment Programs
QSMO	Quality Services Management Office

S

SAMHSA	Substance Abuse and Mental Health Services Administration
SMD	State Medicaid Director
SMI	serious mental illness
SMM	severe maternal morbidity
SNS	Strategic National Stockpile
SSBG	Social Services Block Grant
STI	Sexually-Transmitted Infections
SUPPORT	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment

T

TANF	Temporary Assistance for Needy Families
T-MSIS	Transformed-Medicaid Statistical Information System