

## COVINGTON

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**Via Electronic Filing**

February 16, 2018

Colonel Peter R. Marksteiner  
Chief Executive and Clerk of Court  
United States Court of Appeals for the Federal Circuit  
717 Madison Place, NW, Room 401  
Washington, DC 20439

**Re: *Moda Health Plan, Inc. v. United States* (No. 2017-1994)  
Appellee's Fed. R. App. P. 28(j) Notice of Supplemental Authority**

Dear Colonel Marksteiner:

On February 12, 2018, the Administration released its Proposed Budget for 2019, including for the Department of Health and Human Services ("HHS"), *see Putting America's Health First, FY 2019 President's Budget for HHS* (2018) (Exh. A hereto). That Budget includes over \$12.3 billion to "fully fund" all outstanding Risk Corridor ("RC") obligations. *See* Exh. A at pp. 51 n.7, 54, 93.<sup>1</sup>

This proposed Budget is inconsistent with the Government's principal defenses to Moda's statutory claim under Section 1342 of the Affordable Care Act ("ACA"):

1. The Government argues that the RC program was designed *ab initio* to be "budget neutral," with "payments in from [profitable] insurers the only source of

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<sup>1</sup> The Budget initially lists "Risk Corridor" outlays of \$11.513 billion, *see* p. 51 n.5, p. 93, rather than the total \$12.3 billion of outstanding RC obligations, having applied the current 6.6% sequestration for non-defense spending. However, the Budget proposes that the \$812 million shortfall also be paid, by exempting RC from sequestration. *See* pp. 51 n.7, 54, 93 n.4.

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funding” for payments out to unprofitable insurers such as Moda, *see* Gov. Br. 6. However, if the Government’s RC obligations were so limited, it would have no basis now to state in the Budget that “Current Law” supports outlays sufficient to pay all post-sequestration RC obligations, *see* Exh. A at p. 51 & n. 5.

2. The Government argues that appropriation riders enacted beginning in late 2014 should in any event be interpreted to vitiate any preexisting ACA RC obligations, *see* Gov. Reply 13. However, if the appropriation riders had substantively amended the ACA, the Government would have no basis now to be proposing to appropriate funds to fulfill the entirety of its RC obligations.

Whether this Budget will be enacted is unknown. But whether the RC program is ever fully appropriated has no bearing on Moda’s entitlement to affirmance of the CFC decision, given that this Court has repeatedly made plain that an appropriation to fund a statutory obligation is not a condition precedent to the entry of judgment for the violation of that obligation, *see* Moda Br. 26-31.

Sincerely,

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Enclosure

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**CERTIFICATE OF COMPLIANCE**

This letter complies with the length limits permitted by Fed. R. App. P. 32(j). The body of this letter contains 349 words according to the word count function of Microsoft Word (Office Standard version 2016). The letter's type size and type face comply with Fed. R. App. P. 32.

/s/ Steven J. Rosenbaum

**CERTIFICATE OF SERVICE**

I hereby certify that on this 16th day of February, 2018, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF, and the foregoing document was therefore served on all counsel of record via the CM/ECF system.

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## **EXHIBIT A**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
200 INDEPENDENCE AVENUE S.W., WASHINGTON, D.C. 20201

THIS DOCUMENT IS ALSO AVAILABLE AT [HTTP://WWW.HHS.GOV/BUDGET](http://www.hhs.gov/budget)



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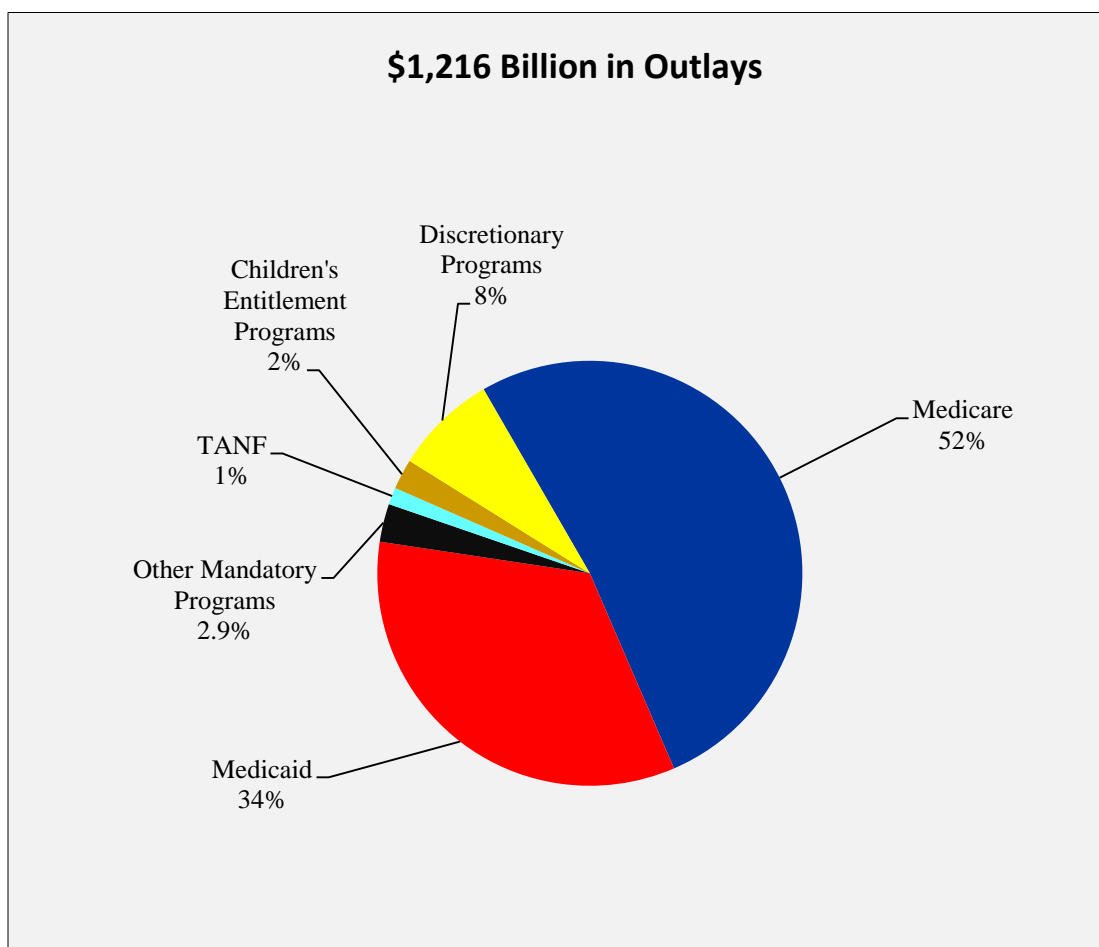




## PUTTING AMERICA'S HEALTH FIRST

### FY 2019 President's Budget for HHS

dollars in millions	2017	2018 /1	2019
<b>Budget Authority /2</b>	1,144,013	1,193,838	1,241,642
<b>Total Outlays</b>	1,116,779	1,167,867	1,215,886
<p>1/ A full-year 2018 appropriation was not enacted at the time the budget was prepared; therefore, the budget reflects the annualized level of the Continuing Resolution (P.L. 115 56), including any funding anomalies and directed or permissive transfers (where applicable).</p> <p>2/ The Budget Authority levels presented here are based on the Appendix and are inclusive of the Addendum to the FY 2019 President's Budget, and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.</p>			



#### General Notes

This document presents the full FY 2019 Budget for HHS, inclusive of the Addendum to the President's FY 2019 Budget to account for the Bipartisan Budget Act of 2018. Numbers in this document may not add to the totals due to rounding. Budget data in this book are presented "comparably" to the FY 2019 Budget, since the location of programs may have changed in prior years or be proposed for change in FY 2019. This approach allows increases and decreases in this book to reflect true funding changes.

## 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 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) 2019 Budget supports the mission of the Department of Health and Human Services (HHS) by making thoughtful and strategic investments to protect the health and well-being of the American people, address the opioid crisis, promote patient-centered health care, strengthen services for American Indians and Alaska Natives, encourage innovation in America's health care future, address drug pricing, advance regulatory reform, and focus resources toward proven and effective initiatives.

The President's Budget request for HHS proposes \$95.4 billion in discretionary budget authority and \$1,120 billion in mandatory funding to carry out the mission of the Department and to fulfill the promises made by the Administration to the American people. The Budget is a commitment to promote a streamlined Federal Government that makes the best possible use of taxpayer dollars and focuses investments in the most effective areas. The Budget also reflects proposals to meet the President's comprehensive Government-wide Reform Plan through a Department initiative called Relmagine HHS. Relmagine HHS is an answer to the President's call for a more efficient and effective Federal Government on behalf of the American people. Likewise, HHS's approach to budgeting identifies resources essential to enabling HHS to fulfill its unique Federal role to enhance the health and well-being of the American people.

### TACKLING THE OPIOID EPIDEMIC

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's Budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The Budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The Budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication assisted therapies;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

#### ***Improving Access to Prevention, Treatment, and Recovery Services***

The Budget directs resources to the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve access to medication assisted treatment services and to improve state capacity to establish and operate comprehensive prevention systems. The Budget also supports rural health grants through the Health Resources and Services Administration (HRSA), which expand opportunities to receive treatment for substance and opioid addiction in high-risk communities in order to improve access to prevention, treatment, and recovery services. Community health centers will have access to new funding for quality improvement efforts that utilize evidence-based models to support behavioral health, including opioid addiction, needs of the populations they serve.

#### ***Targeting Availability and Distribution of Overdose-Reversing Drug***

First responders are on the front lines of the opioid epidemic. The Budget will provide grants through SAMHSA to support community efforts to equip and train first responders with lifesaving drugs. This investment will continue to support the important role of overdose-reversing drugs in improving community preparedness for an overdose in progress.

#### ***Improving our Understanding of the Crisis through Better Data and Reporting***

The Budget supports efforts by the Centers for Disease Control and Prevention (CDC) to prevent the abuse and

overdose of opioids. This investment funds key public health and surveillance activities, including: improving data quality and timeliness to better track the epidemic; strengthening state efforts for effective public health interventions; and supplying health care providers with data and tools to improve prescribing practices. In FY 2019, CDC will continue to increase the awareness and adoption of the *CDC Guideline for Prescribing Opioids for Chronic Pain*.

#### ***Supporting Cutting Edge Research on Pain and Addiction***

The Budget invests \$500 million in the National Institutes of Health (NIH) to support and supplement existing efforts with a public-private collaborative research initiative on opioid abuse. The Partnership will accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose, and to help optimize their implementation.

#### ***Advancing Pain Management***

Interventions to improve safe and appropriate prescribing must balance the use of these drugs for legitimate pain management with the need to curb dangerous practices. The FY 2019 Budget will support the Pain Management Best Practices Inter-Agency Task Force, authorized by the Comprehensive Addiction and Recovery Act of 2016. The Task Force is charged with reviewing, identifying gaps in, and making recommendations to update, pain management best practices (including for prescribing pain medication and managing chronic and acute pain). The Task Force will: determine whether there are gaps or inconsistencies in pain management best practices among Federal agencies; propose recommendations on addressing gaps or inconsistencies; provide the public with an opportunity to comment on any proposed recommendations; and develop a strategy for disseminating information about best practices.

#### **ADDRESSING SERIOUS MENTAL ILLNESS**

In 2016, roughly 1 in 25 adults in the United States, age 18 and older, battled serious mental illness, such as a psychotic or major depressive disorder. A portion of these individuals may cycle repeatedly among the health, behavioral health, and criminal or juvenile justice systems, with each system insufficiently prepared to meet their needs. The new \$10 billion investment proposed in the Budget will support activities that address serious mental illness, and help fight the opioid epidemic.

#### ***Supporting Early Interventions***

The Budget continues to direct 10 percent of state allocations from the Community Mental Health Services Block Grant to bring care more quickly to those experiencing a first episode of psychosis. In addition, the Budget would also provide funding for SAMHSA's Healthy Transitions Program to support early intervention among youth with or at risk of developing a serious mental illness who are transitioning to adulthood. Compared to their peers, these young people are significantly more likely to experience homelessness, be arrested, drop out of school, and be unemployed. Effective outreach, including improvements to state health systems' capacity, is critical to slow the advancement of these illnesses which have a devastating impact on these individuals and their communities.

#### ***Providing Care Where It Is Needed Most***

The Budget will fully fund the new Assertive Community Treatment for Individuals with Serious Mental Illness program, which was authorized by the 21st Century Cures Act, to place individuals in the care of a multidisciplinary behavioral health staff to deliver comprehensive, individualized, and recovery-oriented treatment and case management services which are proven to reduce hospitalization at the same cost with higher patient satisfaction. In addition, the Budget expands Criminal and Juvenile Justice Programs to provide comprehensive treatment and recovery support services for adolescents and adults with co-occurring mental illness and drug or alcohol addiction who come into contact with the criminal justice system, as well as for offenders re-entering the community.

#### **PRIORITIZING BIODEFENSE AND PREPAREDNESS PROGRAMS**

The FY 2019 Budget will continue to improve our Nation's preparedness for, and capabilities to respond to, emerging infectious diseases and incidents involving chemical, biological, radiological, and nuclear agents. The Budget includes \$512 million for the Biomedical Advanced Research and Development Authority and \$510 million for BioShield to support the development and procurement of new medical products (medical countermeasures) that will strengthen our national preparedness and biodefense against chemical and biological threats. These resources would build on prior HHS investments, which have resulted in a robust development pipeline of more than 190 medical

countermeasure candidates and the procurement of 14 new products for the Stockpile, of which 6 have achieved Food and Drug Administration (FDA) approval.

The Budget reflects to transfer the Strategic National Stockpile to the Office of the Assistant Secretary for Preparedness and Response (ASPR), and provides \$575 million to maintain and replenish the Nation's largest supply of life-saving medical countermeasures that can be deployed in the event of a public health emergency.

#### ***Advancing Preparedness and Response Capabilities***

Some disasters require a Federal response as evidenced by the number of powerful hurricanes and historic wildfires in 2017. HHS remains ready to respond to any and all hazards when disaster strikes. The Budget provides \$2.2 billion to ASPR to ensure the Department is able to continue operations in the event of a disaster and to support essential emergency exercises to refine our response in realized emergency situations. Hospital Preparedness Program resources will continue to be allocated to states and localities according to risk, ensuring communities with more risk have the necessary coordination and resources to mitigate loss in the event of disaster. The Budget continues to provide \$50 million to support the National Disaster Medical System's response capability by updating patient care supplies and providing essential training to the team members each year.

#### ***Global Health and Global Health Security***

To protect Americans from the threat of infectious diseases, it is critical that the U.S. Government maintain effective global response capacity and ensure other countries follow through on their commitments to build their own domestic capabilities. Investing in global public health preparedness is far less expensive than mounting an international public health response to control an epidemic. To support this endeavor, the Budget provides a total of \$409 million for CDC's global health activities, which serves to strengthen CDC's international preparedness and response capabilities. This funding will help improve detection programs, response team efforts, and partner collaboration.

Furthermore, substantial progress has been made toward meeting global health security goals regarding the prevention and management of global disease threats as a result of the CDC's Ebola emergency appropriation, which expires at the end of FY 2019.

The FY 2019 Budget would build on this work and provide uninterrupted support by providing \$109 million within CDC's total global health funding for CDC's Global Disease Detection Program, of which \$59 million will be used to support the continuation of CDC's Global Health Security Agenda activities. Specific activities supported by this funding include surveillance and detection efforts, emergency operations infrastructure, technical assistance, and workforce training programs.

#### ***Cybersecurity***

The Budget recognizes that HHS must continue robust operations to meet today's cybersecurity needs and includes \$68 million to ensure the Department is able to protect sensitive and critical information in an ever-changing threat landscape. This investment will continue our operations to detect, manage, and remediate cybersecurity risks. Additionally, the Department will enhance its support and coordination within the health care and public health sectors through the Healthcare Cybersecurity Communications and Integration Center. The Center, in close coordination with the Department of Homeland Security, will share information across HHS and Federal Government partners; state, territorial, and local public health authorities; and the private sector to facilitate information and resource sharing and provide guidance in response to cyber threats.

#### **FOSTERING INNOVATION**

In an effort to better use data and technology to drive innovation and streamline the delivery of government services, the Budget includes \$486 million for the FDA to speed the development and approval of new drugs and medical devices, as well as to increase the quality and safety of next generation manufacturing practices. FDA will invest these resources in developing the scientific base and regulatory capacity necessary to advance the safety, quality, and efficiency of medical device and pharmaceutical manufacturing. In the fast-evolving field of digital health technologies, these resources will help advance new regulatory approaches to support rapid innovation cycles that will reduce the time and cost of market entry for new products while assuring appropriate patient safeguards.

Further, the Administration is committed to supporting innovation through biomedical research conducted by the NIH in an efficient and effective manner. NIH makes crucial contributions to our Nation, including

addressing emerging health threats, developing innovative treatments for disorders and diseases, and sustaining a multifaceted workforce trained to carry out promising research for the future of America's health care.

The Budget recognizes the importance of funding the highest priority scientific discoveries while also maintaining fiscal responsibility. As such, certain research functions from across the Department will be consolidated within NIH and established as three new NIH institutes: the National Institute for Research on Safety and Quality; the National Institute for Occupational Safety and Health, including the Energy Employees Occupational Illness Compensation Program; and the National Institute on Disability, Independent Living, and Rehabilitation Research. By centralizing these research functions within NIH, the Budget continues to foster the valuable research produced by the Department in a more efficient manner to leverage the resources of NIH.

#### **STRENGTHENING THE INDIAN HEALTH SERVICE**

HHS is entrusted with the unique responsibility to provide quality health care services to more than 2.2 million eligible American Indians and Alaska Natives. In many cases Tribes have assumed the responsibility of providing health care for their members with support from the Indian Health Service. The Budget prioritizes funding for direct health services to support improved health outcomes for American Indians and Alaska Natives. The Budget fully funds staffing for new and replacement facilities and contract support costs, and invests \$58 million to assist facilities, including those in the Great Plains Area, with meeting the Centers for Medicare & Medicaid Services (CMS) quality health standards.

#### **ADVANCING HEALTH REFORM**

The Administration remains committed to advancing health care reform that expands choices, increases access, lowers costs for the American people, and provides relief from Obamacare. The Budget includes reforms to reverse the effects of the status quo's Washington-centered, one-size-fits-all approach to health care, and would direct funding and critical resources back to the states and individuals where health care decisions should be made. The Budget encourages patient-centered care and market-based

innovation in order to advance health reform for the American people.

The Budget supports repealing Obamacare and replacing the law with flexibility for states to create a free and open health care market tailored to their citizens' needs. The two-part approach to achieve these reforms is modeled closely after the Graham-Cassidy-Heller-Johnson bill alongside additional reforms to put health care spending on a sustainable fiscal path.

Specifically, the Market-Based Health Care Grant Program will help states stabilize their insurance markets and provide for a smooth transition away from Obamacare. At the same time, these reforms will improve Medicaid's sustainability and help states focus resources on those individuals most in need. The Budget would end the disparity between states that expanded Medicaid under Obamacare and those states that did not expand Medicaid and provides states with a choice between a per capita cap and a block grant.

Additional reforms to ensure Federal health care programs work for the American people include reforming the medical liability system and advancing graduate medical education reform. The President's Budget consolidates Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospitals Graduate Medical Education program into a single grant program for teaching hospitals, and directs funding toward physician specialty and geographic shortages. Patients and providers will be better served by these commonsense reforms. The new grant program would be operated jointly by the CMS and HRSA Administrators.

#### ***Sustainable Medicaid and Medicare Reforms***

Millions of Americans rely on Medicaid and Medicare to meet their everyday healthcare needs, and together Federal health care programs comprise the largest portion of the Federal Budget. As such, the Budget proposes several legislative solutions to improve the programs, promote greater efficiencies, advance patient-centered care, and reduce government-imposed burden on providers.

The Budget supports a new future for Medicaid to restore the Federal-state partnership, while modernizing the program to refocus on the populations the program was intended to serve and deliver better outcomes. The Medicaid reforms will put the program



on a stable fiscal path by restructuring Medicaid financing and providing states with added flexibility, and otherwise improve the state plan and waiver processes.

### ***Improve Drug Pricing and Payments***

The Budget makes significant strides toward addressing and reining in drug prices. The legislative solutions would benefit seniors by protecting Medicare beneficiaries from high drug prices, giving plans more tools to manage spending, and realigning incentives in the Part D drug benefit structure. The proposed changes enhance Part D plans' negotiating power with manufacturers; encourage utilization of higher value drugs; discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the Government; and provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap.

### **PROMOTING UPWARD ECONOMIC MOBILITY**

The FY 2019 Budget advances initiatives to foster independence, work and personal responsibility.

The Budget proposes to reinforce the focus of the Temporary Assistance for Needy Families (TANF) program on work and self-sufficiency for low-income families by strengthening its primary performance measure related to work engagement, and ensuring that states allocate sufficient funds to work, education, and training activities for low-income families. The Budget also proposes establishing Welfare to Work Projects; these rigorously evaluated demonstrations will allow states to streamline funding from multiple public assistance programs, and redesign service delivery so that it is tailored to their constituents' specific needs.

Further, on January 11, 2018, the Administration announced its intention to support Medicaid demonstrations that promote work or community engagement activities (e.g., volunteering, educational activities, or job training) for working age, able-bodied adults, and that link such requirements to improved health and well-being. The Budget promotes such programs that may be designed to help individuals and families rise out of poverty and attain independence.

### **DRIVING EFFICIENCY IN RESEARCH INVESTMENT**

The Budget targets funding within NIH to support the highest priority biomedical research. The FY 2019

Budget provides nearly \$35 billion to improve public health by advancing our knowledge of disease and cures. Increasing efficiencies within the NIH is a priority of the Administration, and NIH would improve agency management: instituting administrative reforms and encouraging innovative partnerships with non-Federal entities.

The Budget supports increased coordination across NIH Institutes and Centers, and proposes to focus grant awards on projects with the highest potential to accrue benefits for public health. Basic science is the bedrock of research, and has proven exceptional value in advancing human health. Increased scrutiny of strategic investments in research will help ensure that funded projects represent the best use of taxpayer resources.

The Budget supports administrative reforms, including the implementation of the largest change management effort in NIH's history to harmonize operational functions that advance scientific innovation. These reforms will align management with best practices and break down administrative silos through greater standardization processes agency-wide.

The Budget will decrease the direct cost of research by capping the percentage of investigator salary that can be paid with grant funds, and by reducing the limit for salaries paid with grant funds from \$187,000 to \$152,000. These policies will target available funding to support the highest priority research on diseases that affect human health. In tandem, the Budget supports burden reduction measures that will further reduce grant award recipient costs associated with research.

The Budget maximizes the utility of Federal research dollars by expanding public-private partnerships that will challenge private sector partners to match Federal investments in mutually determined priority areas.

In the FY 2018 Budget, the Administration proposed reforming NIH's indirect cost rate methodology to ensure that taxpayer dollars were focused on high-impact research and not administrative overhead. Congress subsequently prohibited NIH from implementing these reforms and, in fact, prohibited any further study or exploration of indirect cost rate reforms at NIH. The Administration needs to ensure that taxpayer dollars are focused on high-impact

research, which is central to effective administration of a true research enterprise.

#### **EXERCISING FISCAL STEWARDSHIP**

The FY 2019 President's Budget is a commitment to fiscal stewardship and the bold reforms that will save, strengthen, and secure America's health care future. Without thoughtful leadership and a fiscally sustainable approach to budgeting, the future of America's health care programs is at risk and susceptible to the consequences of deficit spending and an unsustainable national debt. The FY 2019 President's Budget brings Federal spending under control.

HHS represents the largest portion of the Federal Government's Budget and is in a unique role to help restore fiscal solvency to the overall Budget. Toward this end, the Department's budget saves taxpayers an estimated \$637 billion in net legislative savings over ten years.

#### **PROHIBIT CERTAIN ABORTION PROVIDERS FROM RECEIVING FEDERAL FUNDS**

The Budget includes provisions prohibiting certain abortion providers from receiving Federal funds from HHS, including those that received funding under the Title X Family Planning program and Medicaid, among other HHS programs.

**HHS BUDGET BY OPERATING DIVISION /1**

<i>dollars in millions</i>	2017	2018	2019
<b>Food and Drug Administration</b>			
Budget Authority	3,215	2,766	3,257
Outlays	3,312	2,600	3,092
<b>Health Resources and Services Administration</b>			
Budget Authority	10,732	10,864	9,891
Outlays	10,894	10,997	10,634
<b>Indian Health Service</b>			
Budget Authority	5,107	5,176	5,433
Outlays	4,775	5,449	5,410
<b>Centers for Disease Control and Prevention</b>			
Budget Authority	7,653	7,565	6,078
Outlays	7,999	8,108	7,530
<b>National Institutes of Health</b>			
Budget Authority	33,448	33,292	33,888
Outlays	31,062	34,369	35,082
<b>Substance Abuse and Mental Health Services Administration</b>			
Budget Authority	4,123	4,102	3,426
Outlays	3,414	3,734	3,616
<b>Agency for Healthcare Research and Quality /2</b>			
Program Level	415	422	0
Budget Authority	323	322	0
Outlays	318	300	240
<b>Centers for Medicare &amp; Medicaid Services /3</b>			
Budget Authority	1,021,127	1,071,569	1,122,804
Outlays	998,556	1,039,384	1,092,541
<b>Administration for Children and Families</b>			
Budget Authority	54,481	54,126	47,247
Outlays	51,990	54,539	48,971
<b>Administration for Community Living</b>			
Budget Authority	1,940	1,931	1,819
Outlays	1,896	1,953	1,966
<b>Departmental Management/4</b>			
Budget Authority	383	483	315
Outlays	939	1,215	746



## HHS BUDGET BY OPERATING DIVISION

<i>dollars in millions</i>	2017	2018	2019
<b>Opioids and Serious Mental Illness</b>			
Budget Authority	-	-	10,000
Outlays	-	-	2,800
<b>Office of Medicare Hearings and Appeals</b>			
Budget Authority	107	107	251
Outlays	107	107	251
<b>Office of the National Coordinator</b>			
Budget Authority	60	60	38
Outlays	81	102	46
<b>Office for Civil Rights</b>			
Budget Authority	40	39	31
Outlays	22	37	34
<b>Office of Inspector General</b>			
Budget Authority	82	81	80
Outlays	47	76	84
<b>Public Health and Social Services Emergency Fund</b>			
Budget Authority	1,514	1,563	2,304
Outlays	1,770	4,467	3,066
<b>Program Support Center (Retirement Pay, Medical Benefits, Misc. Trust Funds)</b>			
Budget Authority	709	742	743
Outlays	628	1,380	740
<b>Offsetting Collections</b>			
Budget Authority	-891	-799	-772
Outlays	-891	-799	-772
<b>Other Collections</b>			
Budget Authority	-140	-151	-191
Outlays	-140	-151	-191
<b>Total, Health and Human Services</b>			
Budget Authority	<b>1,144,013</b>	<b>1,193,838</b>	<b>1,241,642</b>
Outlays	<b>1,116,779</b>	<b>1,167,867</b>	<b>1,215,886</b>
1/ The Budget Authority levels presented here are based on the Appendix and are inclusive of the Addendum to the FY 2019 President's Budget, and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.			
2/ Includes transfer from the Patient-Centered Outcomes Research Trust Fund.			
3/ 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.			
4/ Includes the Pregnancy Assistance Fund, the Health Insurance Reform Implementation Fund, and the Nonrecurring Expenses Fund; transfers from the Patient-Centered Outcomes Research Trust Fund; and payments to the State Response to the Opioid Abuse Crisis Account.			

## COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

<i>dollars in millions</i>	2017	2018	2019	2019 +/-2018
<b>Discretionary Programs (Budget Authority):</b>				
<b>Food and Drug Administration</b>	2,800	2,781	3,254	+473
<i>Program Level</i>	4,754	5,136	5,799	+663
<b>Health Resources and Services Administration</b>	6,207	6,164	9,569	+3,405
<i>Program Level</i>	10,458	10,557	9,604	-953
<b>Indian Health Service</b>	5,040	5,011	5,424	+413
<i>Program Level</i>	6,389	6,363	6,626	+263
<b>Centers for Disease Control and Prevention</b>	6,354	6,290	5,587	-703
<i>Program Level</i>	12,100	11,973	10,921	-1,053
<b>National Institutes of Health</b>	33,265	33,099	33,846	+747
<i>Program Level</i>	34,229	34,067	34,767	+699
<b>Substance Abuse and Mental Health Services Administration</b>	4,111	4,091	3,426	-665
<i>Program Level</i>	4,258	4,236	3,548	-688
<b>Agency for Healthcare Research and Quality /1</b>	323	322	0	-322
<i>Program Level</i>	415	422	0	-422
<b>Centers for Medicare &amp; Medicaid Services</b>	3,966	3,948	3,544	-404
<i>Program Level</i>	6,027	18,182	5,729	-12,453
<b>Administration for Children and Families /2</b>	19,702	19,144	15,317	-3,827
<i>Program Level</i>	19,702	19,144	15,317	-3,827
<b>Administration for Community Living</b>	1,959	1,953	1,819	-134
<i>Program Level</i>	2,040	2,033	1,837	-197
<b>Office of the Secretary:</b>				
<b>General Departmental Management</b>	460	458	290	-168
<i>Program Level</i>	555	552	381	-171
<b>Opioids and Serious Mental Illness</b>	-	-	10,000	+10,000

## COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

<i>dollars in millions</i>	2017	2018	2019	2019 +/-2018
<b>Office of Medicare Hearings and Appeals</b>	107	107	112	+5
<i>Program Level</i>	107	107	251	+144
<b>Office of the National Coordinator</b>	60	60	38	-22
<i>Program Level</i>	60	60	38	-22
<b>Office for Civil Rights</b>	39	39	31	-8
<b>Office of Inspector General</b>	82	81	80	-1
<i>Program Level</i>	359	365	388	+23
<b>Public Health and Social Services Emergency Fund</b>	1,514	1,563	2,304	+741
<i>Program Level</i>	1,529	1,563	2,304	+741
<b>Discretionary HCFAC</b>	725	725	770	+45
<b>Accrual for Commissioned Corps Health Benefits</b>	28	32	30	-2
<b>Total, Discretionary Budget Authority</b>	<b>86,742</b>	<b>85,866</b>	<b>95,440</b>	<b>+9,574</b>
<i>NEF Cancellation and Rescissions /3</i>	-400	-	-	-
<i>Less One-Time Rescissions</i>	-8,199	-3,936	-	+3,936
<b>Revised, Discretionary Budget Authority</b>	<b>78,143</b>	<b>81,930</b>	<b>95,440</b>	<b>+13,510</b>
<b>Discretionary Outlays</b>	<b>84,559</b>	<b>94,399</b>	<b>95,926</b>	<b>+1,527</b>
1/ The 2019 Budget includes \$256 million to consolidate the Agency for Healthcare Research and Quality's activities within the National Institutes of Health.				
2/ Administration for Children and Families' totals do not include a \$20 million reduction due to a change in mandatory programs for 2017 and 2018 created by the difference between the OMB and CBO baseline assumptions on the mandatory portion of the Promoting Safe and Stable Families (PSSF) account. The reduction is included within the "Less One-Time Rescissions" line.				
3/ The 2017 amount reflects the \$300 million transfer to the Administration for Children and Families and a \$100 million rescission included in the 2017 Continuing Resolution.				

## COMPOSITION OF THE HHS BUDGET

### MANDATORY PROGRAMS

	2017	2018	2019	2019 +/-2018
<b>Mandatory Programs (Outlays):</b> <sup>1 /2</sup>				
Medicare	591,508	581,662	629,882	+48,220
Medicaid	374,682	400,388	412,033	+11,645
Temporary Assistance for Needy Families <sup>3 /4</sup>	16,541	16,957	15,420	-1,537
Foster Care and Adoption Assistance	7,712	8,266	8,615	+349
Children's Health Insurance Program <sup>5</sup>	16,251	17,318	11,424	-5,894
Child Support Enforcement	4,075	4,206	4,334	+128
Child Care Entitlement	2,905	3,010	3,165	+155
Social Services Block Grant	1,661	1,621	307	-1,314
Other Mandatory Programs	17,775	40,837	35,550	-5,287
Offsetting Collections	-890	-797	-770	+27
<b>Subtotal, Mandatory Outlays</b>	<b>1,032,220</b>	<b>1,073,468</b>	<b>1,119,960</b>	<b>+46,492</b>
<b>Total, HHS Outlays</b>	<b>1,116,779</b>	<b>1,167,867</b>	<b>1,215,886</b>	<b>+48,019</b>
1/ Totals may not add due to rounding. The Budget does not incorporate the effects of Public Law 115-120, including the reauthorization of the Children's Health Insurance Program.				
2/ Does not include \$2.2 billion in net costs to HHS due to the Repeal and Replace Obamacare proposal in FY 2019. See the Health Reform chapter for more information.				
3/ Includes outlays for the Temporary Assistance for Needy Families program and Temporary Assistance for Needy Families Contingency Fund.				
4/ The amounts listed for FY 2018 Outlays do not take into account updated scoring of legislative proposals in Temporary Assistance for Needy Families that are displayed in ACF budget documents.				
5/ Includes outlays for the Child Enrollment Contingency Fund.				

## Food and Drug Administration



<i>dollars in millions</i>	2017 /1/3	2018 /2/3	2019 /7	2019 +/- 2018
<b>FDA Programs</b>				
Foods	1,041	1,033	1,041	+8
Human Drugs	1,330	1,611	1,853	+241
Biologics	339	358	403	+45
Animal Drugs and Feeds	195	187	225	+38
Medical Devices	448	505	636	+131
National Center for Toxicological Research	63	63	65	+2
Tobacco Products	596	600	662	+70
Headquarters and Office of the Commissioner	281	314	347	+33
White Oak Consolidation	47	46	57	+11
GSA Rental Payment	232	238	240	+1
Other Rent and Rent Related Activities	117	123	139	+16
<b>Subtotal, Salaries and Expenses</b>	<b>4,690</b>	<b>5,072</b>	<b>5,668</b>	<b>+596</b>
Export Certification Fund	5	5	9	+4
Color Certification Fund	10	10	10	-0
Rare Pediatric Priority Review Vouchers	8	8	8	--
Buildings and Facilities	12	12	12	+0
21 <sup>st</sup> Century Cures Act	20	20	70	+50
Emerging Health Threats	10	10	--	-10
Over-the Counter Monograph	--	--	22	+22
<b>Total, Program Level</b>	<b>4,754</b>	<b>5,136</b>	<b>5,799</b>	<b>+663</b>
Additional Opioids Allocation/ 4	--	--	10	+10
<b>Total, with Additional Opioids Allocation</b>	<b>4,754</b>	<b>5,136</b>	<b>5,809</b>	<b>+673</b>
<b>Current Law User Fees /4</b>				
Prescription Drug	755	911	961	+49
Medical Device	126	193	197	+3
Generic Drug	323	494	501	+8
Biosimilars	22	40	41	+1
Animal Drug /6	24	18	30	+12
Animal Generic Drug /6	11	9	18	+9
Family Smoking Prevention and Tobacco Control Act	635	631	712	+81
Food Reinspection	6	6	6	--
Food Recall	1	1	1	--
Mammography Quality Standards Act	21	21	21	--
Export Certification Fund	5	5	5	--
Color Certification Fund	10	10	10	-0
Rare Pediatric Priority Review Vouchers	8	8	8	--
Voluntary Qualified Importer Program	5	5	5	--
Third Party Auditor Program	1	1	1	--
Outsourcing Facility	1	1	2	+0
<b>Subtotal, Current Law User Fees</b>	<b>1,954</b>	<b>2,355</b>	<b>2,519</b>	<b>+164</b>
<b>Proposed Law User Fees</b>				
Export Certification /8	--	--	4	+4
Over-the Counter Monograph	--	--	22	+22
<b>Subtotal, Proposed Law User Fees</b>	<b>--</b>	<b>--</b>	<b>26</b>	<b>+26</b>



## Food and Drug Administration

<i>dollars in millions</i>	2017/1/3	2018 /2/3	2019 /5	2019 +/- 2018
<b>Less Total, User Fees</b>	<b>1,954</b>	<b>2,355</b>	<b>2,545</b>	<b>+190</b>
<b>FDA Totals</b>				
<b>Total, Discretionary Budget Authority</b>	<b>2,800</b>	<b>2,781</b>	<b>3,254</b>	<b>+473</b>
1/ Reflects FY 2017 Final, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ Reflects a transfer of \$1.5 million to the HHS Office of Inspector General for FDA oversight activities as specified in the FY 2017 appropriation and continued by the FY 2018 Continuing Resolution less a rescission.				
4/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				
5/ Does not reflect priority review voucher user fee for Medical Countermeasures as FDA continues to develop an estimated fee level.				
6/ The animal drug and animal generic user fee programs expire on October 1, 2018. FDA transmitted reauthorization proposals to Congress on January 2, 2018.				
7/ All figures are displayed comparable to the FY 2019 President's Budget. The FY 2017, FY 2018, and FY 2019 columns have been updated to reflect reallocated funding across the programs addressing previous reorganizations that consolidated economists in Headquarters, as well as to better align the funding structure to services related to intergovernmental affairs.				
8/ The FY 2019 President's Budget proposes to increase the statutory user fee limit for export certification.				

*The Food and Drug Administration is responsible for protecting 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 speed innovations that make medicines more effective, safer, and affordable; and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. Furthermore, FDA has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA plays a significant role in the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.*

### FDA PROGRAMS

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA oversees more than \$2.4 trillion in consumption of medical products, food and tobacco. This oversight includes regulating 75 percent of the United States food supply. The Fiscal Year (FY) 2019 Budget includes \$5.8 billion in total resources for FDA, an increase of

\$663 million or 13 percent above the FY 2018 Continuing Resolution. At this total level, the Budget provides an increase of \$190 million in user fees, while increasing budget authority by \$473 million. In addition, the Budget provides an initial allocation of \$10 million to FDA as part of a historic \$10 billion Department-wide investment to address the opioid epidemic and serious mental illness.

The Budget prioritizes resources across core public health activities including advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable; establishing a risk-based food safety system; and

#### PROGRAM HIGHLIGHT

### Novel Drug Approvals

Innovation drives progress. Understanding this principle, FDA supports innovation in the development of new drugs and therapeutic biological products. With its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat, FDA provides scientific and regulatory advice needed to bring new therapies to market.

The availability of new drugs and biological products often means new treatment options for patients and advances in health care for the American public. FDA approved 56 novel drugs and biological products in calendar year 2017. Approvals included new treatments for certain advanced or metastatic breast cancers, to prevent infection after bone marrow transplant, and to reduce the risk of breast cancer returning, the first gene therapies available in the United States.

supporting the government's preparedness infrastructure.

### **ADVANCING ACCESS TO SAFE AND EFFECTIVE MEDICAL PRODUCTS**

In August 2017, FDA issued a historic action making the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases. In the same year, FDA also approved the 200th HIV/AIDS therapy, and announced a Drug Competition Action Plan to advance new policies aimed at bringing more competition to the drug market. FDA has also issued guidance that will assist potential applicants who plan to develop an application to seek approval of a generic version of abuse-deterrent formulations of opioid drugs.

FDA is also closely examining whether regulations need to be revised, updated, or in some cases eliminated to help better keep pace with scientific advancement. As part of this effort, FDA has opened a number of public dockets to solicit feedback from patients, consumers, health providers, caregivers, industry, health groups, academia, as well as state, local and tribal governments, and public health partners. Internal and external stakeholders will be critical to focusing FDA's attention on which policies might need updating.

These activities are only a subset of the many medical product responsibilities FDA carries out. FDA oversees the safety, quality, and effectiveness of a broad scope of medical products used by Americans, including biologics such as vaccines, blood products, and gene therapies; prescription and over-the-counter drugs, radiation emitting products; and medical devices

ranging from dental devices to surgical implants. FDA ensures that regulated products are marketed according to Federal standards and that products available to the public continue to be safe, especially as new clinical information becomes available. FDA continues to incorporate cutting-edge regulatory science into its evaluations to support patient access to safe and effective medical products.

FDA has also integrated implementation of the 21st Century Cures Act into broader agency efforts. FDA has utilized new authorities in the 21st Century Cures Act to pursue new ways to improve the climate for innovation and advance products to those who need them. For example, FDA has announced a comprehensive policy framework for the development and oversight of regenerative medicine products, including novel cellular therapies. This modern framework is intended to balance the agency's commitment to safety with mechanisms to drive further advances in regenerative medicine so innovators can bring new, effective therapies to patients as quickly and safely as possible.

The FY 2019 Budget supports FDA's critical role to ensure safe and effective medical products are advanced to market. To that end, FDA continues to implement requirements under the FDA Reauthorization Act of 2017, which reauthorized select user fee programs and builds upon the goals outlined in previous user fee agreements and in the 21st Century Cures Act. The Budget also assumes reauthorization of the Animal Drugs and Animal Generic Drugs User Fee Acts in FY 2019, consistent with the reauthorization proposal transmitted to Congress in January.

#### **PROGRAM HIGHLIGHT**

### **Generics Spur Access and Competition**

The Federal Food, Drug, and Cosmetic Act provides an incentive to generic drug applicants by granting a 180 day period of exclusivity to the applicant that is first to file a substantially complete application to FDA. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to health care for more patients.

Some "first filers" can block subsequent generic competitors from receiving approval under this exclusivity provision. Similarly, first filers that receive tentative approval but then intentionally delay seeking final approval can block subsequent competitors. As a result, first filers can "park" their exclusivity, and consumers are denied access to generic products and must keep paying brand price.

The Budget includes a legislative proposal to address this problem. The proposal makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity. This means the period of exclusivity would immediately begin for the first filer. This proposal will enhance competition and facilitate more timely access to generic drugs. This proposal is estimated to create \$1.8 billion in Medicare savings over 10 years.



In FY 2019, the Budget requests a total \$3.6 billion at the program level for medical product safety investments, which is \$572 million above the FY 2018 Continuing Resolution. This total includes \$1.8 billion in budget authority, and \$1.8 billion in user fees. The Budget advances FDA's highest priority activities to ensure the safety and efficacy of medical products available to the American public. The total includes \$20 million for the new Oncology Center of Excellence, established in FY 2017. This office leverages the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices to advance the development and regulation of oncology products for patients with cancer. This dedicated funding will allow FDA to more robustly help expedite the development of oncology and hematology medical products and support an integrated approach in the clinical evaluation of drugs, biologics, and devices for the treatment of cancer.

#### ***Fighting the Opioid Epidemic***

The Budget proposes \$10 billion in new resources across HHS to combat the opioid epidemic and address serious mental illness. As part of this effort, the Budget includes an initial allocation of \$10 million in FDA to support investment in regulatory science in development of tools to stem the misuse and abuses of opioids and to provide technical assistance related to clinical study design related to Medication-Assisted Treatments. These funds would support the creation of diagnostics to support health professionals to more optimally deliver evidence-based Medication-Assisted Treatments, and to accelerate the development of generic versions of opioid drug products with abuse deterrent formulations.

The Budget also includes a legislative proposal to modernize the over-the-counter drug monograph system. The Budget envisions a framework that converts burdensome rulemaking to a streamlined administrative order process; removes barriers to innovation; implements a new mechanism for quickly responding to urgent safety issues; reduces the backlog by finalizing unfinished monographs; and creates a user fee program for over-the-counter monograph drugs. To support this effort, FDA will collect an estimated \$22 million in user fee resources in FY 2019 and \$134 million over the 5-year authorization.

In FY 2019, FDA will continue to carry out high priority medical product safety activities including continuing to modernize the approach FDA uses to fulfill its

mandate to promote and protect the public health and uphold FDA's gold standard for regulatory decision-making.

#### **MODERNIZING THE FOOD SAFETY SYSTEM**

Having issued all seven foundational final rules to establish a risk-based food safety system, FDA's implementation of the Food Safety Modernization Act continues by ensuring stakeholders across the public and private sectors are positioned to comply with these rules. In FY 2018, FDA will build on these regulations and guide the modernization of our food safety system, including supporting the food industry in implementing the new prevention-oriented standards; investing in training and capacity of state and local regulators to ensure regulatory oversight nationwide; and enhancing FDA's foreign presence and interactions with partners to increase oversight of importers. These activities ultimately will improve public health by shifting the focus from responding to contamination to preventing it from entering the food supply.

The food safety portfolio at FDA will continue to support important food and feed safety activities that are critical to the public in FY 2019, such as implementing mandatory standards for imported food, rapidly detecting and responding to major foodborne illness outbreaks, and striving to provide consumers with material about healthy choices using the most up-to-date science. FDA will also continue support for food safety research, cosmetics safety, partnerships with academic institutes, and international capacity building.

The Budget includes \$1.4 billion for food safety across FDA programs, which is \$10 million above the the FY 2018 Continuing Resolution. This total includes \$1.4 billion in budget authority, which is \$10 million above the FY 2018 Continuing Resolution, and \$16 million in user fees, flat with the FY 2018 Continuing Resolution. These currently authorized user fees support programs such as the voluntary qualified importer program, export certification, and the third party auditor program. The Budget also supports the development of state safety infrastructure by evaluating whether states will have an increased role in conducting inspections on larger farms on behalf of FDA and continuing outreach and education to small farms as they prepare for their upcoming compliance dates.



## **FDA INFRASTRUCTURE AND FACILITIES**

The FY 2019 Budget funds high priority infrastructure activities that directly support FDA's mission-critical work ensuring food and medical product safety. FDA infrastructure and facilities, including 56 laboratories strategically located across the continental United States and Puerto Rico, provide the necessary capabilities to ensure the agency meets its regulatory responsibilities, strategic priorities, and program initiatives. FDA strategically manages its infrastructure to create high-quality work environments, optimize the use of taxpayer dollars, enhance productivity, and ensure efficient and reliable operations to protect public health. The Budget invests a total of \$435 million, \$31 million above the FY 2018 Continuing Resolution, in FDA infrastructure, including costs to keep up with scheduled infrastructure increases, allow facilities to support cutting-edge and innovative regulatory science, and continue planned activities at both FDA headquarters and in the field.

Safe, secure, and operation-ready buildings, facilities, and laboratories enable FDA to protect Americans. The Budget also provides \$12 million, approximately flat with the FY 2018 Continuing Resolution, to fund repairs and improvements to maintain the condition of FDA-owned facilities.

## **ADVANCING MEDICAL COUNTERMEASURES**

FDA is responsible for assessing the safety and effectiveness of medical countermeasures—including drugs, therapeutic biologics, vaccines, and devices, such as diagnostic tests—to protect against chemical, biological, radiological, nuclear, and emerging infectious disease threats such as pandemic influenza, Ebola virus, and Zika virus. FDA works closely with departmental partners through the Public Health Emergency Medical Countermeasures Enterprise to build and sustain the medical countermeasures programs necessary to respond effectively to public health emergencies. In FY 2017, FDA approved 24 medical countermeasure marketing applications under review. The FY 2019 Budget includes \$24.5 million to continue the Medical Countermeasures program which directly supports medical countermeasures efforts across FDA in support of the Department's preparedness and response activities. These resources will help accelerate the development, evaluation, and approval of critical medical countermeasures. In addition, this funding will support the development

and coordination of policies to advance emergency preparedness and response.

## **REDUCING THE USE AND HARMS OF TOBACCO**

FDA, through the Center for Tobacco Products, executes its regulatory and public health responsibilities in program areas that support the following objectives: reducing initiation; decreasing the harms of tobacco product use; and encouraging cessation. Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year. Tobacco use also causes substantial financial costs, with direct health care and lost productivity costs totaling nearly \$300 billion a year.

In 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act. FDA plans to continue to strike an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes.

The FY 2019 Budget includes \$712 million in user fees to support the FDA tobacco program.

## **USER FEES**

The FDA Reauthorization Act of 2017 renewed the Prescription Drug User Fee Act for the sixth time, the Medical Device User Fee Amendments for the fourth time, and both the Generic Drug User Fee Amendments and the Biosimilar User Fee Act for the second time—allowing FDA to continue to collect these medical product user fees through fiscal year 2022. The new law supports many important FDA medical product activities, including enhancing the ability to capture the patient voice in drug development, and allowing FDA flexibility to inspect medical device facilities based on risk, enabling the Agency to focus its resources where they are most needed. The Budget assumes resources from reauthorizing the animal drugs and animal generics user fee programs set to expire at

the end of FY 2018, proposing a new user fee to support over-the-counter monograph review activities, increasing the allowable fee amount for the export certification fee, and increasing all currently authorized user fee programs by \$142 million. Resources from user fees are critical to enable FDA to carry out its mission and institute performance metrics that lead to greater efficiencies and increased speed at which products are available to the public.

## Health Resources and Services Administration



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Primary Health Care</b>				
Health Centers	4,898	4,981	4,991	+9
<i>Discretionary Budget Authority</i>	1,387	1,381	4,991	+3,609
<i>Current Law Mandatory</i>	3,511	550	--	-550
<i>Proposed Law Mandatory</i>	--	3,050	--	-3,050
Health Centers Tort Claims	100	99	100	+1
Free Clinics Medical Malpractice	1	1	1	--
<b>Subtotal, Primary Care</b>	<b>4,999</b>	<b>5,081</b>	<b>5,092</b>	<b>+10</b>
<b>Health Workforce</b>				
National Health Service Corps	289	310	310	--
<i>Discretionary Budget Authority</i>	--	--	310	+310
<i>Current Law Mandatory</i>	289	65	--	-65
<i>Proposed Law Mandatory</i>	--	245	--	-245
Training for Diversity	83	82	-	-82
Training in Primary Care Medicine	39	39	-	-39
Oral Health Training	37	36	-	-36
Teaching Health Centers Graduate Medical Education	56	60	60	--
<i>Discretionary Budget Authority</i>	--	--	60	+60
<i>Current Law Mandatory</i>	56	30	--	-30
<i>Proposed Law Mandatory</i>	--	30	--	-30
Area Health Education Centers	30	30	-	-30
Health Care Workforce Assessment	5	5	5	--
Public Health and Preventive Medicine Programs	17	17	-	-17
Nursing Workforce Development	229	228	83	-145
Children's Hospital Graduate Medical Education/3	299	298	-	-298
National Practitioner Data Bank User Fees	19	18	19	+1
Other Workforce Programs	99	98	0	-98
<b>Subtotal, Health Workforce</b>	<b>1,200</b>	<b>1,221</b>	<b>477</b>	<b>-744</b>
<b>Maternal and Child Health</b>				
Maternal and Child Health Block Grant	640	637	628	-10
Sickle Cell Demonstration Program	4	4	-	-4
Autism and Other Developmental Disorders	47	47	-	-47
Heritable Disorders	14	14	-	-14
Healthy Start	118	103	104	+1
Universal Newborn Hearing Screening	18	18	-	-18
Emergency Medical Services for Children	20	20	-	-20
Family-to-Family Health Information Centers	5	5	5	--
<i>Discretionary Budget Authority</i>	--	--	5	+5
<i>Current Law Mandatory</i>	5	--	--	--
<i>Proposed Law Mandatory</i>	--	5	--	-5
Home Visiting	372	400	400	--
<i>Discretionary Budget Authority</i>	--	--	400	+400
<i>Current Law Mandatory</i>	372	--	--	--
<i>Proposed Law Mandatory</i>	--	400	--	-400
<b>Subtotal, Maternal and Child Health</b>	<b>1,239</b>	<b>1,248</b>	<b>1,136</b>	<b>-112</b>



## Health Resources and Services Administration

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Ryan White HIV/AIDS Program</b>				
Emergency Relief - Part A	654	651	656	+4
Comprehensive Care - Part B	1,312	1,306	1,315	+9
<i>AIDS Drug Assistance Program [non-add]</i>	<i>900</i>	<i>894</i>	<i>900</i>	<i>+6</i>
Early Intervention - Part C	201	200	201	+1
Children, Youth, Women, and Families - Part D	75	75	75	--
AIDS Education and Training Centers - Part F	34	33	-	-33
Dental Services - Part F	13	13	13	--
Special Projects of National Significance	25	25	-	-25
<b>Subtotal, Ryan White HIV/AIDS</b>	<b>2,313</b>	<b>2,303</b>	<b>2,260</b>	<b>-43</b>
<b>Healthcare Systems</b>				
Organ Transplantation	23	23	24	+1
Cord Blood Stem Cell Bank	12	12	12	--
C.W. Bill Young Cell Transplantation Program	22	22	22	--
Poison Control Centers	19	19	19	--
340B Drug Pricing Program	10	10	26	+16
<i>Discretionary Budget Authority</i>	<i>10</i>	<i>10</i>	<i>10</i>	<i>--</i>
<i>User Fees</i>	<i>-</i>	<i>-</i>	<i>16</i>	<i>+16</i>
Hansen's Disease Programs	17	17	14	-3
<b>Subtotal, Healthcare Systems</b>	<b>104</b>	<b>103</b>	<b>117</b>	<b>+13</b>
<b>Rural Health</b>				
Rural Outreach Grants	65	65	51	-14
Rural Hospital Flexibility Grants	44	43	-	-43
Telehealth	18	18	10	-8
Rural Health Policy Development	9	9	5	-4
State Offices of Rural Health	10	10	-	-10
Radiation Exposure Screening and Education	2	2	2	--
Black Lung Clinics	7	7	7	--
<b>Subtotal, Rural Health</b>	<b>156</b>	<b>155</b>	<b>75</b>	<b>-80</b>
<b>Other Activities</b>				
Family Planning	286	285	286	+1
Program Management	154	153	152	-1
Vaccine Injury Compensation Program Direct Operations	8	8	9	+1
<b>Subtotal, Other Activities</b>	<b>448</b>	<b>445</b>	<b>448</b>	<b>+2</b>

## Health Resources and Services Administration



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>HRSA Budget Totals</b>				
<b>Total, Discretionary Budget Authority</b>	<b>6,207</b>	<b>6,164</b>	<b>9,569</b>	<b>+3,405</b>
User Fees	19	18	35	+17
Current Law Mandatory	4,232	645	--	-645
Proposed Law Mandatory	--	3,730	--	-3730
<b>Total, Program Level</b>	<b>10,458</b>	<b>10,557</b>	<b>9,604</b>	<b>-953</b>
Additional Opioids Allocation/4	--	--	550	+550
<b>Total with Additional Opioids Allocation/4</b>	<b>10,458</b>	<b>10,557</b>	<b>10,154</b>	<b>-403</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ Discretionary funding for Children's Hospitals Graduate Medical Education is discontinued in FY 2019. As part of a larger Graduate Medical Education reform, funding for children's hospitals in FY 2019 will be provided through mandatory resources in a new consolidated GME program.				
4/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				

*The Health Resources and Services Administration (HRSA) is the primary Federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable. HRSA works to improve health through access to quality services, a skilled health workforce and innovative programs.*

Tens of millions of Americans receive quality, affordable health care and other services through the Health Resources and Services Administration's (HRSA) programs and more than 3,000 grantees across the United States. HRSA works across diverse programs—serving everyone from infants to the elderly—to assure that people in the United States have access to a broad range of essential health care and public health services. HRSA also supports the training of health professionals, the distribution of providers to areas where they are needed most, and improvements in health care delivery. In addition, HRSA oversees organ, bone marrow, and cord blood donation. It compensates individuals harmed by vaccination, and maintains databases that protect against health care malpractice, waste, fraud, and abuse.

The Fiscal Year (FY) 2019 President's Budget total program level for HRSA is \$9.6 billion, \$953 million below the FY 2018 Continuing Resolution. This total includes \$9.6 billion in discretionary budget authority and \$35 million in user fees. The FY 2019 Budget shifts mandatory funding for the following programs to discretionary funding: Health Centers, National Health Service Corps, Teaching Health Center Graduate Medical Education, Home Visiting, and Family- to-Family Health Information Centers. At this

funding level, HRSA will continue to prioritize the delivery of critical direct health care services to those Americans that are in most need. In addition, the Budget provides HRSA an initial allocation of \$550 million to fight the opioid crisis.

### ENSURING ACCESS TO DIRECT HEALTH CARE SERVICES

#### Health Centers

One in 12 people across every state and territory receive health care services from a health center. Health centers deliver affordable, accessible, quality, and cost-effective primary health care and preventive services to patients regardless of their ability to pay. Health centers advance a model of coordinated, comprehensive, and patient-centered primary health care, integrating a wide range of medical, dental, behavioral and patient services.

The FY 2019 Budget provides a total of \$5.1 billion for Health Centers in discretionary resources, an increase of \$10 million above the FY 2018 Continuing Resolution. The Health Center Program provides funding and other support to nearly 1,400 health centers across the United States, which operate more than 11,000 health care delivery sites, providing care to more than 25 million individuals every year. Those

served include 1 in 10 children, 1 in 6 Americans living in rural areas, and 1 in 3 individuals living in poverty. More than 200,000 health center staff serve patients and help them stay healthy through preventive care, while reducing costs to health systems. The health center model of care has been shown to reduce the use of costlier providers of care, such as emergency departments and hospitals.

#### ***Ryan White HIV/AIDS Programs***

The Ryan White HIV/AIDS Program enables cities, states, and community-based organizations to support a comprehensive system of primary medical care, medication, and essential support services to more than half a million people living with HIV in the United States. In 2016, more than 551,000 clients received services from funded providers.

The FY 2019 Budget provides a total of \$2.3 billion, \$43 million below the FY 2018 Continuing Resolution, to continue serving more than 50 percent of all people living with diagnosed HIV in the United States. At this funding level, the Budget provides \$900 million for the AIDS Drug Assistance Program and discontinues funding for the Ryan White HIV/AIDS Part F AIDS Education and Training Programs and Special Project of National Significance. The FY 2019 Budget also proposes to reauthorize the Ryan White HIV/AIDS Program to ensure that Federal funds are allocated to target populations experiencing high or increasing levels of HIV infections and diagnoses while continuing to support Americans already living with HIV across the Nation.

The proposed reauthorization will include data-driven programmatic changes and will simplify, modernize, and standardize certain statutory requirements and definitions to be consistent across the Ryan White Parts to reduce burden on recipients.

The Ryan White HIV/AIDS Program helps to ensure that individuals with HIV are linked to and retained in care, able to adhere to medication regimens, and remain virally suppressed. These goals are critical to ensuring optimal HIV health outcomes among people living with HIV, as well as preventing further transmission of the virus, and ultimately, ending the HIV epidemic. Toward this goal, HRSA and the Centers for Disease Control and Prevention are collaborating to accelerate the elimination of perinatal HIV transmission in the United States. Perinatal HIV transmission, also known as

mother-to-child transmission, has declined by more than 90 percent since the early 1990s.

#### **SECRETARY'S PRIORITIES**

#### **HRSA's Response to Substance Misuse and the Opioid Epidemic**

Research shows that drug overdose deaths are 45 percent higher in rural areas compared to urban communities. In FY 2017, HRSA awarded \$3 million to focus on the treatment, prevention, and awareness of opioid abuse in rural communities. The Substance Abuse Treatment Telehealth Network Grant Program works to improve access to health care services, particularly substance abuse treatment, in rural communities using telehealth networks. The Rural Health Opioid Program seeks to increase access to treatment and recovery services for opioid abuse within rural communities especially in hard hit areas such as Kentucky, Maine, and Ohio. Rural residents struggling with substance abuse issues, particularly opioid use disorder, often face unique challenges such as isolation and stigma. Both programs aim to strengthen interventions to overcome these challenges.

Additionally, only three percent of rural primary care physicians have the Drug Enforcement Administration waiver necessary to prescribe buprenorphine to treat opioid addiction. In FY 2019, HRSA will expand substance abuse treatment in underserved areas by awarding enhanced loan repayment to National Health Service Corps behavioral health applicants with DATA 2000 waivers. These waivers enable clinicians to provide medication-assisted treatment services in treatment settings other than opioid treatment programs.

#### **OPTIMIZING THE NATION'S HEALTH WORKFORCE**

The FY 2019 Budget provides a total of \$477 million for HRSA health workforce programs, which is \$744 million below the FY 2018 Continuing Resolution. HRSA's health workforce programs strengthen the health workforce and connect skilled professionals to communities in need. The FY 2019 Budget continues to prioritize health workforce programs that require service commitments in underserved areas and maintains funding for the National Center for Health Workforce Analysis, a national resource for health workforce research, information, and data.

#### ***National Health Service Corps***

The National Health Service Corps builds healthy communities by supporting qualified health care providers dedicated to working in areas of the United



States with limited access to care. The FY 2019 Budget provides a total of \$310 million in discretionary funding for the National Health Service Corps. Today, nearly 10,200 primary care medical, dental, and mental and behavioral health National Health Service Corps providers are working nationwide to provide essential health services to approximately 10.7 million Americans. HRSA will continue to assess potential changes to enhance the ability of the National Health Service Corps to support the Administration's efforts to end the opioid abuse epidemic and to expand access to services for individuals with serious mental illness.

#### ***NURSE Corps Scholarship and Loan Repayment Program***

The NURSE Corps supports nursing students, registered nurses, and advanced practice registered nurses who agree to work full-time in a health care facility with a critical shortage of nurses in return for nursing school scholarships or for repayment of qualifying nursing educational loans.

The FY 2019 Budget provides \$83 million, an increase of \$1 million above the FY 2018 Continuing Resolution, to continue supporting approximately 202 scholarships and 1,015 loan repayments. Over 85 percent of NURSE Corps participants continue providing care at a critical shortage facility after completion of their service commitment.

#### ***Teaching Health Center Graduate Medical Education***

The Teaching Health Center Graduate Medical Education Program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. Teaching Health Centers are located predominantly in Federally Qualified Health Centers, Rural Health Clinics, and Tribal health centers, which prioritize care for underserved communities. The FY 2019 Budget provides \$60 million in discretionary funding for Teaching Health Center Graduate Medical Education.

Over half of Teaching Health Center Graduate Medical Education program training sites are in Medically Underserved Communities. Training in these communities increases health care services and primary care workforce in underserved communities. In FY 2019, HRSA anticipates supporting approximately 57 residency programs.

#### ***Health Workforce Program Discontinuation***

The FY 2019 Budget discontinues a number of workforce programs and continues to prioritize programs that provide scholarships and loan repayments to health care students and professionals willing to meet service requirements in health professional shortage areas.

The FY 2019 Budget also discontinues discretionary funding for the Children's Hospital Graduate Medical Education Program. The FY 2019 Budget proposes to better target Federal spending on graduate medical education and increase transparency and accountability. The Budget consolidates graduate medical education spending in Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a new mandatory graduate medical education capped grant program. The grant program would be jointly operated by the CMS and HRSA Administrators. Funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages. Comprehensive reform will ensure the important work of children's hospitals in supporting graduate medical education continues.

### **KEEPING FAMILIES AND COMMUNITIES HEALTHY**

#### ***Maternal and Child Health***

The FY 2019 Budget continues to prioritize direct health care services and provides states and communities the flexibility to meet local needs. This funding helps to improve the health of all mothers, children, and their families, in particular those with low incomes. Additionally, the Budget identifies \$112 million in savings by discontinuing smaller maternal and child health programs and not making new awards within the Maternal and Child Health Block Grant's Special Projects of Regional and National Significance (SPRANS). States may continue to support these activities with their Maternal and Child Health Block Grant awards.

The FY 2019 Budget requests \$628 million in funding for the Maternal and Child Health Block Grant. This funding supports services to more than half of the pregnant women and nearly one-third of all infants and children in the country. The request maintains funding for state grants, as well as existing competitive and non-formula grants and contracts that support critical

components of the maternal and child health system, but does not provide funding for new SPRANS awards.

Across the country, there continues to be significant disparities in infant mortality. For that reason, the FY 2019 Budget requests \$104 million for Healthy Start, which connects individuals with services that can reduce infant mortality and improve perinatal outcomes. This program provides grantees with flexibility to tailor services according to community need.

The Budget provides \$400 million in discretionary resources for grants to states to provide home visiting services to at-risk pregnant women, mothers, and their families. These services build upon decades of scientific research that shows that home visits by a nurse, social worker, or early childhood educator during pregnancy and in the first years of life have the potential to improve children's health, development, and ability to learn. Additionally, research shows that home visits provide a positive return on investment by reducing reliance upon emergency room visits and public benefits receipt, decreasing interaction with child protective services and increasing parental earnings.

#### ***Family Planning***

Since 1970, the Title X Family Planning Program has aided individuals and families with comprehensive family planning and related health services, such as the treatment and prevention of sexually transmitted diseases and the screening of cervical cancer.

The FY 2019 Budget maintains funding for this program at \$286 million. With at least one Title X services grantee in every state, the District of Columbia, and in each of the territories, the Family Planning Program will serve approximately 4 million patients in FY 2019, of which 90 percent have family incomes at or below 200 percent of the Federal poverty level.

#### ***Rural Health***

The FY 2019 Budget provides \$75 million for HRSA's Federal Office of Rural Health Policy, which is \$80 million below the FY 2018 Continuing Resolution. The Budget maintains the discontinuations proposed in the FY 2018 President's Budget and continues to prioritize funding for critical direct health care services and rural health activities.

#### ***Fighting the Opioid Epidemic***

The Budget provides \$10 billion in new resources across HHS to combat the opioid epidemic. As part of this effort, the Budget provides an initial allocation totaling \$550 million in HRSA that includes \$150 million to address substance abuse, including opioid abuse, and the overdose crisis in highest risk rural communities. This funding will allow communities to develop plans to address local needs. Additionally, this funding will provide additional loan repayment awards through the National Health Service Corps to support the recruitment and retention of health professionals needed in rural areas to provide evidence-based substance abuse treatment and prevent overdose deaths. In addition, \$400 million is allocated for community health centers, of which \$200 million is set aside to provide quality improvement incentive payments to community health centers that implement evidence-based models to address behavioral health, including opioid addiction, issues to meet the health needs of the population served by the health center.

#### **OTHER PROGRAMS**

##### ***340B Drug Pricing Program***

The FY 2019 Budget provides a total of \$26 million for the 340B Drug Pricing Program, of which \$10 million is discretionary budget authority and \$16 million is available through a new user fee on drug purchases by covered entities, for an increase of \$16 million above the FY 2018 Continuing Resolution.

The 340B Drug Pricing Program enables over 12,500 covered entities across the United States to gain as much value from Federal resources as possible through the purchase of discounted prescription drugs, to reach more eligible patients, and provide more comprehensive services. The new user fee will help improve the program's operations and oversight.

The FY 2019 Budget proposes to improve 340B Program integrity and ensure that the benefits of the program are used to help low-income and uninsured patients. This proposal includes broad regulatory authority for the 340B Drug Pricing Program to set enforceable standards of program participation and requires all covered entities to report on use of program savings.



***Program Management***

The FY 2019 Budget provides \$152 million for program management activities, \$1 million below the FY 2018 Continuing Resolution. At this funding level, HRSA will maintain oversight of grant and contract recipients, support program integrity efforts, reduce improper payments, as well as develop and maintain its information technology infrastructure.



## Indian Health Service

<i>dollars in millions</i>	2017 /1	2018 /2	2019/3	2019 +/- 2018
<b>Services</b>				
<b>Clinical Services</b>	3,359	3,336	3,689	+353
<i>Hospitals and Health Clinics</i>	1,935	1,922	2,190	+268
<i>(non-add)</i>				
<i>Accreditation Emergencies</i>	29	29	58	+29
<i>(non-add)</i>				
<i>Purchased/Referred Care</i>	929	923	955	+32
<i>(non-add)</i>				
<b>Preventive Health</b>	160	159	89	-70
<i>Public Health Nursing</i>	79	78	87	+9
<i>(non-add)</i>				
<i>Health Education (non-add)</i>	19	19	--	-19
<i>Community Health Representatives (non-add)</i>	60	60	--	-60
<b>Other Services</b>	176	175	168	-6
<i>Tribal Management Grant Program (non-add)</i>	2	2	--	-2
<i>Direct Operations (non-add)</i>	70	70	73	+3
<b>Contract Support Costs/4</b>	800	800	822	+22
<b>Subtotal, Services and Contract Support Costs</b>	<b>4,494</b>	<b>4,469</b>	<b>4,768</b>	<b>+299</b>
<b>Facilities</b>				
<b>Health Care Facilities Construction</b>	118	117	80	-38
<b>Sanitation Facilities Construction</b>	102	101	102	+1
<b>Facilities and Environmental Health Support</b>	227	225	229	+3
<b>Maintenance and Improvement</b>	76	75	76	+1
<b>Medical Equipment</b>	23	23	20	-3
<b>Subtotal, Facilities</b>	<b>545</b>	<b>542</b>	<b>506</b>	<b>-36</b>
<b>Diabetes Grants</b>				
<b>Discretionary Budget Authority</b>	--	--	150	+150
<b>Total, Budget Authority</b>	<b>5,040</b>	<b>5,011</b>	<b>5,424</b>	<b>+413</b>
<b>Funds From Other Sources</b>				
<b>Health Insurance Collections</b>	1,194	1,194	1,194	--
<b>Rental of Staff Quarters</b>	9	9	9	--
<b>Diabetes Grants</b>				
<b>Current Law Mandatory</b>	147	75	--	-75
<b>Proposed Mandatory Law</b>	--	75	--	-75

<b>Subtotal, Diabetes Grants</b>	<b>147</b>	<b>150</b>	<b>--</b>	<b>-150</b>
<b>Subtotal, Other Sources</b>	<b>1,349</b>	<b>1,352</b>	<b>1,202</b>	<b>--</b>
<b>Total, Program Level</b>	<b>6,389</b>	<b>6,363</b>	<b>6,626</b>	<b>+263</b>
<b>Additional Opioids Allocation</b>	<b>--</b>	<b>--</b>	<b>150</b>	<b>+150</b>
<b>Total with Additional Opioids Allocation/5</b>	<b>--</b>	<b>--</b>	<b>6,776</b>	<b>+513</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96) and directed or permissive transfers (where applicable). Excludes an anomaly of \$13 million for staffing and operating costs for newly-constructed health care facilities (P.L. 115-96).				
3/ The Budget requests a total of \$159 million for staffing and operating costs of new and replacement facilities and \$95 million for current services, which is allocated across several funding lines.				
4/ The total estimated Contract Support Costs amount of \$800 million is reflected in the FY 2018 funding level.				
5/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				

*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 Fiscal Year (FY) 2019 Budget requests \$5.4 billion for the Indian Health Service (IHS), which is \$413 million or eight percent above the FY 2018 Continuing Resolution. The Budget continues to prioritize the provision of direct health care services across Indian Country through targeted funding increases to support improved health outcomes for American Indians and Alaska Natives. The Administration continues to honor its commitment to members of more than 567 Federally-recognized Tribes.

The FY 2019 Budget provides increased funding for Clinical Services programs, which fund direct health care services through hospitals and health clinics, dental health, mental health, alcohol and substance abuse services, and the Purchased/Referred Care Program. The Budget also fully funds staffing for new and replacement facilities, and supports Indian self-determination by fully funding Contract Support Costs, which assists Tribes that administer their own health programs and facilities.

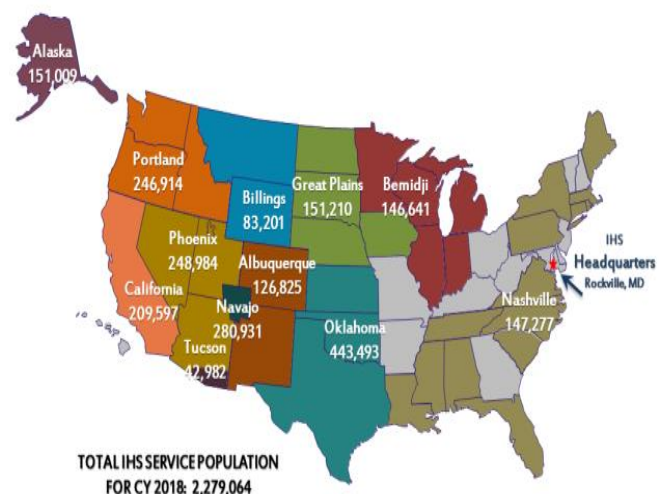
### FULFILLING THE UNIQUE ROLE OF THE INDIAN HEALTH SERVICE

IHS partners with Tribes to provide direct health care services for a growing population of more than 2.2 million eligible American Indians and Alaska Natives. By partnering with Tribes, IHS ensures maximum Tribal participation in administering programs that directly impact Tribal communities.

Tribes also directly manage more than sixty percent of IHS's total budget.

Comprehensive health care services are delivered through a network of over 608 hospitals, clinics, and health stations across the Nation. The Budget reflects a continued commitment to Indian Country by investing in direct health care services. The FY 2019 Budget provides \$3.7 billion for clinical services, an increase of \$353 million above the FY 2018 Continuing Resolution. This increase will allow IHS to expand direct health care services across the IHS system. Direct health care services include outpatient and inpatient care in hospitals and clinics, behavioral health services, and dental health services. The Budget also

### IHS SERVICE POPULATION BY AREA



provides \$95 million for current services to offset the increasing cost of providing health care services due to medical inflation and pay increases.

#### ***Purchased/Referred Care***

The Budget provides \$955 million for the Purchased/Referred Care program, which is an increase of \$32 million above the FY 2018 Continuing Resolution, to support medical care for catastrophic injuries, specialized care, and other critical care services. The Purchased/Referred Care program provides access to health care services where no IHS/Tribal facility is available or when the facility cannot provide the services needed through contracts with providers outside of the IHS health care system. IHS has been able to support a growing number of medical services in several areas across the country through the Purchased/Referred Care program, and this increase helps IHS maintain that expansion.

#### ***Behavioral Health***

American Indians and Alaska Natives have a high prevalence of behavioral health problems compared to the broader United States population. Specifically, this population has the highest suicide rates of any racial/ethnic population. Similarly, American Indians and Alaska Natives have the highest rate of substance use disorders, including alcohol abuse, compared to any other racial/ethnic population. To combat these health disparities, the FY 2019 Budget requests a total of \$340 million for Mental Health, Alcohol and Substance Abuse programs, which is an increase of \$30 million above the FY 2018 Continuing Resolution.

#### ***Fighting the Opioid Epidemic***

The Budget provides \$10 billion in new resources across HHS to combat the opioid epidemic and address serious mental illness. As part of this effort, the Budget includes an initial allocation of \$150 million in IHS to provide multi-year competitive grants based on need for opioid abuse prevention, treatment, and recovery support in Indian Country. American Indians and Alaska Natives had the highest drug overdose death rates in 2015, and the largest percentage change increase in drug overdose deaths from 1999-2015 of any population at 519 percent.

#### ***Preventive Health Services***

IHS provides preventive health care, including immunizations, case management, and patient follow-up care, to improve the health status of American Indians and Alaska Natives. In FY 2019, the Budget

provides \$89 million for Preventive Health services, which is a decrease of \$70 million below the FY 2018 Continuing Resolution. In order to prioritize direct health care services and staffing of newly constructed facilities, the Budget discontinues the Health Education program and the Community Health Representatives program. Funding for Public Health Nursing and immunization programs are continued at nearly the same level as the FY 2018 Continuing Resolution. These activities deliver direct health care services across Indian Country and allow many who live in rural and isolated communities to access care.

#### ***Special Diabetes Program for Indians***

American Indians and Alaska Natives are substantially more likely to have diagnosed diabetes than the general population. The prevalence of this disease also comes with increased complications for patients and health care costs for IHS and Tribes. The Special Diabetes Program for Indians has changed the diabetes landscape across the IHS system by improving access to quality, evidence-based diabetes care. The program has significantly reduced diabetes complications among American Indians and Alaska Natives, including a 54 percent decrease in kidney failure rates and a 50 percent reduction in diabetic eye diseases, such as blindness.

#### **PROGRAM HIGHLIGHT**

##### **Quality Health Care**

The IHS Quality Framework outlines how IHS is working to improve patient experience and outcomes, strengthen organizational capacity, and ensure the delivery of reliable, high-quality health care at IHS facilities. In October 2017, IHS announced results that the Quality Framework has produced to date; including establishing patient wait time standards for primary and urgent care settings and implementing emergency department telehealth consultation in the Great Plains Area and Billings Area.

The Budget prioritizes quality care by providing a total of \$58 million to assist facilities, including those in the Great Plains Area, with meeting CMS quality health care standards. The Quality Framework and continued investments demonstrate IHS's commitment to providing quality health care across Indian Country.

To ensure sustained and additional improvements for the health of American Indians and Alaska Natives, the FY 2019 Budget continues funding for this essential

program at \$150 million and shifts funding from mandatory to discretionary. These funds allow IHS and Tribes to continue to provide primary prevention awareness, education, and care, and to sustain efforts to control and eradicate this disease across Tribal communities.

#### ***Staffing Increases***

The Budget includes an additional \$159 million to support staffing and operating costs for six new or replacement health facilities to be completed in FY 2018 and FY 2019. This increase will allow the newly constructed facilities to expand the provision of health care in areas where the existing capacity is overextended. Newly constructed facilities include Red Tail Hawk Health Center in Arizona, Fort Yuma Health Center in California, Muskogee (Creek) Nation Health Center in Oklahoma, the Northern California Youth Regional Treatment Center in California, the Yukon-Kuskokwim Primary Care Center in Alaska, and the Cherokee Nation Regional Health Center in Oklahoma. Three of the facilities are Joint Venture projects in which IHS partners with Tribes to build new health care facilities. Specifically, Tribes provide the funding to support the construction of the new or replacement facility, and IHS works with Congress to provide funding for staffing and operating costs for the facility. These important partnerships will continue to increase access to care and decrease health disparities faced by American Indians and Alaska Natives.

#### ***Health Insurance Reimbursements***

The FY 2019 Budget request for IHS estimates \$1.2 billion in health insurance reimbursements from third party collections, including Medicare, Medicaid, the Veterans Health Administration, and private health insurance. The collection of health insurance reimbursements is essential for maintaining accreditation standards by covering the costs of hiring additional medical staff, purchasing equipment, and making necessary building improvements.

#### ***Other Programs***

The Budget continues the same level of funding as the FY 2018 President's Budget for other services at \$168 million, which is \$6 million below the FY 2018 Continuing Resolution.

### **FACILITIES AND CONSTRUCTION**

IHS and tribally-run facilities cover nearly 18 million square feet in 35 States across the country. IHS is responsible for the construction and maintenance of

healthcare facilities as well as the purchase and maintenance of medical equipment in those facilities. To prioritize direct health care services and staffing and operating costs for new and replacement facilities, the Budget reduces facilities funding to \$506 million, a decrease of \$36 million below the FY 2018 Continuing Resolution.

#### ***Health Care Facilities Construction***

IHS constructs new and replacement health care facilities through a process governed by the 1993 Health Facilities Construction Project Priority List, developed by IHS in consultation with Tribes. The 2010 reauthorization of the Indian Health Care Improvement Act incorporated the priority list into statute. The Budget provides \$80 million for Health Care Facilities Construction, \$38 million below the FY 2018 Continuing Resolution. This funding level continues construction of two facilities on the priority list: the Alamo Health Center in New Mexico and the Dilkon Alternative Rural Health Center in Arizona.

#### ***Sanitation Facilities Construction***

The Sanitation Facilities Construction Program provides new and existing homes across Indian Country with safe drinking water and waste disposal. Under this program, infant mortality rates and mortality rates for gastroenteritis and other environmentally-related diseases have been reduced by approximately 80 percent since 1973. The Budget requests \$102 million for these activities, which is \$1 million above the FY 2018 Continuing Resolution and \$26 million above the FY 2018 President's Budget.

#### ***Other Facilities Improvement and Construction Programs***

The FY 2019 Budget includes \$76 million for Maintenance and Improvement to maintain, repair, and improve existing IHS and Tribal health care facilities, which is \$1 million above the FY 2018 Continuing Resolution. The Facilities and Environmental Health Support program, which supports an extensive array of real property, as well as community and institutional environmental health, and injury prevention, is funded at \$229 million, which is +\$3 million above the FY 2018 Continuing Resolution. Lastly, the Budget provides \$20 million to purchase and maintain medical equipment, which is -\$3 million below the FY 2018 Continuing Resolution.

#### **FURTHERING INDIAN SELF-DETERMINATION**

Under the Indian Self-Determination and Education Assistance Act of 1975, Tribes and Tribal organizations can take over the operation of IHS programs. Today, self-governance affords Tribes the most flexibility to tailor health care services to the needs and priorities of their communities and more than 60 percent of the IHS budget is administered directly by Tribes.

#### ***Contract Support Costs***

The Budget fully funds Contract Support Costs at an estimated \$822 million and continues the use of an indefinite appropriation, which allows IHS to guarantee full funding of this program. Funding for Contract Support Costs supports the costs incurred by Tribes for activities that are necessary for administering health care service programs under self-determination contracts and self-governance compacts.



## Centers for Disease Control and Prevention

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
Immunization and Respiratory Disease	793	745	701	-44
<i>Prevention and Public Health Fund (non-add)</i>	324	293	-	-293
<i>Balances from PHSSEF Pandemic Flu (non-add)</i>	15	-	-	--
Vaccines For Children	4,437	4,401	4,726	+326
HIV/AIDS, Viral Hepatitis, STIs and TB Prevention	1,115	1,110	1,117	+8
Emerging and Zoonotic Infectious Diseases /3	576	568	508	-60
<i>Prevention and Public Health Fund (non-add)</i>	52	47	-	-47
Chronic Disease Prevention and Health Promotion	1,114	1,078	939	-138
<i>Prevention and Public Health Fund (non-add)</i>	338	305	-	-305
Birth Defects, Developmental Disabilities, Disability and Health	137	137	110	-27
Environmental Health	215	178	157	-21
<i>Prevention and Public Health Fund (non-add)</i>	17	15	-	-15
Injury Prevention and Control	286	284	266	-18
Public Health Scientific Services /3	496	494	468	-26
<i>PHS Evaluation Funds (non-add)</i>	-	-	136	+136
Occupational Safety and Health /4	334	333	-	-333
World Trade Center Health Program /5	351	420	469	+49
Energy Employee Occupational Illness Compensation Program /4	50	55	-	-55
Global Health	434	432	409	-23
Public Health Preparedness and Response /6	1,402	1,395	800	-595
Buildings and Facilities	10	10	30	+20
CDC-Wide Activities and Program Support	274	257	155	-102
<i>Prevention and Public Health Fund (non-add)</i>	160	144	-	-144
Agency for Toxic Substances and Disease Registry (ATSDR)	75	74	62	-12
User Fees	2	2	2	--
<b>Total Program Level</b>	<b>12,100</b>	<b>11,973</b>	<b>10,921</b>	<b>-1,053</b>
Additional Opioids Allocation /7	-	-	175	+175
<b>Total, with Additional Opioids Allocation</b>	<b>12,100</b>	<b>11,973</b>	<b>11,096</b>	<b>-878</b>
<b>Less Funds from Other Sources</b>				
Vaccines for Children	4,437	4,401	4,726	+326
Energy Employee Occupational Illness Compensation Program /4	50	55	-	-55
World Trade Center Health Program /5	351	420	469	+49
PHS Evaluation Funds	-	-	136	+136
Prevention and Public Health Fund /8	891	805	-	-805
User Fees	2	2	2	--
Balances from PHSSEF Pandemic Flu	15	-	-	--
<b>Total Discretionary Budget Authority</b>	<b>6,354</b>	<b>6,290</b>	<b>5,587</b>	<b>-703</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ The FY 2019 Budget shifts Emerging and Zoonotic Infectious Disease lab safety activities to Public Health Scientific Services. FY 2017 and FY 2018 are comparably adjusted for this change.				
4/ The FY 2019 Budget consolidates the National Institute for Occupational Safety and Health and the Energy Employee Occupational Injury Compensation Act program from CDC to NIH.				
5/ Reflects Federal share obligations only; New York City share is not included. Obligations for FY 2017 reflect actual; FY 2018/FY 2019 reflect estimates.				
6/ The FY 2019 Budget reflects the transfer of the Strategic National Stockpile from CDC to the Public Health and Social Services Emergency Fund.				
7/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				
8/ Source of funds displayed consistent with prior year presentations and the assumptions for the FY 2019 Budget.				



*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 our 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 health protection agency, saving lives by protecting people from health threats, promoting the health and well-being of Americans of all ages, and preventing infections, injuries, and illnesses from ever occurring. Safeguarding Americans' health and security is more important than ever. CDC works from home and abroad to protect America, increasing the health security of our nation. Whether the threat is a disease outbreak, chronic condition, environmental hazard, natural disaster, or deliberate attack, CDC works 24 hours a day, seven days a week to keep Americans safe—both at home and around the world.

CDC supports these efforts through high-quality public health research, including population health surveillance and epidemiology at national and state levels, building the science basis for decision-making on public health programs, policies, and services. CDC puts science into action by translating research into tools and actions that save more lives and tracking disease to take the pulse of America's health. CDC responds to, contains and eliminates threats with over 100 labs with world-class scientists identifying diseases, food-borne outbreaks, biosecurity threats and environmental hazards.

CDC strengthens the public health of the Nation's communities, working with state, local, and territorial public health departments to investigate and protect against health threats. CDC provides these entities with support and technical know-how to increase the impact of response and prevention. Almost 85 percent of CDC's domestic funding is provided directly to state and local entities to detect and control disease, prevent the leading causes of death, and prepare for health threats.

CDC accomplishes its public health mission through three key pillars: a deep commitment to and reliance on science; surveillance that helps guide investigations and interventions; and service to those who need assistance domestically and globally.

The Fiscal Year (FY) 2019 Budget for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) is a program level of \$10.9 billion, a decrease of \$1 billion relative to the FY 2018 Continuing Resolution. This total includes \$5.6 billion in budget authority and \$136 million in Public Health Service (PHS) Evaluation Funds. In addition, the Budget provides an initial allocation of \$175 million to CDC to fight the opioid crisis. When accounting for these resources, the total for CDC is \$11.1 billion, which is -\$878 million below the FY 2018 Continuing Resolution.

At this funding level, CDC will continue to keep Americans safe through immediate emergency public health response, rapid disease detection and containment, and preventing diseases from reaching the United States. The Budget prioritizes funding for key areas where CDC can have the greatest impact, including: continuing the fight against opioid abuse, misuse, and overdose; sustaining successes in global health security; supporting focused efforts on infectious disease prevention and control; and investing in CDC's infrastructure that is necessary for supporting mission-critical activities.

The Budget maintains the FY 2018 Budget proposal to increase CDC flexibility in allocating resources and implementing policies that best support mission-critical activities based on current science and public health expertise. Programmatic flexibility is necessary to support a nimble management of resources, allowing CDC to focus on the highest priority issues impacting Americans.

## **IMMUNIZATION AND RESPIRATORY DISEASES**

The National Center for Immunization and Respiratory Diseases serves to prevent disease, disability, and death through immunization and by controlling respiratory diseases. CDC partners with state and local health agencies and private health care providers to implement a safe and effective immunization system. CDC also works with Federal, state, and local partners to ensure capacity for detecting and responding to emerging and reemerging respiratory infectious



disease threats. In addition, CDC works closely with domestic and international partners to build surveillance and laboratory capacity to respond to and control seasonal and pandemic influenza.

The FY 2019 Budget includes \$5.4 billion supporting these activities, of which \$701 million is for the discretionary programs supported within CDC's National Center for Immunization and Respiratory Diseases. This funding level for discretionary programs is \$44 million below the FY 2018 Continuing Resolution.

Influenza poses one of the world's greatest infectious disease challenges. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands of people die from flu every year. CDC works to improve the control of, prevention of, and response to seasonal and novel influenza through international and domestic scientific and programmatic leadership. The Budget includes \$180 million to support these activities, which is \$9 million above the FY 2018 Continuing Resolution. Through the Vaccines for Children Program, CDC improves access to immunization services. This program provides vaccines to over 50 percent of the children in the United States. Per a 2014 CDC report, among children born during 1994-2013, vaccination will prevent an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths over the course of their lifetimes, at a net savings of \$295 billion in direct costs and \$1.38 trillion in total societal costs. The Budget includes \$4.7 billion in mandatory funding to support the Vaccines for Children program in FY 2019.

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

Every year, millions of Americans are infected with HIV, viral hepatitis, sexually-transmitted infections, or tuberculosis and tens of thousands die from their infection. Most of these infections share commonalities, from modes of transmission to demographic, social, and economic conditions that increase risk. CDC's National Center for HIV/AIDS, Viral Hepatitis, Sexually-Transmitted Infections (STIs), and Tuberculosis Prevention focuses on high impact prevention and control efforts to reduce incidence, morbidity, mortality, and health disparities due to these infections. CDC prioritizes cost-effective, scalable programs, policies, and research to achieve the greatest impact on reducing the incidence of HIV, viral hepatitis, STIs, and tuberculosis—all of which have

immense personal, societal, and economic costs. The FY 2019 Budget includes a total of \$1.1 billion for these activities, which is \$8 million above the FY 2018 Continuing Resolution.

CDC supports the *National HIV/AIDS Strategy: Updated to 2020*, with a high-impact prevention approach to reducing new HIV infections. This effort has yielded successes by leveraging scientifically proven, cost-effective, and scalable HIV prevention interventions, targeted to the most heavily affected populations and geographic areas. As a result of sustained testing efforts, the proportion of Americans with HIV who know their status reached 85 percent in 2015. The Budget includes \$749 million for CDC's domestic HIV/AIDS research and prevention efforts, which is \$35 million below the FY 2018 Continuing Resolution. In FY 2019, CDC and the Health Resources and Services Administration (HRSA) will collaborate to prioritize efforts to accelerate the elimination of perinatal HIV transmission.

#### **PROGRAM HIGHLIGHT**

##### **Infectious Disease Initiatives**

**Elimination Initiative:** In recent years, major increases in infectious diseases have occurred as a result of the opioid crisis, including a tripling of the number of hepatitis C infections. The FY 2019 Budget includes \$40 million to support a new demonstration initiative, which will focus efforts in select states/jurisdictions at high-risk for infectious disease, including those with high rates of opioid-related transmission. This new initiative will jointly support efforts to eliminate HIV transmission, viral hepatitis, sexually-transmitted infections, and tuberculosis.

##### **Accelerating the Elimination of Perinatal HIV**

**Transmission:** Perinatal HIV transmission, also known as mother-to-child transmission, can happen at any time during pregnancy, labor, delivery, and breastfeeding. Advances in HIV research, prevention, and treatment have made it possible for many women living with HIV to give birth without transmitting the virus to their babies. If treated early in her pregnancy, a woman's risk of transmitting HIV to her baby can be reduced to one percent or less. The availability of these effective interventions and the significant reductions in the number of HIV-infected infants in the United States, indicate that elimination of perinatal HIV transmission is possible. In FY 2019, CDC and HRSA will work together to prioritize prevention, treatment, and education efforts to accelerate the elimination of this form of transmission.

CDC's most recent data from 2016 shows there were more cases of chlamydia, gonorrhea, and syphilis (including congenital syphilis in babies) than ever

reported before. The FY 2019 Budget includes a total of \$152 million, which is \$1 million above the FY 2018 Continuing Resolution. This funding will support ongoing surveillance, prevention and control of sexually-transmitted infections. Funding will also continue to support contact tracing, disease intervention specialist activities, and training and education for health care professionals.

The United States has one of the lowest tuberculosis rates in the world thanks to an aggressive strategy of supporting prevention, control, laboratory services, research, and training at state, local, and territorial health departments. CDC is the only U.S. agency that conducts field-based clinical and operational tuberculosis research. A recent CDC study found that, over a 20-year period, tuberculosis prevention efforts in the United States averted up to 319,000 cases, saving up to \$14.5 billion in health care costs. CDC's goal is to eliminate tuberculosis in the United States. To support this effort, the Budget includes \$142 million, an increase of \$1 million above the FY 2018 Continuing Resolution. The Budget includes \$40 million to support a new Elimination Initiative to jointly address diseases such as HIV, viral hepatitis, sexually-transmitted infections, and tuberculosis. This demonstration project will focus efforts in select states/jurisdictions at high risk for infectious diseases to implement intensive prevention, screening, and treatment/referral to treatment efforts.

### EMERGING AND ZONOTIC INFECTIOUS DISEASES

CDC's National Center for Emerging and Zoonotic Infectious Diseases works globally to prevent, detect, and respond to outbreaks of a wide variety of infectious diseases—natural, accidental, or intentional. State and local health departments, other Federal agencies, and foreign ministries of health look to CDC to assist with wide-ranging problems—from illness and death in 28 States caused by *Listeria*-contaminated cantaloupes, to an outbreak of anthrax in hippos and humans in Kenya, to new outbreaks of dengue in south Florida. The Budget includes \$508 million to support CDC's National Center for Emerging and Zoonotic Infectious Diseases, which is \$60 million below the FY 2018 Continuing Resolution.

The United States continues to be vulnerable to vector borne disease threats occurring within and outside our borders. Vector-borne diseases transmitted by ticks, mosquitoes, fleas, and other insects account for 17 percent of the estimated global burden of all

infectious diseases. CDC's vector-borne diseases program is the focal point of our Nation's capacity to detect, control, and prevent bacterial, rickettsial, and viral pathogens transmitted by ticks and insects. The Budget maintains the elevated level of funding proposed in the FY 2018 Budget for these diseases at \$49 million, which is \$13 million above the FY 2018 Continuing Resolution. At this funding level, CDC will continue to address new and existing vector-borne disease threats, advance innovation and discovery, and provide support to states, particularly those that are at the greatest risk of outbreaks.

Foodborne illness is a common, costly—yet preventable—public health problem, impacting 48 million Americans every year, resulting in approximately 3,000 deaths. The U.S. Department of Agriculture estimates that foodborne illnesses cost \$15.6 billion each year. CDC recognizes that foodborne diseases are a serious threat to our nation's health and provides the vital link between illness in people and the food safety systems of government agencies and food producers. CDC scientists have started using whole genome sequencing to show which bacterial strains are most alike genetically—which indicates those infections may have the same source. The Budget maintains support for CDC's Food Safety activities at a total of \$54 million, which is \$0.4 million above the FY 2018 Continuing Resolution.

### PUBLIC HEALTH SCIENTIFIC SERVICES

Today's public health landscape requires thinking beyond traditional approaches of collecting and sharing health information and statistics. Accurate and timely data is needed to inform public health decisions and research that reaches across CDC and beyond. CDC's Office of Public Health Scientific Services leads CDC initiatives around surveillance, cultivates agency-wide involvement, and finds new approaches to assess current and future needs of data collection. The Budget includes \$468 million for these activities, which is \$26 million below the FY 2018 Continuing Resolution.

CDC also provides strategic leadership to the National Center for Health Statistics, which serves as the Nation's principal health statistics agency, gathering and compiling statistical information to guide public health and health policy decision-making. The Budget includes \$155 million for health statistics, \$4 million below the FY 2018 Continuing Resolution level.

## PROGRAM HIGHLIGHT

**Preventing Opioid Abuse and Overdose**

Across this nation, there has been an alarming trend in increases in drug overdose deaths, with overdose deaths from prescription and illicit opioids having more than quadrupled in the United States since 1999. Over 350,000 people have died from overdoses involving opioids—prescription or illicit—in the United States from 1999 through 2016.

Taking on the foundation of the opioid overdose epidemic means looking at where a difference can be made in the inappropriate prescribing of opioids—preventing people from getting addicted in the first place. Anyone taking prescription opioids can become addicted to them, and taking opioids for longer periods of time or in higher doses increases the risk of addiction, overdose, and death. Illicitly-manufactured fentanyl and heroin also pose a significant risk factor for Americans addicted to opioids. By improving prescribing practices, CDC is working to prevent people from getting addicted to opioids in the first place.

In March 2016, CDC released the *CDC Guideline for Prescribing Opioids for Chronic Pain* for primary care clinicians treating adult patients for chronic pain in outpatient settings. The Guideline is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose.

CDC also recently launched the Rx Awareness campaign to increase awareness that prescription opioids can be addictive and dangerous. The campaign tells the real stories of people whose lives have been impacted by opioid misuse.

support overdose prevention activities, including a focus on safe prescribing practices through improved use of state-based Prescription Drug Monitoring Programs; provide additional funding to states to support enhanced surveillance efforts; and working with states to support improved timeliness of morbidity and mortality data through efforts such as improving laboratory capacity.

**BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES**

The National Center on Birth Defects and Developmental Disabilities strives to advance the health and well-being of our Nation's most vulnerable populations. These efforts aim to save babies by studying and addressing the causes of birth defects, help children reach their potential by understanding

CDC laboratories routinely work with some of the most deadly germs in the world—identifying health threats and conducting vital public health research. CDC constantly develops and reviews extensive laboratory guidelines and procedures to protect both the public and laboratory workers. The Budget includes \$8 million targeted to lab safety activities, which maintains the FY 2018 Continuing Resolution.

**INJURY PREVENTION AND CONTROL**

Approximately 192,900 Americans die from violence and injuries each year—nearly one person every three minutes. Violence and injuries cost more than \$671 billion in medical care and lost productivity each year. Injuries and violence can be prevented, and their consequences reduced. CDC's National Center for Injury Prevention and Control serves as the Nation's leading authority on injury and violence, applying science and offering real-world solutions to keep Americans safe, healthy, and productive. To support this mission, CDC collects data to identify problems and monitor progress, uses research to understand what works, and promotes evidence-based strategies to inform real-world solutions. The FY 2019 Budget includes \$266 million in budget authority for injury prevention and control activities, \$17 million below the FY 2018 Continuing Resolution.

**Fighting the Opioid Epidemic**

The FY 2019 Budget continues to prioritize activities to address the opioid epidemic, with a total funding level of \$126 million, which is \$1 million above the FY 2018 Continuing Resolution. CDC contributes to the Department's five-point strategy to combat the opioid crisis and is committed to an approach that protects the public's health and prevents opioid overdose deaths by improving data, strengthening state and local efforts, and equipping health care providers. With the rise in deaths attributable to illicit opioids, CDC is providing surveillance and response expertise to inform public safety and substance use treatment efforts addressing illicit opioids. In addition, CDC is enhancing efforts at the community and local levels, recognizing that within states there may be particular geographic areas in which higher rates of opioid overdose are more likely to occur.

The Budget proposes \$10 billion in new across HHS to combat the opioid epidemic and address serious mental illness. As a part of this effort, the Budget includes an initial allocation of \$175 million in FY 2019 in CDC to: provide additional funding to states to

## PROGRAM HIGHLIGHT

**Emerging Threats to Mothers and Babies Initiative**

Mothers and babies are often at higher risk during any kind of public health crisis. Supported through supplemental Zika response funding, the innovative Zika pregnancy and infant registry was established to ensure that mothers and babies are adequately monitored and quickly informed about the impact of an emerging threat. The continuation and expansion of this surveillance system is critical to better understanding the long-term implications of not only Zika, but also for other emerging infectious diseases, such as pandemic influenza, and other emerging threats, including prenatal exposure to opioids. The FY 2019 Budget includes an additional \$10 million to support an initiative that will enable CDC to continue to work with states to maintain ongoing registries and continue to monitor mothers and babies for the impact of Zika and serve as a tool for other emerging public health threats.

This additional surveillance will inform public health action for mothers and babies, including prevention strategies, clinical guidance, enhanced follow-up, targeted screening and evaluation, and identification of medical and early interventions to help children thrive. In addition, CDC will work collaboratively with state, local, and territorial health departments to extend the monitoring of babies born to mothers with evidence of Zika infection to better understand the full impact of Zika on child development, and work with healthcare providers and others to develop better assessment and communication tools.

developmental disabilities, reduce complications of blood disorders, and improve the health of people living with disabilities. The FY 2019 Budget includes \$110 million to support birth defects and developmental disabilities, which is \$27 million below the FY 2018 Continuing Resolution. This funding level includes \$10 million in new resources to support and improve ongoing surveillance efforts to address emerging threats to mothers and babies, including the Zika virus and opioids-related neonatal abstinence syndrome.

Birth defects are common, costly, and critical—causing one in five deaths during the first year of life. In 2013, the total costs for hospital care of people with birth defects exceeded \$23 billion. CDC's unique state-based birth defects tracking and public health research provide a wealth of information that are used to identify causes of birth defects, find opportunities to prevent them, and improve the health of those living with birth defects.

Developmental disabilities are some of the most significant child health issues facing American families—with one in six children impacted by one or more developmental disabilities or delays. Specifically, this area includes conditions such as autism spectrum disorder, attention-deficit/hyperactivity disorder, and hearing loss. CDC helps children maximize their potential by providing a better understanding of these conditions and helping parents and health care providers make informed decisions so that children and their families get the support they need.

**CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION**

Chronic diseases—such as heart disease, cancer, chronic lung diseases, stroke, and diabetes—account for most deaths in the United States and globally. They are the major causes of sickness, disability, and health care costs in the nation. Chronic diseases are responsible for seven in 10 deaths among Americans each year, and the vast majority of health care costs.

CDC works to prevent and control chronic diseases and their risk factors through the National Center for Chronic Disease Prevention and Health Promotion, working with partners to strengthen health for states, American Indians and Alaska Natives, localities, and territories. CDC works to prevent chronic diseases and their risk factors through four domains: epidemiology and surveillance, environmental approaches, health

care system interventions, and community-clinical links.

The FY 2019 Budget includes \$939 million for chronic disease prevention and health promotion activities, which is \$138 million below the FY 2018 Continuing Resolution. At this funding level, CDC will prioritize the most critical efforts to prevent and control chronic diseases and associated risk factors. Within this total, the FY 2019 Budget maintains the FY 2018 Budget proposal to reform state-based chronic disease programs within CDC, by establishing the *America's Health* Block Grant. This \$500 million block grant program will provide states with the flexibility to support interventions to best address public health challenges specific to their state.

The Budget includes \$337 million for cancer prevention and control, which is \$17 million below the FY 2018 Continuing Resolution. In alignment with the FY 2018 Budget, this funding is allocated to foster a more flexible cancer program overall, allowing cross-cutting



activities to provide support to multiple types of cancer.

## ENVIRONMENTAL HEALTH

CDC's National Center for Environmental Health aims to maintain and improve the health of the American people by promoting a healthy environment and by preventing premature death and avoidable illness and disability caused by non-infectious, non-occupational environmental and related factors. CDC is committed to safeguarding the health of populations that are particularly vulnerable to certain environmental hazards—children, the elderly, and people with disabilities.

CDC tracks health effects caused by the environment through surveillance; conducts research; develops standards, guidelines, and recommendations to improve health and decisions about health; and provides expert assistance to other public health agencies and organizations. CDC also helps reduce environmental hazards and their adverse health effects through programs that address issues such as lead poisoning among children, the adverse health effects of natural disasters, air pollution, and nuclear radiation.

The FY 2019 Budget includes \$157 million to support environmental health, which is \$21 million below the FY 2018 Continuing Resolution. At this level, CDC will focus on supporting the core environmental health

programs that are essential to protecting Americans' health. This funding level includes \$17 million in funding for the Childhood Lead Prevention Program, which is the same as the FY 2018 Continuing Resolution. At this funding level, CDC will remain committed to the goal of eliminating elevated blood lead levels in children in the United States as a major public health problem by 2020.

## OCCUPATIONAL SAFETY AND HEALTH

The FY 2019 Budget consolidates the funding and administration of activities within the National Institute for Occupational Safety and Health from CDC to the National Institutes of Health (NIH). In addition to activities supported by discretionary funding, this reform will also consolidate the Energy Employee Occupational Injury Compensation Act program from CDC to NIH. The Budget includes \$469 million in mandatory funding for the World Trade Center Health Program, which CDC will continue to administer.

## PUBLIC HEALTH PREPAREDNESS AND RESPONSE

CDC's Office of Public Health Preparedness and Response strengthens National preparedness for public health emergencies including natural, biological, chemical, radiological, and nuclear incidents. The Budget provides \$800 million to support a range of activities at CDC and state and local public health departments. The funding level is \$575 million below

### PROGRAM HIGHLIGHT

#### Support for the Global Health Security Agenda

Established in 2014, the Global Health Security Agenda is a global effort to strengthen the world's ability to prevent, detect, and respond to public health emergencies and infectious disease threats, whether they are naturally occurring, or accidentally or intentionally released. Ensuring that the world is safe from global pandemics also provides positive impacts for the United States economy. Public health emergencies can disrupt local, regional, and international markets, causing economic instability around the world. When this happens, American exports and jobs could be affected in all 50 States. With successes in global health security, the United States is able to safeguard the country's collective health and economic stability.

CDC plays a leading role in the implementation of the Global Health Security Agenda. CDC brings extensive experience in public health emergency management, disease tracking, surveillance systems, training, infection control, and laboratory systems targeting high-hazard pathogens. The investments made to-date have led to substantial progress in preventing and containing infectious disease outbreaks from reaching the United States. Some highlights of the many accomplishments include:

- Establishing Emergency Operations Centers in 12 countries, centralizing incident management structure for respond to outbreaks;
- Equipping high-containment laboratories in seven countries with security and electronic inventory management; and
- Capacity improvements in the national laboratory systems of 13 countries, providing new equipment and capabilities to better detect and contain dangerous pathogens.

CDC's activities have largely been supported by resources included in the FY 2015 Ebola emergency supplemental appropriation, which will expire at the end of FY 2019. To ensure this program continues to serve in protecting the American people, the FY 2019 Budget includes an additional \$59 million. Investment in global health security protects our national wellbeing, both from infectious disease outbreaks and acts of bioterrorism.

the FY 2018 Budget, due to the transfer of the Strategic National Stockpile from CDC to the Public Health and Social Services Emergency Fund. This reorganization streamlines the medical countermeasure development enterprise and increases operational efficiencies during emergency responses. Additional information on the Strategic National Stockpile, including the FY 2019 Budget request, can be found in the Public Health and Social Services Emergency Fund chapter.

CDC is committed to directly supporting state and local health departments in the planning and preparation for, and response to, a public health emergency. The Budget provides \$660 million to the Public Health Emergency Preparedness cooperative agreements, which is \$4 million above the FY 2018 Continuing Resolution. These cooperative agreements will continue to fund 62 awardees, including all 50 States, eight United States territories and freely-associated States, and four localities. In FY 2019, the cooperative agreement awards will continue to allocate funding based on a risk determination and link awards to performance. Incorporating risk into the funding formula ensures that resources are allocated to states and localities according to need. CDC will ensure effective use of Federal funds by tracking recipient programmatic performance to inform future grant awards. State and local health departments use this funding to improve the capabilities of health departments across the country so that local communities can effectively manage public health emergencies.

## **GLOBAL HEALTH**

In today's interconnected world, diseases can spread from an isolated, rural village to any major city in as little as 36 hours. The United States cannot protect its borders and the health of its citizens without addressing diseases elsewhere in the world. CDC works continuously to protect Americans and save lives around the world by detecting and controlling outbreaks at their source. To accomplish this goal, CDC helps other countries increase their ability to prevent, detect, and respond to health threats on their own. The Budget includes \$409 million for CDC's global health efforts, \$23 million below the FY 2018 Continuing Resolution. At this funding level, \$59 million will support the continuation of CDC's activities associated with the Global Health Security Agenda. These resources will continue to support capacity building in other countries to stop outbreaks at their source before they reach the U.S. homeland.

This funding level also includes support of ongoing efforts with the ultimate goal of polio eradication. To achieve and maintain worldwide polio eradication, CDC and its partners must minimize the risk of poliovirus reintroduction to areas declared polio-free through dedicated, ongoing surveillance. In FY 2019, CDC will conduct surveillance, supporting prompt detection to prevent potential outbreaks. CDC will continue collaboration with public-private partners and ministries of health to provide epidemiologic, laboratory, and programmatic support in developing, monitoring, and evaluating programs and national-level surveillance.

## **BUILDINGS AND FACILITIES**

Safe, secure, and operation ready buildings, facilities, and laboratories enable CDC to protect Americans from disease threats. Investment is needed nationwide to protect the condition of CDC's facilities portfolio valued at \$3.8 billion. Lab operations are demanding on building systems, causing more rapid deterioration and higher cost to maintain than a comparable office building. Additionally, the square footage of CDC's facilities has roughly doubled since 2000, while the investment in maintenance has not kept pace, leading to rapidly declining conditions of the facilities. Furthermore, aging facilities are costly to maintain and operate, requiring significant preventive maintenance to avoid further deterioration.

The FY 2019 Budget includes \$30 million for CDC's buildings and facilities repair and improvements, an increase of \$20 million above the FY 2018 Continuing Resolution. These investments are needed to maintain primary building systems, built-in laboratory equipment, roof replacements, electrical and mechanical repairs, chemical storage unit installation, structural repairs, and fireproofing repairs and upgrades. For dedicated staff who implement CDC's mission, these investments are vital to ensuring a safe and secure environment.

## **AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)**

The Agency for Toxic Substances and Disease Registry (ATSDR) is a nonregulatory, congressionally-mandated public health agency that protects communities from harmful health effects related to exposure to natural and man-made hazardous substances. One in four people in the United States lives within four miles of a

hazardous waste site. With staff in Atlanta as well as 10 regional offices and 25 State health departments across the country, ATSDR is available 24 hours a day, seven days a week to respond to local concerns and protect the public's health during environmental emergencies like chemical spills and natural disasters. ATSDR's top priority is to protect Americans from harmful chemical exposures. To support this effort, ATSDR responds to environmental health emergencies; provides state and local entities guidance and technical

assistance; investigates environmental health threats; conducts research on the health impacts of hazardous waste sites; and builds capabilities of state and local health partners.

The FY 2019 Budget includes \$62 million for ATSDR, \$12 million below the FY 2018 Continuing Resolution. At this funding level, ATSDR will prioritize the most critical community requests for public health assessments and consultations.

## National Institutes of Health

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Institutes/Centers</b>				
National Cancer Institute	5,660	5,651	5,626	-24
National Heart, Lung, and Blood Institute	3,210	3,185	3,112	-73
National Institute of Dental and Craniofacial Research	425	423	413	-10
National Inst. of Diabetes & Digestive & Kidney Diseases	2,010	2,008	1,965	-42
National Institute of Neurological Disorders and Stroke	1,779	1,772	1,839	+67
National Institute of Allergy and Infectious Diseases	4,906	4,873	4,762	-111
National Institute of General Medical Sciences	2,646	2,633	2,573	-60
Eunice K. Shriver Natl. Inst. of Child Health & Human Development	1,377	1,371	1,340	-31
National Eye Institute	731	728	711	-17
Natl Inst. of Environmental Health Sciences: Labor/HHS Appropriation	713	709	693	-16
National Inst. of Environmental Health Sciences: Interior Appropriation	77	77	54	-23
National Institute on Aging	2,049	2,035	1,988	-46
Natl. Inst. of Arthritis & Musculoskeletal & Skin Diseases	557	554	545	-9
Natl. Inst. on Deafness and Communication Disorders	436	434	424	-10
National Institute of Mental Health	1,605	1,591	1,612	+21
National Institute on Drug Abuse	1,071	1,083	1,137	+54
National Institute on Alcohol Abuse and Alcoholism	482	480	469	-11
National Institute of Nursing Research	150	149	146	-3
National Human Genome Research Institute	528	525	513	-12
Natl. Institute of Biomedical Imaging and Bioengineering	357	355	347	-8
Natl. Institute on Minority Health and Health Disparities	288	287	281	-7
Natl. Center for Complementary and Integrative Health	134	134	131	-3
National Center for Advancing Translational Sciences	704	701	685	-16
Fogarty International Center	72	72	70	-2
National Library of Medicine	407	405	395	-9
Office of the Director	1,729	1,706	2,004	+298
Buildings and Facilities	129	128	200	+72
National Institute for Research on Safety and Quality /3	-	-	380	+380
National Institute for Occupational Safety and Health /4	-	-	255	+255
The National Institute on Disability, Independent Living, and Rehabilitation Research /4	-	-	95	+95
<b>Total, Program Level</b>	<b>34,229</b>	<b>34,067</b>	<b>34,767</b>	<b>+699</b>
Additional Opioids Allocation/5	--	--	750	+750
	<b>34,229</b>	<b>34,067</b>	<b>35,517</b>	<b>1,449</b>
<b>Less Funds from Other Sources</b>				
PHS Evaluation Funds (NIGMS)	-824	-819	-741	+78
Current Law Mandatory Funding – Type 1 Diabetes (NIDDK)	-140	-38	-	+38
Proposed Law Mandatory Funding – Type 1 Diabetes (NIDDK)	-	-113	--	+113
Patient-Centered Outcomes Research Trust Fund /3	-	-	-124	-124
Energy Employees Occupational Illness Compensation Program Act	-	-	-55	-55
<b>Total, Discretionary Budget Authority</b>	<b>33,265</b>	<b>33,099</b>	<b>33,846</b>	<b>+747</b>



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Appropriations</b>				
Labor/HHS Appropriation	33,188	33,022	33,792	+770
Interior Appropriation	77	77	54	-23
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ The FY 2019 Budget consolidates the activities of the Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality (NIRSQ). NIRSQ will receive the mandatory resources from the Patient-Centered Outcomes Research Trust Fund in FY 2018 (\$124 million).				
4/ The FY 2019 Budget consolidates the National Institute for Occupational Safety and Health from the Centers for Disease Control and Prevention, including the Energy Employee Occupational Injury Compensation Act program, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) from the Administration for Community Living within NIH and includes them in the NIH budget as separate entities. NIH will assess the feasibility of integrating health services research activities more fully into existing NIH Institutes and Centers over time.				
5/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				

*The mission of the National Institutes of Health (NIH) 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 works to improve health by promoting prevention and developing new treatments, contributes to society by driving economic growth and productivity, and expands the biomedical knowledge base by funding cutting-edge research and cultivating the biomedical workforce of today and tomorrow. Each of the NIH Institutes and Centers targets a specific research agenda, often focusing on particular diseases and conditions or body systems.

Americans are living about 30 years longer than they did in 1900. Quality of life is improving. Over the last quarter century, the proportion of older people with chronic disabilities has dropped by nearly one-third.

The Budget includes \$34.8 billion in Fiscal Year (FY) 2019 for the National Institutes of Health, \$699 million above FY 2018 Continuing Resolution. This total includes \$711 million in resources made available through the 21st Century Cures Act and \$180 million in mandatory resources. The Budget recognizes the importance of funding the highest priority scientific discoveries while also maintaining fiscal responsibility of Federal resources. The Budget supports new strategies to leverage public-private partnerships to accelerate discovery, consolidation of research functions from across the Department, and investment in efforts to accelerate biomedical innovations into applied health technologies. Within the total for FY 2019, the Budget includes \$9.2 billion in the Office

of the Director, giving the Director authority to transfer these resources amongst Institutes and Centers, to support high priority research areas. An illustrative allocation of these resources is included in this section. In addition, the Budget provides an initial allocation of \$750 million to NIH as part of the HHS-wide \$10 billion investment to fight the opioid crisis and address serious mental illness. When accounting for these resources, the total for NIH is \$35.5 billion, which is +\$1.4 billion above the FY 2018 Continuing Resolution.

The President's Budget proposes the consolidation of targeted HHS research programs within NIH. These entities would be initially established as three new NIH institutes: the National Institute for Research on Safety and Quality; the National Institute for Occupational Safety and Health, including the Energy Employees Occupational Illness Compensation Program; and the National Institute on Disability, Independent Living, and Rehabilitation Research. NIH will assess the feasibility of integrating health services research activities more fully into existing NIH Institutes and Centers over time.

#### RESEARCH PRIORITIES IN FY 2019

##### *Tackling Complex Challenges by Leveraging Partnerships*

NIH is exploring collaborative ways to leverage both public and private resources to tackle major public health issues and assure careful stewardship of public funds. NIH will seek to form partnerships across the

government to ensure strategic investments and reduce unnecessary redundancies. In addition, public-private partnerships can create efficiencies of scale and facilitate development of innovative technologies or treatments, thereby increasing the pace of biomedical research. Leveraging resources and expertise, NIH is engaged in several significant partnerships addressing the opioid crisis, cancer biomarkers, and Alzheimer's disease to name a few. Continued emphasis on public-private partnerships will ensure NIH's careful stewardship of public funds and increase the pace of research to benefit patients more quickly.

#### ***Accelerating Medicines Partnership***

One of NIH's most successful partnership models is the Accelerating Medicines Partnership, a public-private partnership between NIH, the Food and Drug Administration (FDA), ten biopharmaceutical companies, and multiple non-profit organizations.

Managed by the Foundation for NIH, the Partnership aims to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics. Ultimately, the goal is to increase the number of new diagnostics and therapies for patients and to reduce the time and cost of developing them. The Partnership launched in 2014 with three projects: (1) Alzheimer's disease; (2) type 2 diabetes; and (3) the autoimmune disorders rheumatoid arthritis and systemic lupus erythematosus. NIH recently initiated a partnership on Parkinson's disease.

A critical component of the Partnership is that all partners have agreed to make the Accelerating Medicines Partnership data and analyses publicly accessible to the broad biomedical community. As such, accomplishments to date include multiple public data releases for the Partnership and developing the Type 2 Diabetes Knowledge Portal to hold publicly available data sets from many sources for diabetes research, including European data.

#### ***Future Partnerships: Combatting the Opioid Epidemic***

Opioid misuse and addiction is an ongoing and rapidly evolving public health crisis. Driven by the abuse and misuse of prescription pain relievers such as oxycodone, synthetic opioids such as fentanyl, and the illegal drug heroin, the opioid epidemic not only poses a tremendous public health challenge, but also threatens our social and economic welfare. The

urgency and scale of this crisis calls for innovative scientific solutions. As part of a larger government-wide effort to address the opioid crisis, NIH will enhance existing research efforts, investing \$500 million in a public-private partnership to accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose and to help optimize their implementation. Of this amount, \$400 million is an initial allocation from the new \$10 billion proposal to combat the opioid epidemic and address serious mental illness.



In consultation with experts from government, industry, and academia, NIH has proposed a coordinated strategy with two primary aims: (1) Develop new formulations and combinations of medications to treat opioid misuse, and prevent and reverse overdose; and (2) Accelerate development of new non-addictive pain therapies. Several effective therapies exist to treat opioid misuse and reverse overdose from opioid drugs. Medication-assisted treatment in which patients dealing with opioid misuse receive medications (methadone, buprenorphine, or naloxone) in conjunction with psychosocial support can be effective. However, only a small proportion of these patients are retained in treatment for long-term recovery. NIH will support research on treatments for substance abuse, and work with private-sector partners to develop new formulations and combinations of medications to treat opioid misuse and prevent and reverse overdose, with the goal of making a wide range of therapeutics accessible to those who need them as quickly as possible.

Much of the opioid epidemic has struck patients seeking relief from very real sources of pain. The development of new pain treatments that lack the addictive properties of many of today's pain medications could prevent many incidences of future opioid misuse. NIH will work with FDA and pharmaceutical partners to build a public-private partnership to accelerate the development of new non-addictive pain therapies and make these therapies available to patients in need. Finally, NIH will work

## PROGRAM HIGHLIGHT

**Precision Medicine – All of Us Program**

In 2018, NIH is launching the national roll-out of the All of Us Research Program, a historic effort to gather data from one million or more diverse United States volunteers to accelerate advances in precision medicine. Precision medicine is a revolutionary approach for disease prevention and treatment that takes into account individual differences in lifestyle, environment, and biology. While some advances in precision medicine have been made, it is not used for most diseases.

This program is building a national resource—one of the world's largest, most diverse biomedical data sets in history—to accelerate medical breakthroughs and gain unprecedented insights into the biological, environmental, and behavioral influences of disease. Researchers may request access to the data, which will be de-identified to protect participant privacy, to conduct analyses on how individual differences affect health and disease, potentially leading to better treatment and prevention strategies.

The FY 2019 Budget, including resources from the 21st Century Cures Act, supports the ramp up of the program. After pilot testing systems and forming partnerships with community organizations. National enrollment is anticipated to begin in spring 2018. This effort will enable a new era of medicine in which researchers, health care providers, and patients work together to develop individualized care. To learn more, please visit <https://www.joinallofus.org/>.

with other Federal partners to incentivize development of new therapies and to develop and evaluate metrics for high-quality opioid treatments.

The FY 2019 Budget also provides \$350 million from the new \$10 billion investment for dedicated opioids, serious mental illness, and pain related research at NIH.

***Supporting Basic Research to Drive New Understanding of Health and Disease in Living Systems***

NIH is the largest funder of basic biomedical research in the United States, providing a critical research foundation for both the public and private sectors to build upon. NIH supports a robust basic research portfolio, which studies both how healthy living systems function outside the context of a particular disease as well as research to understand the mechanisms of disease. Studies of healthy systems help researchers recognize how such systems go wrong in cases of disease and injury, and which elements might need to be restored in order to treat such conditions. Characterizing the underlying mechanisms of disease enables scientists to comprehend fully the

underlying causes of disease onset and progression, identify key risk factors, or scout out new potential targets for therapies and cures. For example, fully addressing the magnitude of the opioid epidemic requires not only understanding how pain is typically sensed and perceived, but also how changes in neural circuits create a state of dependency. Understanding both normal function and disease states is important to developing better therapies for pain without the potential for future addiction.

It is difficult to predict where new scientific breakthroughs will arise, given that many breakthroughs involve unexpected connections between otherwise incremental advances. In order to maintain the flexibility to capture unexpected breakthroughs and make progress in as many research areas as possible, NIH funds a broad spectrum of basic science research. In addition, NIH seeks to provide the resources, infrastructure, and overarching vision that allows the field to fully capitalize on scientific opportunities as they arise, helping to usher in new breakthroughs which can transform a field and catalyze faster progress.

***Investing in Translational and Clinical Research to Improve Health***

Building on a solid foundation of basic research, NIH supports translational research that applies basic knowledge to discover new strategies for intervening in disease processes through better detection, prevention, or treatment. These strategies, which could develop a potential medication, a new vaccine, a medical device, a community-based prevention program, or a wide range of other intervention types, are then optimized and tested in clinical or real world settings to assess their efficacy and effectiveness. NIH is deliberate in its support of translational and clinical sciences, following the guidance of its strategic plan to fund those studies in which the scientific opportunities are ripe, and the public health needs, whether emerging or chronic, are greatest. NIH supports the creation of the infrastructure, resources, and tools to provide a platform for innovation. To facilitate integrated understanding of health and disease at all levels, from molecular underpinnings to social factors to treatment response, NIH is investing in large population studies to learn more about how people are the same and different. This integration has the potential for unprecedented precision in the ways in which health is addressed, making it possible for every individual to receive preventive and therapeutic care

tailored specifically to their needs, ushering in an era of precision medicine.

#### ***Stewardship of NIH Facilities***

NIH owns 281 facilities with over 15 million gross square feet of space, including its research hospital, laboratories, and offices. It has a large and growing backlog of maintenance and repair. At Congressional direction, an independent review is being conducted of the capital needs of the NIH main campus.

#### ***Fostering a Diverse and Talented Biomedical Research Workforce for Today and Tomorrow***

Inquisitive and talented people, who work in every state of the Nation, are the agents through which NIH achieves its mission. A sustainable and diverse biomedical research workforce, comprising all levels of researchers, is necessary for ensuring innovation in the biomedical sciences. NIH remains committed to the development, support, and retention of a motivated and diverse workforce with a broad range of expertise.

#### **PROGRAM HIGHLIGHT**

##### **Accelerating Regenerative Medicine**

Regenerative medicine is a multidisciplinary approach that employs novel technologies to restore form and function lost due to aging, disease, or injury. There is enormous potential for regenerative medicine to improve the health of the nation. For example, over 20 million Americans suffer from chronic kidney disease at a cost of some \$48 billion/year – but regenerative medicine may make it possible to restore that function and make dialysis or donor transplants no longer needed. Over one million Americans deal with the complications of type 1 diabetes – and the development of an artificial pancreas using regenerative medicine may end their need for frequent glucose checks and insulin injections. Other diseases and conditions that would benefit from this innovative approach include chronic lung diseases, eye disorders, those suffering from traumatic loss of limbs, and cardiovascular and heart diseases.

A specialized form of regenerative medicine involves the use of a cutting-edge technology termed CRISPR that allows scientists to edit the genetic code with great precision. This technology has great potential to correct genetic disorders such as cystic fibrosis, hemophilia, or sickle cell disease. Over 100,000 Americans suffer from sickle cell disease, with estimated costs exceeding \$1 billion a year. Sickle cell patients have defective hemoglobin, the red blood cell molecule responsible for transporting oxygen throughout the body. Scientists are investigating the use of CRISPR to correct the defective hemoglobin in a patient's own hematopoietic stem cells, which would then be infused back into the patient to correct the condition.

The FY 2019 Budget supports the enhanced focus on this promising new approach to accelerate treatments and cures.

NIH cultivates the human capital needed to fulfill its mission by providing support for early- and mid-career investigators, investing in outstanding researchers with high potential, strengthening a diverse biomedical research community, and by investing in clinician-scientists.

With respect to early-stage investigators, and those at risk of losing all NIH funding, the Next Generation Researchers Initiative (NGRI) began in FY 2017 to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers. For FY 2019, the Budget includes a dedicated fund of \$100 million in the Office of the Director from which Institutes and Centers would be able to draw to supplement the NGRI efforts undertaken with their own appropriations.

#### ***Innovation through Competition***

The Budget allocates \$50 million for prize competitions under the authority of section 105 of the America COMPETES Reauthorization Act of 2010. This will focus on the types of innovation highlighted in section 2002 “Eureka Prize Competitions” of the 21st Century Cures Act, including monitoring the effect of innovations funded through prize competitions on advancing biomedical science or improving health outcomes.

#### ***Advancing Data Science***

In 2012, NIH established the Big Data to Knowledge (BD2K) initiative and created a new Associate Director for Data Science position. In the years since, NIH has established extramural Centers of Excellence, piloted a “Data Commons,” and supported enhanced training of data scientists and bioinformaticians.

In FY 2019, NIH will begin the next phase of its data science activities with a \$30 million fund, managed by the Associate Director, to build on the success of BD2K as that initiative enters its final stages.

#### ***Administrative Reforms***

The Budget supports the continued execution of the largest change management initiative in the history of NIH. These activities will harmonize the agency's internal functions and better ensure administrative operations effective and efficient.

#### ***Stretching the Grant Dollar Further***

The Budget proposes two initiatives that will stretch available grant dollars to fund more research by placing limits on the payment of investigator salaries with



them. The Budget will both cap the percentage of investigator salary that can be paid with grant funds to 90 percent of total salary, and reduce the limit for salaries paid with grant funds from \$187,000 to \$152,000.

## **MAXIMIZING THE IMPACT OF NIH RESEARCH**

### ***Occupational Safety and Health***

Established in 1970, the National Institute for Occupational Safety and Health (NIOSH), currently administered by the Centers for Disease Control and Prevention, is mandated to assure “every man and woman in the Nation safe and healthful working conditions and to preserve our human resources.” The Budget provides \$200 million for research needed to prevent the societal cost of work-related fatalities, injuries, and illnesses in the United States.

Through the National Occupational Research Agenda, a public-private partnership, NIOSH works closely with diverse partners to identify the most critical issues in workplace safety and health. NIOSH and its partners then stimulate and conduct innovative research that addresses needs in a wide range of industries central to our society and economy, including manufacturing, mining, and emergency responders.

In addition, the Budget includes \$55 million in mandatory funding for the Energy Employees Occupational Illness Compensation Program Act. NIOSH conducts activities to assist claimants and support the role of the Secretary of HHS. NIOSH is primarily responsible for conducting occupational dose reconstructions for cancer claims and for overseeing the petition process for adding additional classes of employees. This program provides compensation and medical benefits to employees who worked at certain Department of Energy facilities, including contractors, subcontractors, and certain vendors. The Department of Labor manages claims filed under the Act.

### ***Disability, Independent Living, and Rehabilitation Research***

The mission of the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), currently administered by the Administration for Community Living, is to generate new knowledge and promote its effective use to improve the abilities of people with disabilities to perform activities of their choice in the community, and to expand society’s capacity to provide full opportunities and accommodations for its citizens with disabilities. The Budget provides \$95 million for

NIDILRR activities, which compliments existing NIH research portfolios addressing disabilities and aging. NIDILRR sponsors comprehensive and coordinated programs of research and related activities to maximize the full inclusion, social integration, employment, and independent living of individuals with disabilities of all ages.

### ***Healthcare Research and Quality***

To reduce potential overlap and streamline Federal health research, the FY 2019 Budget consolidates the activities of the Agency for Healthcare Research and Quality (AHRQ) into NIH as the National Institute for Research on Safety and Quality (NIRSQ).

This consolidation will combine two agencies that both support health services research, and create an entity within NIH that can better coordinate and ensure a continued focus on research to improve health care quality and patient safety. The form of this consolidation will be further informed by the findings and recommendations of a study launched in FY 2018 to review the coordination of health services and translational research. Within NIH, the FY 2019 Budget includes \$256 million in budget authority for NIRSQ to continue selected unique, systemically-important activities formerly funded by AHRQ that have demonstrated effectiveness in improving healthcare quality.

To continue progress on patient safety, the Budget includes \$70 million for this area of research within NIRSQ, the same level as the FY 2018 Continuing Resolution within AHRQ. These patient safety research and dissemination activities have provided the foundation of evidence upon which nationwide efforts have been built to reduce medical errors, prevent health care-associated infections, and combat antibiotic resistance.

The Budget includes funding for Health Services Research, Data, and Dissemination, which provides support for continuing the Healthcare Cost and Utilization Project, a widely used data resource; investigator-initiated research grants, a source of innovative projects; and the Evidence-Based Practice Centers, which produce highly regarded systematic evidence reviews. In addition, the Budget includes \$5 million, an increase of \$2 million, to support a new evidence dissemination contract on opioid abuse prevention and treatment in primary care, part of the Administration’s commitment to address the opioid

epidemic. No funding is included for potentially duplicative or lower priority activities formerly funded by AHRQ, including the Consumer Assessment of Healthcare Providers and Systems and the Health Information Technology Research portfolio. Research on this subject can be funded under NIRSQ's general health services investigator-initiated research.

#### PROGRAM HIGHLIGHT

### Reducing Diagnostic Error

Although HHS has made major advances in patient safety in recent years, errors of diagnosis continue to cause unnecessary harm for too many patients. Researchers estimate that at least 5 percent of adults seeking outpatient care experience a diagnostic error, which contributes to up to 17 percent of adverse hospital events. The National Academies of Science, Engineering, and Medicine have called for a greater focus on identifying and preventing these errors.

In recent years, AHRQ has issued funding opportunity announcements to support research projects to identify measurement gaps, measure the frequency and causes of misdiagnoses, and develop effective interventions to prevent them. NIRSQ will continue projects to develop clinical decision support tools to bring electronic information to clinicians at the right time to assist with making the right diagnosis. Additional projects are supporting the design of learning healthcare organizations that can collect and effectively utilize patient-reported outcome data for diagnostic decisions, and integrate findings to improve their daily work. The FY 2019 Budget supports the enhanced focus on this issue and implementation of this research agenda.

Within NIRSQ, the Budget provides \$72 million for the Medical Expenditure Panel Survey, which offers the ability to identify trends and patterns in cost and access to health care, along with insights into what kinds of coverage are offered by employers and states. The Budget features an increase of \$2 million to support additional questions on mental health and surveying a larger number of households to achieve greater precision and quantities of state and regional-level statistics, particularly for states with smaller populations. NIRSQ will provide \$7 million, \$4 million below AHRQ's FY 2018 Continuing Resolution level, in administrative support to the United States Preventive Services Task Force.

To further drive improvement in Americans' healthcare, NIRSQ is projected to receive \$124 million in mandatory resources from the Patient-Centered Outcomes Research Trust Fund to disseminate findings from comparative clinical effectiveness studies and train researchers on how to conduct high-quality studies in this area of research.

# Substance Abuse and Mental Health Services Administration



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/-2018
<b>Mental Health</b>				
Community Mental Health Services Block Grant	563	559	563	+4
Programs of Regional and National Significance	396	395	283	-112
<i>Suicide Prevention Programs (non-add)</i>	69	67	69	+2
Children's Mental Health Services	119	118	119	+1
Projects for Assistance in Transition from Homelessness	65	64	65	--
Protection and Advocacy for Individuals with Mental Illness	36	36	36	--
<b>Subtotal, Mental Health</b>	<b>1,178</b>	<b>1,172</b>	<b>1,065</b>	<b>-107</b>
<b>Substance Abuse Prevention</b>				
Programs of Regional and National Significance	222	222	121	-101
Drug Free Communities	--	--	100	+100
<b>Subtotal, Substance Abuse Prevention</b>	<b>222</b>	<b>222</b>	<b>221</b>	<b>-1</b>
<b>Substance Abuse Treatment</b>				
Substance Abuse Prevention and Treatment Block Grant	1,858	1,845	1,858	+13
Programs of Regional and National Significance	350	352	255	-97
State Targeted Response to the Opioid Crisis Grants	500	497	/3	-497
<b>Subtotal, Substance Abuse Treatment</b>	<b>2,709</b>	<b>2,694</b>	<b>2,113</b>	<b>-581</b>
<b>Health Surveillance and Program Support</b>				
Program Support	77	76	73	-3
Health Surveillance	47	47	49	+2
Performance and Quality Information Systems	10	10	13	+3
Public Awareness and Support	13	13	12	-1
Data Request and Publications User Fees	2	1	2	--
Behavioral Health Workforce Data and Development	1	1	1	--
<b>Subtotal, Health Surveillance and Program Support</b>	<b>150</b>	<b>149</b>	<b>149</b>	<b>--</b>
<b>SAMHSA Budget Totals</b>				
<b>Total, Program Level</b>	<b>4,258</b>	<b>4,236</b>	<b>3,548</b>	<b>-688</b>
<i>Less Funds from Other Sources:</i>				
<i>Prevention and Public Health Fund/5</i>	<i>-12</i>	<i>-11</i>	<i>--</i>	<i>+11</i>
<i>PHS Evaluation Funds</i>	<i>-134</i>	<i>-133</i>	<i>-121</i>	<i>+12</i>
<i>User Fees for Data Request and Publications</i>	<i>-2</i>	<i>-1</i>	<i>-2</i>	<i>--</i>
<b>TOTAL, Discretionary Budget Authority</b>	<b>4,111</b>	<b>4,091</b>	<b>3,426</b>	<b>-665</b>
Additional Opioids Allocation	--	--	1,240	+1,240
<b>TOTAL with Additional Opioids Allocation /3</b>	<b>4,258</b>	<b>4,236</b>	<b>4,788</b>	<b>+552</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/The Budget includes \$1 billion in discretionary funding for State Opioid Targeted Response grants as part of the \$10 billion proposal to address the opioid epidemic and serious mental illness.				
4/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				
5/ Source of funds displayed consistent with prior year presentations and the assumptions for the FY 2019 Budget.				

*The Substance Abuse and Mental Health Services Administration reduces the impact of substance abuse and mental illness on America's communities.*

The Fiscal Year (FY) 2019 President's Budget provides a program level of \$3.5 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA), which is a reduction of \$688 million below the FY 2018 Continuing Resolution. In addition, the Budget provides \$1.2 billion to SAMHSA for a variety of new and expanded efforts to fight the opioid crisis. When accounting for these resources, the total for SAMHSA is \$4.8 billion, which is an increase of \$552 million above the FY 2018 Continuing Resolution. The Budget focuses on improving the Federal response to the opioid crisis and in helping health systems serve those with serious mental illness more effectively.

## **SUBSTANCE ABUSE**

In 2016, 29 million Americans, or about 11 percent, used an illicit drug, a figure driven primarily by marijuana and misuse of prescription pain relievers. Approximately 24 million people used marijuana and 3.3 million misused prescription pain relievers. The Budget provides \$2.3 billion for substance abuse prevention and treatment activities, which is \$582 million below the FY 2018 Continuing Resolution. In addition, the Budget provides an initial allocation of \$1.2 billion to SAMHSA from the historic \$10 billion investment for a variety of new and expanded efforts to fight the opioid crisis. The Budget does not include funding across SAMHSA for Minority Fellowship Programs, and also discontinues funding for the Screening, Brief Intervention, and Referral to Treatment program, which is \$30 million below the FY 2018 Continuing Resolution. This successful demonstration has been taken up across the country and can be paid for by public and third party insurance.

### ***Expanding the Fight against the Opioid Crisis***

The President's Budget makes significant investments in the fight against the opioid crisis, which follows the HHS action in October of 2017 to declare the opioid crisis to be a public health emergency. Opioid misuse, abuse, and overdose impose immense costs on the nation, contributing to two-thirds of the 174 deaths every day from drug overdose. Deaths by drug overdose are the leading cause of unintentional injury death for Americans under the age of 50. Between 2000 and 2015, more than half a million people have died from drug overdoses.

The Budget includes \$10 billion in new resources across HHS to combat the opioid epidemic and address serious mental illness. In FY 2019, an initial allocation provides \$1.2 billion in SAMHSA for a variety of new and expanded efforts to fight the opioid crisis. Of that amount, \$1 billion is included to expand State Targeted Response Grants, an increase of \$503 million above the FY 2018 Continuing Resolution amount for these activities. Additional funds will help States provide services to reduce injection drug use and related HIV/AIDS and Hepatitis C infection rates, allow communities to purchase the overdose-reversing drug naloxone for first responders, and expand the use of drug courts, as well as services to pregnant and postpartum women.

The FY 2019 Budget also provides \$123 million in SAMHSA to support existing activities targeted to fighting the opioid epidemic, which is \$1 million above the FY 2018 Continuing Resolution.

The Budget maintains \$56 million to expand the availability of medication-assisted treatment, the most effective evidence-based treatment for opioid addiction. The Budget also maintains \$20 million for Comprehensive Addiction and Recovery Act authorized programs, the same amount as the FY 2018 Continuing Resolution. The programs will expand training for first responders on the use of the opioid-overdose reversing drugs such as Naloxone, equip these first responders with the needed drugs, and provide additional support services to help those in recovery succeed, including pregnant women and families struggling with addiction. The Budget maintains \$10 million in funding for states to enhance opioid abuse prevention strategies and also maintains \$9 million to ensure Opioid Treatment Programs are operating safely and effectively.

### ***Substance Abuse Prevention and Treatment Block Grant***

The Budget provides \$1.9 billion for the Substance Abuse Prevention and Treatment Block Grant, which is \$13 million above the FY 2018 Continuing Resolution. This formula grant to states represents nearly a third of public funds expended for prevention and treatment of substance abuse and contributes to a public health system that treats approximately 2 million individuals per year. This flexible funding source allows states to



identify their most pressing needs and target funding to them. These needs often include building infrastructure such as payment systems and anti-fraud efforts, as well as activities for which third party insurance does not reimburse.

#### ***Advancing Approaches to Preventing Substance Abuse***

The Budget includes \$221 million for substance abuse prevention efforts, which is \$1 million below the FY 2018 Continuing Resolution. This funding is intended to improve substance abuse prevention in states and communities across the Nation. Within this amount, the Budget includes \$100 million for the Drug Free Communities program to be directly appropriated to and administered by SAMHSA. SAMHSA has administered the program for several years for the Office of National Drug Control Policy. This total also includes \$62 million, the same as the FY 2018 Continuing Resolution, for grant programs to fight underage drinking, expand the availability of opioid overdose-reversing drugs, and to expand tribal behavioral health services. This total also provides funding for SAMHSA regulatory efforts to support Federal drug-free workplace efforts, and to provide states, tribes, and communities with technical assistance and training on best practices to prevent substance abuse. The Budget provides \$58 million for the Strategic Prevention Framework, which is \$60 million below the FY 2018 Continuing Resolution, to prioritize other high-need programs.

#### **MENTAL HEALTH**

An estimated 43 million Americans have a mental, behavioral, or emotional disorder that substantially interfered with or limited major life activities in 2016. Of these, approximately 10 million people—or four percent of all American adults—had a serious mental illness. A recent study estimated that the financial cost of mental disorders, which included estimated expenditures for mental health treatment, projections of lost earnings and public disability insurance payments associated with mental illness, was at least \$467 billion in the United States in 2012. This total does not include criminal justice costs, which are significant. Approximately 250,000 individuals with serious mental illness are incarcerated at any given time—and about half of these individuals were arrested for non-violent offenses such as trespassing or disorderly conduct. The Budget provides \$1.1 billion, which is \$107 million below the FY 2018 Continuing Resolution, for mental health activities. Within this

amount, the Budget expands efforts to effectively address the needs of those with the most serious mental health issues.

#### ***Responding to Serious Mental Illness***

The Budget includes \$889 million, which is \$31 million above the FY 2018 Continuing Resolution, targeted specifically to programs that assist those with Serious Mental Illness. The Budget proposes to increase funding for two programs to help those with serious mental illness. In addition, the FY 2019 Budget includes \$10 billion to combat the opioid epidemic and address serious mental illness.

The Budget includes \$15 million for a new Assertive Community Treatment for Individuals with Serious Mental Illness program, authorized by the 21st Century Cures Act, to help communities establish, maintain, or expand evidence--based efforts to avoid the ineffective cycling of patients with serious mental illness through emergency and inpatient settings. This team-based practice is proven to reduce hospitalization of those with serious mental illness at the same cost with higher patient satisfaction. In addition, the Budget expands Criminal and Juvenile Justice Programs to \$14 million, an increase of \$10 million above the FY 2018 Continuing Resolution. This investment will provide comprehensive treatment and recovery support services for adolescents and adults who come into contact with the criminal justice system with co-occurring mental illness and drug or alcohol addiction, as well as for offenders re-entering the community. A recent evaluation of the program showed that in the first six months, participants' reported mental health issues declined by 20 percent, alcohol and other drug use declined by 60 percent, nearly 74 percent of participants reported physical health improvements, and employment rates increased from 36 percent to 45 percent.

#### ***Community Mental Health Services Block Grant***

The Budget includes \$563 million for the Community Mental Health Services Block Grant, \$4 million above the FY 2018 Continuing Resolution. This formula grant to states provides a flexible source of funding required to be used exclusively in addressing the needs of adults living with serious mental illness and children experiencing serious emotional disturbances. States target local needs with this funding, prioritizing activities that insurance does not cover such as physician training, anti-fraud efforts, and planning necessary to efficiently operate public health systems.

## PERFORMANCE HIGHLIGHT

**National Suicide Prevention Lifeline**

The Budget maintains support for the National Suicide Prevention Lifeline, 1-800-273-TALK, which coordinates a network of 164 crisis centers across the United States. These crisis centers provide suicide prevention and crisis intervention services for individuals seeking help at any time, day or night. The National Suicide Prevention Lifeline averaged nearly 156,000 calls per month in FY 2017, with over 90 percent of callers reporting that calling the crisis hotline helped stop them from killing themselves. More than 54,000 callers per month identified themselves as veterans and were seamlessly connected to a specialized veterans' suicide prevention hotline developed in collaboration with the Department of Veterans Affairs.

**Children's Mental Health Services**

The Budget maintains the Children's Mental Health Services program at \$119 million, which is \$1 million above the FY 2018 Continuing Resolution. This competitive grant program for states, tribes, and communities provides evidence-based services and supports for children and youth with serious emotional disturbances. Recipients use these funds to create networks that provide fully comprehensive care—including effective collaboration between child- and youth-serving systems such as juvenile justice, child welfare, and education. Recent research by the National Institute of Mental Health indicates that there is an opportunity to improve treatment for youth who are at high risk of forming serious mental illness through earlier intervention. The Budget proposes to allocate up to 10 percent of this program for a new demonstration to translate this research into practice.

**Suicide Prevention**

In 2016, nearly 10 million adults thought seriously about attempting suicide. Within this number, 2.8 million made suicide plans, 1.3 million made a serious, non-fatal suicide attempt, and nearly 43,000 people committed suicide. The Budget provides \$69 million for Suicide Prevention programs, which is \$2 million above the FY 2018 Continuing Resolution.

These programs provide technical assistance to disseminate best practices and competitive grants to reduce suicide deaths. Recipients in communities across the country increase awareness of suicide warning signs and knowledge of how to help those in need. In addition, the programs improve emergency room referral processes and clinical care practice standards, and assist States in developing and implementing suicide prevention strategies. The funding also supports American Indian/Alaska Native Suicide Prevention through specialized technical assistance and support.

**Primary and Behavioral Healthcare Integration**

The Budget does not include funding for the Primary and Behavioral Healthcare Integration program, which is \$52 million below the FY 2018 Continuing Resolution. States can use the mental health and substance abuse block grants to support the integration of primary and behavioral health care systems. The Certified Community Behavioral Health Center program, for example, is currently testing this approach through a demonstration in eight States.

**HEALTH SURVEILLANCE AND PROGRAM SUPPORT**

The Budget includes \$149 million to support nationwide Health Surveillance efforts and related program oversight necessary to effectively monitor a wide array of Federal programs. This net reduction of \$2 million below the FY 2018 Continuing Resolution prioritizes activities for which there is a unique Federal role, such as certain public health surveillance associated with the National Survey on Drug Use and Health. Included within this total is \$15 million to re-establish the Drug Abuse Warning Network, a national public health surveillance system that will improve emergency room monitoring of mental and substance abuse crises, including those related to opioids. Authorized by the 21st Century Cures Act, this program is necessary to more effectively respond to the opioid crisis. This activity will improve the availability of early warning information, such as information on non-fatal overdoses which may not otherwise be attributable to opioids. This program will not duplicate existing data collection efforts.

## Centers for Medicare & Medicaid Services: Overview



<i>dollars in millions</i>	2017	2018	2019	2019 +/- 2018
<b>Current Law /1 /2</b>				
Medicare /3	597,414	588,346	651,789	+63,443
Medicaid	374,681	402,088	420,241	+18,153
CHIP	16,251	12,818	5,724	-7,094
State Grants and Demonstrations /4	503	583	578	-5
Other Health Insurance Programs /5	8,683	30,880	16,692	-14,188
Center for Medicare and Medicaid Innovation	1,136	1,278	1,592	+314
<b>Total Net Outlays, Current Law</b>	<b>998,668</b>	<b>1,035,993</b>	<b>1,096,616</b>	<b>+60,623</b>
<b>Proposed Law /2</b>				
Medicare /3	-	38	-15,396	-15,434
Medicaid	-	-1,700	-8,209	-6,509
CHIP	-	4,500	5,700	+1,200
General Revenue Payments for Hospitals /6	-	-	14,540	+14,540
Cost-Sharing Reduction Impacts	-	-180	-471	-291
Program Management /7	-	812	12	-800
<b>Total Proposed Law</b>	<b>-</b>	<b>3,470</b>	<b>-3,824</b>	<b>-7,294</b>
<b>Total Net Outlays, Proposed Law /8</b>	<b>998,668</b>	<b>1,039,463</b>	<b>1,092,792</b>	<b>+53,329</b>
1/ Reflects the annualized level of the Continuing Resolution that ended April 28, 2017, including the across the board reduction, the 21 <sup>st</sup> Century Cures Act, and directed transfers. 2/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120. 3/ Current law Medicare outlays net of offsetting receipts. 4/ The following programs/laws were excluded from the Current Law Outlays table because outlays were less than \$1 million: Ticket to Work and Work Incentives Improvement Act, Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens, and the Medicaid Emergency Psychiatric Demonstration. 5/ Reflects other CMS health insurance programs. FY 2018 assumes outlays of \$11,513 million (post-sequester) for the Risk Corridors Program. 6/ Reflects hospital payments that are proposed to be administered by CMS but financed outside of the Part A Trust Fund. 7/ Includes legislative proposal to fully fund the Risk Corridors Program, including exempting the program from sequestration. 8/ Total net proposed law outlays equal current law outlays plus the impact of proposed legislation and offsetting receipts. Includes Trust Fund outlays for the Office of Medicare Hearings and Appeals for Fiscal Years 2017-2019.				

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

The Fiscal Year (FY) 2019 Budget estimate for the Centers for Medicare & Medicaid Services (CMS) is \$1.1 trillion in mandatory and discretionary outlays, a net increase of \$53.3 billion from FY 2018. This level finances Medicare, Medicaid, the Children's Health Insurance Program (CHIP), other health insurance programs, program integrity efforts, and operating costs. CMS's legislative package promotes fiscal

responsibility, increases state flexibility, builds on the recent repeal of the onerous individual mandate to provide real health care choices to Americans, reforms graduate medical education, and curbs the practice of defensive medicine. In total, the Budget proposes targeted savings of \$632.0 billion in CMS mandatory programs over the next decade.

## BUDGETARY REQUEST

CMS is dedicated to moving toward a health care system that will drive down costs, give Americans more choices, and put patients and doctors in control of their health care. To achieve these outcomes, CMS will empower patients and doctors to make decisions about their health care while reducing burdensome regulations and building a patient-centered system of care that increases competition, quality, and access. CMS will continue to usher in a new era of state flexibility and local leadership. Because the States are in the best position to assess the unique needs of their populations and drive reforms, this shift will result in better health care outcomes.

### Medicare

The Budget includes legislative proposals in Medicare that are designed to improve drug pricing and payment, address opioids, reform payment and delivery systems, and simplify government-imposed provider burdens, address fraud waste and abuse, and reform the Medicare appeals process. Overall these proposals produce net savings of \$493.7 billion over 10 years. The Budget also restructures and brings accountability to payments not directly related to Medicare's health insurance role, financing them outside the Trust Funds.

### Medicaid

The Budget includes legislative proposals in Medicaid which produce net savings to the Federal budget of \$1,438.8 billion over 10 years. The Budget makes fundamental reforms to Medicaid's fiscal structure by moving to a per capita cap or block grant structure. The Budget also proposes other Medicaid reforms to reset the Federal-State partnership, such as providing states greater flexibility to administer their Medicaid programs and refocusing the program on traditional Medicaid populations.

### Repeal and Replace Obamacare

The Budget includes \$679.7 billion in net deficit savings over 10 years from the repeal and replacement of Obamacare. The President is committed to rescuing states, consumers, and taxpayers from the failures of Obamacare, and supporting states as they transition to more sustainable health care programs that provide appropriate choices for their citizens.

### Reform Medical Liability

The Budget proposes medical liability reforms that will reduce medical malpractice costs and the practice of defensive medicine, saving HHS programs a combined \$30.8 billion over ten years; decreasing provider burdens; and reducing costs for patients, states, and insurers.

### Reform Graduate Medical Education

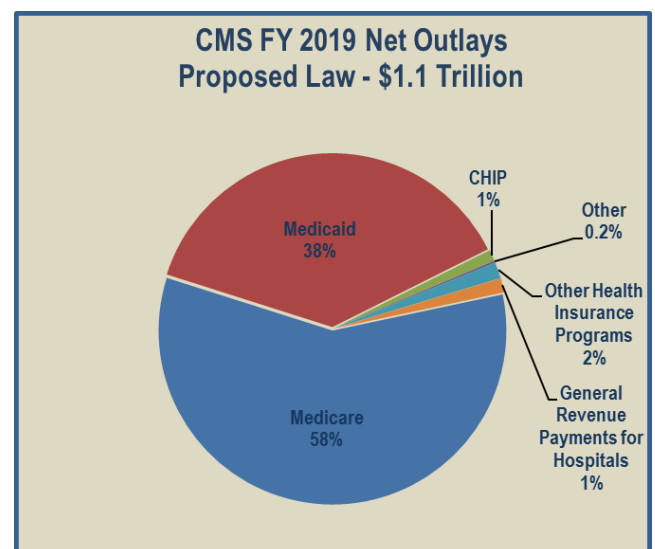
The Budget includes a proposal to consolidate and better target Federal spending for Graduate Medical Education to physician specialty and geographic shortages, which saves a net \$48.1 billion over ten years. The grant program would be jointly operated by the CMS and Health Resources and Service Administration Administrators.

### Program Integrity

The Budget includes investments to combat fraud and abuse and new legislative authorities which support the continued effort to shift away from the "pay-and-chase" model toward preventing fraud, waste, and abuse on the front end.

### Discretionary Program Management

The Budget includes \$3.5 billion for Program Management, enabling CMS to continue to administer Medicare, Medicaid, and CHIP effectively. The Budget also includes user fee and other legislative authorities that ensure CMS more equitably and efficiently administers its programs.





## Health Care Reform

The Fiscal Year (FY) 2019 Budget supports bold, crosscutting reforms to our Nation's health care system that save money, strengthen programs, and secure the promises of the Federal Government's major benefits programs. These reforms replace Obamacare with flexibility for states to create a free and open health care market tailored to local needs. These reforms also ensure that Medicaid and other programs focus on the Americans that they were intended to serve—the elderly, people with disabilities, children, and pregnant women. In short, the FY 2019 Budget enacts reforms to ensure our health care programs work for the American people, provide Americans with access to care that meets their needs, increase options for patients and providers, and build financial stability and responsibility.

In 2017, the Administration worked with Congress to take the first step towards relieving Americans from the failures of Obamacare by repealing the unpopular individual mandate in the Tax Cuts and Jobs Act (P.L. 115-97). The Budget supports the Exchanges while Congress works on broader health care reforms in order to ease the transition to the open health care markets of the future. The Budget also supports providing additional flexibilities to State Medicaid programs, which are discussed in more detail in the Medicaid chapter.

### 2019 LEGISLATIVE PROPOSALS

#### *Repeal and Replace Obamacare*

The Administration is committed to rescuing states, consumers, and taxpayers from the failures of Obamacare and to supporting states as they transition to more sustainable health care programs that provide appropriate choices for their citizens. The Budget supports a two-step approach to repealing and replacing Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill, as soon as possible.

The Administration supports the comprehensive Medicaid reform in the Graham-Cassidy-Heller-Johnson bill, including modernization of Medicaid financing and repeal of the Obamacare's Medicaid expansion. Medicaid financing reform will empower states to design individual, state-based solutions that prioritize Medicaid dollars for traditional Medicaid populations

and support innovations like community engagement initiatives for able-bodied adults.

Additionally, the Market-Based Health Care Grant Program included in the Graham-Cassidy-Heller-Johnson legislation will provide more equitable and sustainable funding to states to develop affordable health care options for their citizens. The block grant program will empower states to improve the functioning of their own health care market through greater choice and competition, with states and consumers in charge.

The second step of the repeal and replace proposal builds upon the Graham-Cassidy-Heller-Johnson bill to make the system more efficient by including proposals to align the Market-Based Health Care Grant Program, Medicaid per capita cap, and block grant growth rates with the Consumer Price Index for all Urban Consumers. The Budget stabilizes long-term health care spending while allowing states to share in program savings to promote innovation. [\$306.6 billion in savings to HHS and \$679.7 billion in government-wide net deficit reduction over 10 years]

#### *Reduce the Grace Period for Exchange Premiums*

This proposal reduces the grace period for individuals on Exchange plans to make premium payments from 90 days to 30 days. [\$1.3 billion in savings to Treasury over 10 years; no HHS budget impact]

#### *Permit Federally-Facilitated Exchange States to Conduct Qualified Health Plan Certification*

This proposal allows states to certify Qualified Health Plans regardless of their Exchange model (State-Based Exchange, State-Based Exchange on the Federal Platform, or Federally Facilitated Exchange). The Centers for Medicare & Medicaid Services (CMS) would maintain review over issues related to program integrity. [No budget impact]



## NEW INITIATIVE

**The Budget Repeals and Replaces Obamacare**

The Budget supports a two-part approach to repealing and replacing Obamacare. First, the Budget supports the enactment of legislation modeled after the Graham-Cassidy-Heller-Johnson bill. Second, the Budget includes reforms to help set government health care spending on a sustainable fiscal path. This proposal reduces the Federal deficit by \$679.7 billion over 10 years.

(dollars in millions)

<b>Step One – Proposal Modeled After Graham-Cassidy-Heller-Johnson</b>	
	FYs 2019-2028
HHS Impacts	\$458,711
Medicaid (non-add)	-\$1,083,570
Other HHS Programs (non-add)	\$1,542,281
Non-HHS	-\$373,133
Step One Impact	\$85,578
<b>Step Two – Improving Program Sustainability and Achieving Deficit Reduction</b>	
	FYs 2019-2028
HHS Impacts	-\$765,284
Medicaid (non-add)	-\$305,665
Other HHS Programs (non-add)	-\$459,619
Non-HHS	\$0
Step Two Impact	-\$765,284
<b>Total</b>	
	FYs 2019-2028
HHS Impacts	-\$306,573
Medicaid (non-add)	-\$1,389,235
Other HHS Programs (non-add)	\$1,082,662
Non-HHS	-\$373,133
Total Budget Impact	-\$679,706

**Provide Appropriation to Pay Cost-Sharing Reductions**

This proposal provides a mandatory appropriation for Cost-Sharing Reduction payments for FY 2018 through the end of calendar year 2019. [No budget impact]

**Fully Fund the Risk Corridors Program**

This proposal provides a mandatory appropriation to fully fund the Risk Corridors Program, including exempting the program from sequestration. [Budget Impact: \$812 million in FY 2018]

**Prohibit Governmental Discrimination against Health Care Providers that Refuse to Cover Abortion**

The Budget also proposes to prohibit the Federal Government, as well as state and local governments that receive Federal financial assistance for health-related activities, from penalizing or discriminating against health care providers based on the providers' refusal to be involved in, or provide coverage for, abortion services. [No budget impact]

**Reform Medical Liability**

The current medical liability system disproportionately benefits a relatively small group of plaintiffs and lawyers at the expense of adding to the cost of health care for every American and imposing a burden on health care providers. The current medical liability system does not work for patients or providers, nor does it promote high-quality, evidence-based care. The Budget proposes medical liability reforms that will save HHS programs \$30.8 billion over 10 years and \$52.1 billion to the Federal Government overall. A significant portion of these savings are attributable to the estimated reduction in unnecessary services and curbing the practice of defensive medicine. These medical liability reforms will benefit all Americans by cutting unnecessary health care spending.

In addition to reducing health care costs, these reforms help physicians focus on patients and on evidence-based medicine rather than on frivolous lawsuits. By providing a safe harbor based on clinical guidelines, physicians can focus on delivering effective care, and, if an inherently risky medical procedure does not work out 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 health care 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 three-year statute of limitations;

- Allowing courts to modify attorney's 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.
- [\$30.8 billion in savings to HHS programs and \$52.1 billion in government-wide net deficit reduction over 10 years]

#### ***Reform Graduate Medical Education Payments***

Effective FY 2019, this proposal consolidates Federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospitals Graduate Medical Education program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2019 would equal the sum of Medicare and Medicaid's 2016 payments for graduate medical education, plus 2016 spending on Children's

Hospitals Graduate Medical Education, adjusted for inflation. This amount would then grow at the Consumer Price Index for all Urban Consumers minus one percentage point each year. Payments would 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 would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would 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 health care professional shortages and educational priorities. [\$48.1 billion in savings over 10 years]



## Health Care Reform

### FY 2019 Health Care Reform Legislative Proposals

<i>dollars in millions</i>	<i>2019</i>	<i>2019 -2023</i>	<i>2019 -2028</i>
<b>Repeal and Replace Obamacare</b>			
Subtotal, Non-Medicaid HHS Impact	2,190	463,309	1,082,662
<i>Market-Based Health Care Grant Program (non-add)</i>	-	497,315	1,185,381
<i>Other HHS Impact (non-add)</i>	2,190	-34,006	-102,719
<i>Medicaid Impact (non-add)</i>	-2,885	-429,395	-1,389,235
<i>Subtotal, HHS Impact (non-add)</i>	-695	33,914	-306,573
<i>Subtotal, Non-HHS Impact (non-add)</i>	3,452	-136,397	-373,133
<i>Total, Government-wide Impact (non-add) /1/2</i>	2,757	-102,483	-679,706
<b>Reform Graduate Medical Education Payments</b>			
General Fund Impact (HHS impact)	14,540	80,610	168,150
<i>Medicare Impact (non-add)</i>	-13,310	-82,460	-195,040
<i>Medicaid Impact (non-add)</i>	-1,600	-9,000	-21,200
<i>HRSA Impact (non-add) /3</i>	-	-	-
<i>Total, HHS-wide Impact (non-add)</i>	-370	-10,850	-48,090
<b>Reform Medical Liability</b>			
Cost-Sharing Reductions Impact (HHS impact)	-1	-1	-1
<i>Medicare Impact (non-add)</i>	-88	-6,233	-30,703
<i>Medicaid Impact (non-add) /1</i>	-57	-57	-57
<i>Non-HHS Impact (non-add)</i>	-32	-4,265	-21,358
<i>Total, Government-wide Impact (non-add) /1/2</i>	-178	-10,557	-52,119
<b>Other Health Care Reform</b>			
Extend CHIP funding through 2019 with Reforms (Cost-Sharing Reductions impact) /4	-470	-950	-950
<i>Extend CHIP funding through 2019 with Reforms (non-add) (Treasury impact) /4</i>	-2,390	-2,735	-2,735
<i>Reduce the Grace Period for Exchange Premiums (non-add) (Treasury impact)</i>	-975	-1,300	-1,300
Permit Federally-Facilitated Exchange States to Conduct Qualified Health Plan Certification (HHS impact)	-	-	-
Provide Appropriation to Pay Cost-Sharing Reductions (HHS impact)	-	-	-
Fully Fund the Risk Corridors Program (HHS impact)	-	-	-
Prohibit Governmental Discrimination Against Health Care Providers that Refuse to Cover Abortion (HHS impact)	-	-	-
<i>Total, Government-wide Impact (non-add)</i>	-3,835	-4,985	-4,985
<b>Total Outlays, Health Reform Proposals (HHS non-Medicaid Impact)</b>	<b>16,259</b>	<b>542,968</b>	<b>1,249,861</b>
1/ Savings reduced to account for the interaction with the proposal to enact a modified Graham-Cassidy-Heller-Johnson bill. 2/ Includes savings to programs overseen by the Department of the Treasury, the Department of Veterans Affairs, and the Office of Personnel Management. 3/ Discretionary funding for Children's Hospitals Graduate Medical Education (GME) is discontinued in FY 2019. As part of a larger Graduate Medical Education reform, funding for children's hospitals in FY 2019 will be provided through mandatory resources in a new consolidated GME program.			



4/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120.

Note: Italicized items are for display purposes only. Other items are included in Health Reform Proposals total.

Note: totals may not add due to rounding.

## Medicare



<i>dollars in millions</i>	2017	2018	2019	2019 +/- 2018
<b>Current Law Outlays and Offsetting Receipts</b>				
<b>Benefits Spending (gross) /1</b>	<b>696,690</b>	<b>697,462</b>	<b>768,625</b>	<b>+71,164</b>
Less: Premiums Paid Directly to Part D Plans /2	-10,171	-10,360	-10,733	-373
<b>Subtotal, Benefits Net of Direct Part D Premium Payments</b>	<b>686,519</b>	<b>687,102</b>	<b>757,893</b>	<b>+70,791</b>
Related-Benefit Expenses /3	13,265	15,244	15,539	+295
Administration /4	8,514	9,830	10,094	+264
<b>Total Outlays, Current Law</b>	<b>708,298</b>	<b>712,176</b>	<b>783,526</b>	<b>+71,350</b>
Premiums and Offsetting Receipts	-110,884	-123,830	-131,737	-7,907
<b>Current Law Outlays, Net of Offsetting Receipts</b>	<b>597,414</b>	<b>588,346</b>	<b>651,789</b>	<b>+63,443</b>
<b>Proposed Law</b>				
Medicare Proposals, Net of Offsetting Receipts	-	-	-15,434	-15,434
Medicare Trust Fund Administration/5	-	38	38	-
<b>Subtotal, Medicare Proposed Law</b>	<b>-</b>	<b>38</b>	<b>-15,396</b>	<b>-15,434</b>
<b>Total Net Outlays, Proposed Law</b>	<b>597,414</b>	<b>588,384</b>	<b>636,394</b>	<b>+48,010</b>
<b>Mandatory Total Net Outlays, Proposed Policy /6</b>	<b>591,508</b>	<b>581,662</b>	<b>629,882</b>	<b>+48,220</b>
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 and 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/ Includes \$38 million in outlays for supporting the State Health Insurance Assistance Programs through the Administration for Community Living. Please see the Administration for Community Living chapter for more information. 6/ Removes total Medicare discretionary amount: FY 2017 -\$5,906 million; FY 2018 -6,722 million; and FY 2019 -\$6,512 million.				

In Fiscal Year (FY) 2019, the Office of the Actuary has estimated that gross current law spending on Medicare benefits will total \$768.6 billion. Medicare will provide health insurance to 61 million individuals who are aged 65 or older, disabled, or have end-stage renal disease.

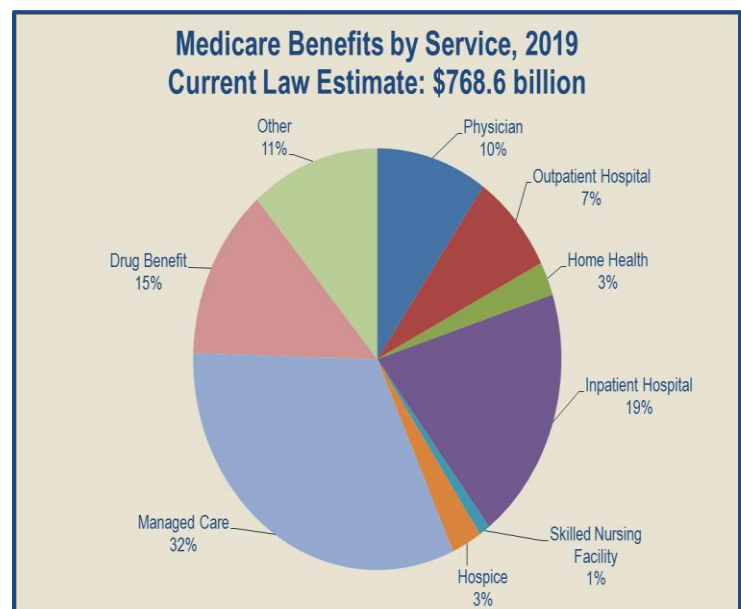
### THE FOUR PARTS OF MEDICARE

#### **Part A (\$209.4 billion gross fee-for-service spending in 2019)**

Medicare Part A pays for health care provided in inpatient hospitals and skilled nursing facilities, for home health care when related to a hospital stay, and for hospice care. Part A financing comes primarily from a 2.9 percent payroll tax paid by both employees and employers.

Generally, individuals with 40 quarters of Medicare-covered employment are entitled to Part A without paying a premium, but most services require beneficiary coinsurance. In 2018, beneficiaries pay a

\$1,340 deductible for a hospital stay of 1–60 days, and a \$167.50 daily coinsurance for days 21–100 in a skilled nursing facility.



**Part B (\$210.1 billion gross fee-for-service spending in 2019)**

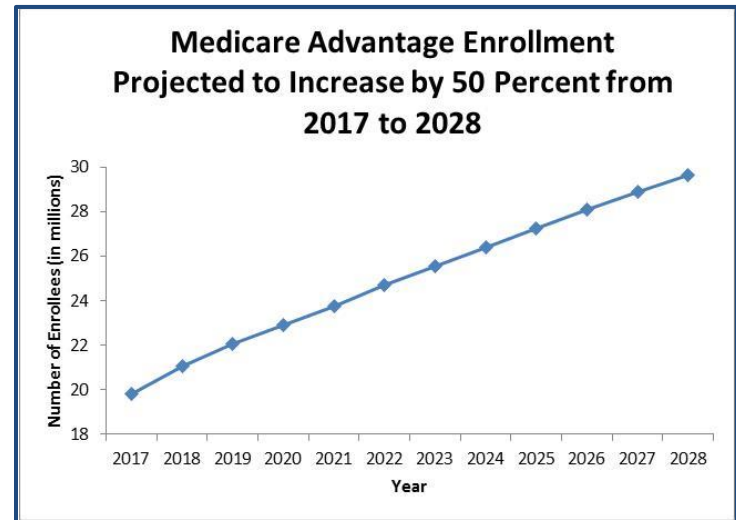
Medicare Part B pays for physician, outpatient hospital, end-stage renal disease, laboratory, durable medical equipment, certain home health, and other medical services. Part B coverage is voluntary, and about 91 percent of all Medicare beneficiaries, including those in fee-for-service and Medicare Advantage, are enrolled in Part B. Approximately 25 percent of Part B costs are financed by beneficiary premiums, with the remaining 75 percent covered by general revenues. The standard monthly Part B premium is \$134 in Calendar Year (CY) 2018, the same as the CY 2017 premium. A statutory “hold harmless” provision applies each year to about 70 percent of enrollees. For these enrollees, any increase in Part B premiums must be lower than the increase in their Social Security benefits. After several years of no or very small increases, Social Security benefits increased by 2.0 percent in 2018 due to the cost-of-living adjustment. Some beneficiaries who were held harmless against Part B premiums increases in prior years now pay a higher premium in 2018. Some beneficiaries also pay a higher Part B premium based on their income: those with annual incomes above \$85,000 (single) or \$170,000 (married) will pay from \$187.50 to \$428.60 per month in 2018. The Part B deductible in 2018 is \$183 for all beneficiaries.

**Part C (\$247.6 billion gross spending in 2019)**

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 which vary based on the services offered by the plan and the efficiency of the plan.

In 2019, Medicare Advantage enrollment will total approximately 22 million, or 39.5 percent of all Medicare beneficiaries enrolled Parts A and B. CMS data confirm that 99 percent of Medicare beneficiaries will have access to at least one Medicare Advantage plan in 2018. Additionally, while premiums have remained stable, Medicare Advantage supplemental

benefits have increased, and enrollment is growing faster than in traditional Medicare.

**Part D (\$101.5 billion gross spending in 2019)**

Medicare Part D offers a standard prescription drug benefit with a 2018 deductible of \$405 and an average estimated monthly premium of \$33. Enhanced and alternative benefits are also available with varying deductibles and premiums. Beneficiaries who choose to participate are responsible for covering a portion of the cost of their prescription drugs. This portion may vary depending on whether the medication is generic or a brand name and on how much the beneficiary has already spent on medications that year. Low-income beneficiaries are responsible for varying degrees of cost-sharing, with co-payments ranging from \$0 to \$8.35 in 2018 and low or no monthly premiums. For 2019, the number of beneficiaries enrolled in Medicare Part D is expected to increase by about 3.5 percent to 47.1 million, including about 13.2 million beneficiaries who receive the low-income subsidy. In 2018, approximately 56 percent of those with Part D coverage are enrolled in a stand-alone Part D Prescription Drug Plan, 41 percent are enrolled in a Medicare Advantage Prescription Drug Plan, and the remaining beneficiaries are enrolled in an employer plan or the Limited Income Newly Eligible Transition plan. Overall, approximately 77 percent of all Medicare beneficiaries receive prescription drug coverage through Medicare Part D or employer-sponsored retiree health plans, and approximately another 10 percent through other creditable coverage.

**Medicare Enrollment**

(in millions)

	2017	2018	2019	2019 +/- 2018
Aged 65 and Over	49.1	50.7	52.4	+1.7
Disabled	8.9	8.8	8.7	-0.1
<b>Total</b>	<b>58.0</b>	<b>59.5</b>	<b>61.1</b>	<b>+1.6</b>

Source: CMS Office of the Actuary estimates.

The Medicare Part D coverage gap, or “donut hole,” is being closed through a combination of manufacturer discounts and gradually increasing Federal subsidies. Beneficiaries fall into the coverage gap once their total drug spending exceeds an initial coverage limit (\$3,750 in 2018), until they reach the threshold for qualified out-of-pocket spending (\$5,000 in 2018), at which point they are generally responsible for five percent of their drug costs. Until 2010, beneficiaries were responsible for 100 percent of their drug costs in the coverage gap. In 2018, non-low income subsidy beneficiaries who reach the coverage gap will pay 35 percent of the cost of covered Part D brand drugs and biologics and 44 percent of the costs for all generic drugs in the coverage gap. Beneficiaries are required to pay only 25 percent of the costs of covered Part D drugs in 2020 and beyond.

In 2017, more than 4.6 million beneficiaries reached the coverage gap and saved more than \$5.7 billion on their medications due to the prescription drug discount program. These savings averaged about \$1,237 per person.

**MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS**

The mission of the Quality Improvement Organization Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The organizations are experts in the field working to drive local change, which can translate into national quality improvement. The current five-year contract cycle, or 11th Scope of Work, began August 1, 2014. The 12th Scope of Work will begin in FY 2019.

There are two types of Quality Improvement Organizations that work with providers and beneficiaries: Quality Innovation Network contractors and Beneficiary and Family Centered Care contractors. In FY 2018, the final year of the 11th Scope of Work, Quality Innovation Network contractors worked to reduce patient harms, such as infection reduction among nursing home residents, and provide staff training for hospital quality improvement. Beneficiary and Family Centered Care organizations perform the program’s statutory case review work, including beneficiary complaints, concerns related to early discharge from health care settings, and patient and family engagement. Since 2016, Quality Innovation Network contractors have provided clinicians with technical assistance related to MACRA’s Quality Payment Program and offered beneficiaries immediate case review assistance.

**PROGRAM UPDATE****Medicare Access and CHIP Reauthorization Act: Progress Implementing New Medicare Card Project**

The Medicare Access and CHIP Reauthorization Act (MACRA) requires that CMS remove Social Security Numbers from Medicare cards by April 2019. To meet this goal, CMS established the New Medicare Card Project (formerly known as the Social Security Removal Initiative). Through this initiative CMS will assign a new Medicare Beneficiary Identifier to replace the Social Security Number and mail new Medicare cards to every Medicare beneficiary by April 2019. Removing Social Security Numbers from Medicare cards will protect beneficiaries from identity theft and the Medicare program from fraudulent or illegal payment for Medicare benefits resulting from stolen identification numbers.

CMS is on track to meet the April 2019 deadline and will begin mailing new Medicare cards to beneficiaries in April 2018.

## PERFORMANCE HIGHLIGHT

**Strengthening Patient and Family Engagement**

The primary focus of the Beneficiary and Family Centered Care Quality Improvement Organizations is to improve healthcare services for Medicare beneficiaries by providing patients and families with case review assistance. Quality Improvement Organizations have focused on improving beneficiary satisfaction with the review experience, and surpassed the baseline target in FY 2016 with at 65.7 percent satisfaction rate.

Fiscal Year	Beneficiary Satisfaction with Quality Improvement Organization Assistance	
	Target	Result
2019	75%	N/A
2018	75%	N/A
2017	70%	N/A
2016	62%	65.7% (Target Met)

**2019 LEGISLATIVE PROPOSALS**

The FY 2019 Budget includes targeted Medicare proposals designed to improve drug pricing and payments, address the opioid epidemic, reform delivery and payment systems, and simplify government-imposed provider burdens. Together, this package will yield net savings to the Medicare Trust Funds of \$494 billion over 10 years. A few Medicare proposals have general revenue or other impacts that would offset a portion of these savings government-wide. This package extends the solvency of the Hospital Insurance Trust Fund by approximately eight years, in part by ensuring Medicare payments are directly related to its health insurance role, financing certain payments to hospitals outside the Trust Fund and slowing their growth rate.

**Drug Pricing and Payment Improvements****Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management**

The Budget modernizes the Part D drug benefit, based upon 12 years of program experience, to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter. Seniors will benefit from the Budget's proposals, which are designed to better protect beneficiaries from high drug prices, give plans more tools to manage spending, and address the misaligned

incentives of the Part D drug benefit structure. The proposed changes enhance Part D plans' negotiating power with manufacturers, encourage utilization of higher value drugs, discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the Government, and provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap. Descriptions of each piece of this five part proposal are below.

***Require Medicare Part D Plans to Apply a Substantial Portion of Rebates at the Point of Sale***

This proposal requires Part D sponsors to apply at least one-third of total rebates and price concessions at the point of sale. This will improve price transparency and allow beneficiaries to share directly in the savings from discounts negotiated by plans. [\$42.2 billion in costs over 10 years]

***Establish a Beneficiary Out-of-Pocket Maximum in the Medicare Part D Catastrophic Phase***

This proposal increases Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over four years from 15 percent to 80 percent, and simultaneously decreasing Medicare's reinsurance liability from 80 to 20 percent. Additionally, beneficiary coinsurance would decrease from 5 to 0 percent, creating a true out-of-pocket maximum in Part D for the first time in the program's history. Collectively, these changes provide beneficiaries with more predictable annual drug expenses and incentivize plans to better manage spending throughout the entirety of the benefit. [\$7.4 billion in costs over 10 years]

***Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap***

Under the current benefit structure, required discounts paid by manufacturers in the coverage gap are counted towards the calculation of beneficiary true out-of-pocket costs, which ultimately determine the speed of beneficiaries' progression through the coverage gap. As a result, plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate beneficiaries through the coverage gap and into the catastrophic phase, where Medicare is liable for 80 percent of spending. This proposal restructures the coverage gap discount program to exclude manufacturer discounts from the calculation of true out-of-pocket costs in order to correct this



misaligned incentive. [\$47.0 billion in savings over 10 years]

***Increase Medicare Part D Plan Formulary Flexibility***

This proposal changes Part D plan formulary standards to require a minimum of one drug per category or class rather than two. It also expands plans' ability to use utilization management tools for specialty drugs and drugs in protected classes to empower plans to better manage the Part D drug benefit. [\$5.5 billion in savings over 10 years]

***Eliminate Cost-Sharing on Generic Drugs for Low-Income Beneficiaries***

This proposal encourages the use of higher value products among low-income subsidy enrollees by reducing cost sharing for generics to \$0, including biosimilars and preferred multiple source drugs. [\$210 million in savings over 10 years]

***Other Drug Pricing and Payment Improvements***

***Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries***

This proposal permanently authorizes a current demonstration that allows CMS to contract with a single plan to provide Part D coverage to low-income beneficiaries while their eligibility is processed. This plan serves as the single point of contact for beneficiaries seeking reimbursement for retroactive claims. Under current law, these beneficiaries are assigned at random to a qualifying Part D plan, which is reimbursed based on the standard Part D prospective payment, regardless of their utilization of Part D services during this period. Under the demonstration, the plan is paid using an alternative methodology whereby payments are closer to actual costs incurred by beneficiaries during this period. The current demonstration, which runs through 2019, has shown the proposed approach to both save money and be less disruptive to beneficiaries. [\$300 million in savings over 10 years]

***Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates***

Beginning in 2019, this proposal requires all Part B drug manufacturers to report average sales price (ASP) data and provide the Secretary with the authority to apply penalties for manufacturers who do not report required data, similar to penalties currently used in Medicaid, where if data is not reported within 30 days

of the end of the quarter manufacturers face civil monetary penalties of up to \$10,000 per day. Requiring that all manufacturers of Part B drugs report ASP data improves the accuracy of CMS's drug prices and helps prevent CMS from relying on other, less appropriate prices, such as Wholesale Acquisition Costs. [No budget impact]

***Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs***

Effective CY 2019, this proposal limits growth of the Average Sales Price (ASP) portion of payment of Part B drugs to the Consumer Price Index for all Urban Consumers. Each quarter when CMS establishes the ASP +6 percent payment amounts, CMS would pay the lesser of (1) the actual ASP +6 percent or (2) the inflation-adjusted ASP +6 percent. The base for determining growth of a drug's price will be the initial ASP, or the first quarter of CY 2017 for drugs that had an ASP prior to the date of enactment. [Budget impact not available]

***Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B***

Beginning in CY 2019, this proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D. The Secretary will exercise this authority when there are savings to be gained from price competition. [Budget impact not available]

***Modify Payment for Drugs Hospitals Purchased through the 340B Discount Program and Require a Minimum Level of Charity Care for Hospitals to Receive a Payment Adjustment Related to Uncompensated Care***

Beginning in CY 2019, this proposal allows CMS to apply savings from a reduction in payment to hospitals for drugs purchased under the 340B program in a non-budget neutral manner. Under a regulation that goes into effect CY 2018, hospital payment for 340B drugs is reduced from ASP +6 percent to the average sales price -22.5 percent to reflect the minimum average discount 340B hospitals receive. Statute requires the savings to be redistributed within the payment system in a budget neutral manner. Under this proposal, the savings from hospitals that provide uncompensated care equaling at least one percent of their patient care costs are redistributed based on their share of aggregate uncompensated care. Hospitals not

meeting that threshold are not eligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Funds. [Budget impact not available]

#### ***Reduce Wholesale Acquisition Cost Based Payments***

When ASP data are not available, Medicare largely reimburses new, single-source Part B drugs at 106 percent of wholesale acquisition cost (WAC). Unlike an ASP, a drug's WAC does not incorporate prompt-pay or other discounts benefitting the manufacturer. If discounts are available on these new Part B drugs, Medicare is paying more than it otherwise would under the ASP-based formula. Beginning in 2019, this proposal reduces the payment rate for drugs from 106 percent to 103 percent of Wholesale Acquisition Cost to reduce excessive payments. [Budget impact not available]

#### ***Address Opioids***

##### ***Require Plan Participation in Program to Prevent Prescription Drug Abuse in Medicare Part D***

The Comprehensive Addiction Recovery Act of 2016 directed CMS to propose a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse and require those determined to be at risk to only receive opioids from a specifically designated provider and/or pharmacy. This proposal strengthens the provisions specified in CARA by providing the Secretary with authority to establish a mandatory prescriber and/or pharmacy lock-in program in Medicare Part D that all Part D plans will be required to participate in beginning in 2020. [\$100 million in savings over 10 years]

##### ***Provide Comprehensive Coverage of Substance Abuse Treatment in Medicare***

Under this proposal, CMS will conduct a demonstration to test the effectiveness of covering comprehensive substance abuse treatment in Medicare. This demonstration could be expanded nation-wide if successful in key metrics, such as reducing opioid-related deaths among beneficiaries, reducing hospitalization for opioid poisoning, and reducing emergency room utilization for opioid-related issues. Medicare will provide bundled reimbursement on a per-week-per-patient basis to providers for methadone treatment or similar medication-assisted therapy and will recognize opioid treatment programs and substance abuse treatment facilities as independent

#### **PROGRAM HIGHLIGHT**

### **Addressing the Impact of the Opioid Epidemic on Medicare Beneficiaries**

The Budget includes several proposals that work to address the impact that the opioid epidemic has on our nation's seniors. The Medicare population has among the highest and fastest-growing rates of opioid use disorders, currently at more than 6 of every 1,000 beneficiaries.<sup>1,2</sup> Many seniors take multiple medications and receive prescriptions from multiple doctors, making tracking and controlling any misuse of these prescriptions a substantial challenge. HHS has made tackling this issue, and the opioid epidemic more broadly, a top priority.

The Budget proposes to conduct a demonstration to expand access to comprehensive substance abuse treatment for Medicare beneficiaries, including medication assisted treatment. This demonstration would be expanded nationwide if successful. A corresponding expansion of medication assisted treatment is also proposed for Medicaid beneficiaries, who likewise have rates of opioid use disorder beyond those of other populations.

The Budget also proposes to address opioid misuse in Medicare by giving the Secretary authority to require plan participation in a program to prevent prescription drug abuse in Part D, essentially strengthening the statutory authority already provided through the Comprehensive Addiction Recovery Act of 2016 to "lock" an at-risk beneficiary into a single prescriber or pharmacy. To address potentially abusive prescribing practices the Budget proposes to allow the Secretary to work with the Drug Enforcement Agency (DEA) to revoke a provider's DEA Certificate of Registration after CMS revokes a provider's Medicare enrollment based on a pattern of abusive prescribing.

1/ Lembke A, Chen J. Use of Opioid Agonist Therapy for Medicare Patients in 2013. JAMA Psychiatry. 2016; 73(9): 990-992.

2/ Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy. January 5, 2017. See: <https://www.cms.gov/Outreach-and-.../CMS-Opioid-Misuse-Strategy-2016.pdf>

provider types. Outpatient counseling will be billed separately as clinically necessary. Payment for methadone treatment or other similar medication-assisted therapy would be site-neutral. The model may target beneficiaries determined to be at-risk, as defined by the Overutilization Monitoring System, to voluntarily receive comprehensive substance abuse treatment, including medication assisted treatment and substance use disorder counseling. [Budget impact not available]

## **Reform of Delivery and Payment Systems**

### ***Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts***

Currently Medicare beneficiaries in high-deductible health plans are not allowed to make tax-deductible contributions to their Health Savings Accounts (HSAs) or Medicare Savings Accounts (MSAs). This proposal would give Medicare beneficiaries greater flexibility to take control of their health. It would allow beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs, subject to the annual HSA contribution limits as determined by the Internal Revenue Service. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs. Beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Medicare beneficiaries who have an employer-sponsored, high-deductible health plan would also be allowed to make contributions to their HSAs, although Medicare would not cover any of the deductible. [\$180 million in Medicare costs over 10 years]

### ***Modify Medicare Payments to Hospitals for Uncompensated Care***

Effective FY 2020, this proposal removes uncompensated care payments from the Inpatient Prospective Payment System and establishes a new process to distribute uncompensated care payments to hospitals based on share of charity care and non-Medicare bad debt, as reported on Worksheet S-10 of the cost report. Under this proposal, empirically justified Disproportionate Share Hospital (DSH) payments are not changed. The total amount of available uncompensated care is equal to FY 2018 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. This proposal more closely aligns Medicare payment policy with private insurers, who do not typically cover uncompensated care. [\$138.4 billion in Medicare savings over 10 years; this proposal would increase spending from general revenues by \$68.9 billion over 10 years, for a net savings to the Federal Government of \$69.5 billion 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***

For FY 2019 to FY 2023, the four primary post-acute care settings, including skilled nursing facilities, home health agencies, inpatient rehabilitation facilities, and long-term care hospitals, will receive a lower annual Medicare payment update. Beginning in FY 2024, this proposal implements a unified post-acute care payment system that spans these settings, with payments based on episodes of care and patient characteristics rather than the site of service. Rates for the provider types included in this proposal are updated on a fiscal year basis, including those whose payment systems are currently updated on a calendar year basis. The first year of implementation is required to be budget neutral relative to estimated payments that would otherwise have been paid in FY 2024 absent this change. Payment rates are 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. Payments are to be risk-adjusted. The Secretary has the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate. Beneficiary coinsurance amounts are equal to those under current law. For example, to the extent a beneficiary uses a provider's services, they are responsible for the current law copayment rate. [\$80.2 billion in savings over 10 years]

### ***Reduce Medicare Coverage of Bad Debts***

For most institutional provider types, Medicare currently reimburses 65 percent of bad debts resulting from beneficiaries' non-payment of deductibles and coinsurance. Effective FY 2019, this proposal reduces Medicare reimbursement of bad debt from 65 percent to 25 percent over three years. Rural hospitals with fewer than 50 beds, Critical Access Hospitals, Rural Health Clinics, and Federally Qualified Health Centers are exempt from the reduction. This proposal will more closely align Medicare policy with private payers, who do not typically reimburse for bad debt. [\$37.0 billion in savings over 10 years]



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

Medicare pays for services at certain off-campus hospital outpatient departments under the Physician Fee Schedule. Most off-campus facilities are exempt from this site neutral payment policy, including grandfathered off-campus hospital outpatient departments that were billing or under construction as of November 2, 2015, emergency departments, and cancer hospitals. This proposal eliminates all exemptions effective CY 2019. [\$34.0 billion in savings over 10 years]

***Reform and Expand Durable Medical Equipment Competitive Bidding***

This proposal eliminates the requirement under the durable medical equipment competitive bidding program that CMS pay a single payment amount based on the median bid price, and instead, pay winning suppliers at their own bid amounts. Additionally, this proposal expands competitive bidding to all areas of the country, including rural areas. Expanding competitive bidding to rural areas will set prices for items and services in rural areas based on competitions in those areas rather than on competitions in urban areas. In the event that in a rural area less than two suppliers submit bids, CMS will use a reference price from other, similar rural areas. [\$6.5 billion in savings over 10 years]

***Address Excessive Hospital Payments by Reducing Payment when a Patient is Quickly Discharged to Hospice***

Effective FY 2019, this proposal establishes a hospital transfer policy when Medicare beneficiaries have a shorter than average hospital stays prior to being transferred to hospice. The hospital transfer policy is the same policy used for discharges to post-acute care facilities when the inpatient length of stay is at least one day less than the geometric mean length of stay for the Medicare Severity-Diagnosis Related Groups. This proposal would set Medicare payments at a rate more reflective of the resource intensity of the given stay and would better align with how Medicare pays early discharge to other facilities. [\$1.3 billion in savings over 10 years]

***Cancel Funding from the Medicare Improvement Fund***

This proposal cancels the funding available in the Medicare Improvement Fund. [\$193 million in savings over 10 years]

***Expand Basis for Beneficiary Assignment for Accountable Care Organizations***

Effective CY 2019, this proposal allows the Secretary to base beneficiary assignment on a broader set of primary care providers, to include Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists, in addition to physicians. This option broadens the scope of Accountable Care Organizations to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries. [\$140 million in savings over 10 years]

***Allow Accountable Care Organizations to Cover the Cost of Primary Care Visits to Encourage Use of the Accountable Care Organization Providers***

This proposal allows Accountable Care Organizations (ACOs) to pay beneficiaries for a primary care visit, encouraging beneficiaries to engage in their care and make contact with ACO-affiliated providers. Beneficiaries with no supplemental insurance would have all or part of their cost sharing covered by the ACO, and beneficiaries with supplemental insurance, such as Medigap, will receive a payment of the same amount from the ACO. Participation from the ACOs is voluntary; they are required to offer this to all of their aligned beneficiaries, and no additional payments would be made to the ACO to cover the costs of this investment. [\$60 million in savings over 10 years]

***Expand the Ability of Medicare Advantage Organizations to Pay for Services Delivered via Telehealth***

Beginning in 2019, this proposal expands the ability of Medicare Advantage (MA) organizations to deliver medical services via telehealth by eliminating the requirement for MA organizations to provide specified covered Part B services exclusively through face-to-face encounters. [No budget impact]

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

Effective CY 2020, this proposal establishes a new exception to the physician self-referral law for arrangements that arise due to participation in Advanced Alternative Payment Models. The Department, in consultation with the HHS Office of Inspector General, will identify the types of arrangements and the minimum risk levels and level of participation in the model required for such exceptions. Effective CY 2020, this proposal also establishes a new process for physicians to self-report

inadvertent, technical non-compliance violations of the law. Finally, effective CY 2020, this proposal excludes physician-owned distributors from the indirect compensation exception if more than 40 percent of the physician-owned distributor's business is generated by physician-owners. [Budget impact not available]

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

Effective CY 2020, this proposal establishes a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. High utilizer practitioners are practitioners whose average per capita utilization of each of the defined in-office ancillary services is two standard deviations above the national per capita rate for the given service area. Patients would be attributed to the physician who provided the plurality of their evaluation and management 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]

***Simplify Government-Imposed Provider Burdens in Medicare***

***Repeal the Independent Payment Advisory Board***

The Budget proposes to repeal the Independent Payment Advisory Board (IPAB). The Independent Payment Advisory Board, as enacted in the Patient Protection and Affordable Care Act, represents government overreach that circumvents the normal legislative process. Fundamental changes to the Medicare program should be debated and passed through a representative body, not an unelected Board. All remaining unobligated administrative funds would be rescinded. [\$29.5 billion in costs over 10 years]

***Eliminate the Reporting Burden and Arbitrary Requirements for the Use of Electronic Health Records***

The Budget supports the Administration's commitment to improving interoperability of health information technology by modifying the Medicare meaningful use programs for hospitals and physicians. Effective FY 2019, the Budget proposes to provide hospitals and physicians the freedom to use electronic health records as they deem best by removing ineffective Federal penalties, reducing reporting burden, and eliminating low-value metrics of meaningful use. [No budget impact]

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

Currently, physicians must document a beneficiary's face-to-face encounter with a physician or non-physician practitioner as a condition for Medicare payment for a durable medical equipment order, which can be overly burdensome on providers and suppliers. This proposal enables CMS not to impose this face-to-face requirement on all providers. [No budget impact]

**PROGRAM HIGHLIGHT**

***Simplifying the Quality Payment Program***

Clinicians are working hard to meet the statutory requirements of the Quality Payment Program, established by the Medicare Access and CHIP Reauthorization Act. While CMS has tried to streamline requirements through regulations, the Budget significantly simplifies the program and reduces provider burden. The Budget reforms the current Merit-based Incentive Payment System by removing two performance categories and only evaluating performance based on meaningful quality and cost measures. Performance would be assessed by CMS without requiring any reporting from clinicians, thereby leaving more time for clinicians to focus on patient care. The Budget also removes the thresholds that clinicians must meet in order to receive a bonus for participating in Advanced Alternative Payment Models, and instead rewards all clinicians who are able to take part in these models.

***Simplify and Eliminate Reporting Burdens Associated with the Merit-based Incentive Payment System***

Effective CY 2021, this proposal simplifies the Merit-based Incentive Payment System (MIPS) for physicians and other clinicians by adopting broader claims and beneficiary survey calculated measures that assess clinician performance on quality and cost during the performance period at the group-level only. This proposal would use payment adjustments under current statute to fund the incentive pool during the corresponding payment year and would retain the \$500 million in annual additional performance bonus payments for top performers. The payment adjustments will apply only to payments made under the Physician Fee Schedule rather than to all payments made under Medicare Part B. This proposal provides the Secretary with authority to set the MIPS performance threshold during the 2019-2020 transition years. [No budget impact]

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

This proposal modifies how the five percent bonus is determined in order to better reward clinicians who participate in Advanced Alternative Payment Models. Instead of receiving a five percent bonus on all physician fee schedule payments if they meet or exceed the payment or patient thresholds as under current law and regulations, clinicians will receive a five percent bonus on physician fee schedule revenues received through the Advanced Alternative Payment Models in which they participate. 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. [Budget impact not available]

***Reforming the Medicare Appeals Process***

The Budget includes the following proposals to reform the Medicare appeals process across all four levels at CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board:

***Provide Additional Resources for Medicare Appeals***

This proposal provides the Department \$127 million per year in mandatory funding to invest in addressing the backlog of pending Medicare appeals. The Secretary is authorized to transfer funding across levels 3 and 4 of the appeals system. [\$1.1 billion in net Medicare costs over 10 years]

***Change the Medicare Appeal Council's Standard of Review***

This proposal changes the Departmental Appeal Board'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. [No budget impact]

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

This proposal establishes a post-adjudication user fee for all unfavorable Medicare appeals, other than beneficiary appeals, at the Office of Medicare Hearings and Appeals, the 3rd level of appeals, and the Departmental Appeals Board, the 4th level of appeals. The user fee amount will support a portion of the

administrative costs required to adjudicate appeals. [No budget impact]

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

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 \$1,600 in calendar year 2018 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. [No budget impact]

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

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 \$1,600 in calendar year 2018 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. [No budget impact]

***Expedite Procedures for Claims with No Material Fact in Dispute***

This proposal allows the Office of Medicare Hearings and Appeals to issue decisions 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 Administrative Law Judge cannot find in favor of an appellant due to binding limits on authority. [No budget impact]

***Limit Appeals When No Documentation is Submitted***

This proposal limits the right to appeal a redetermination of a claim that was denied because no documentation was submitted to support the items or services billed. This proposal does not apply to beneficiary appeals. [No budget impact]

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

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 level of appeal or above. Exceptions may be made 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. [No budget impact]

#### ***Require a Good-Faith Attestation on All Appeals***

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. [No budget impact]

### **Medicare Interactions**

#### ***Reduce Fraud, Waste, Abuse, and Improper Payments in Medicare***

The Budget includes a number of Medicare program integrity proposals that strengthen the Department's and states' ability to fight fraud, waste, and abuse in the Medicare program and to reduce improper payments. See the Program Integrity chapter for proposal descriptions. [\$907 million in Medicare savings over 10 years]

#### ***Legislative Proposals for Medicare-Medicaid Enrollees***

The Budget includes three proposals to improve the quality and efficiency of care for Medicare-Medicaid, dually-eligible beneficiaries. See the Medicaid chapter for proposal descriptions. [\$693 million in Medicare savings over 10 years, attributed to the proposal to *Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries*]

#### ***Reform Graduate Medical Education Payments***

The Budget includes a proposal to consolidate and better target Federal spending for Graduate Medical Education. See the Health Care Reform chapter for a proposal description. [\$195.0 billion in Medicare savings over 10 years]

#### ***Reform Medical Liability***

The Budget includes a set of proposals to reform medical liability, which reduce medical malpractice costs and the practice of defensive medicine, and curb

the unnecessary provision of Medicare services. See the Health Care Reform chapter for proposal descriptions. [\$30.7 billion in Medicare savings over 10 years]

#### ***Change Conditions on First Generic Exclusivity to Spur Access and Competition***

Effective FY 2019, this proposal makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity. See the Food and Drug Administration chapter for a proposal description. [\$1.8 billion in Medicare savings over 10 years]

### **2019 ADMINISTRATIVE PROPOSALS**

#### ***Implement a More Accurate Payment System for Home Health***

This proposal implements a new patient case-mix classification methodology to more accurately account for clinical differences among patients in Medicare's payments to home health agencies. This proposal shifts the focus from volume of services to a more patient-centered model that relies on patient characteristics. This new methodology, referred to as the home health grouping model, would be implemented for periods of care starting on or after January 1, 2020. [\$16.7 billion in savings over 10 years]

#### ***Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters***

This proposal phases in the use of encounter data for Medicare Advantage payment risk adjustments. Beginning in payment year 2019, CMS will calculate risk scores by adding 25 percent of the risk score using encounter data and fee-for-service diagnoses with 75 percent of the risk score using plan-reported Risk Adjustment Processing System and fee-for-service diagnoses. CMS will increase the weighting of encounter data-based risk scores over subsequent years by moving to a risk score incorporating 50 percent of the encounter data/fee-for-service-based risk score in payment year 2020, a risk score incorporating 75 percent of the encounter data/fee-for-service-based risk score for payment year 2021, and a risk score of 100 percent encounter data/fee-for-service-based risk score in payment year 2022. [\$11.1 billion in savings over 10 years]

***Eliminate Excessive Payment to Medicare Advantage Employer Group Waiver Plans by Basing Payment on Competitive Individual Market Plan Bids***

For payment year 2019 and future years, this proposal calculates the bid-to-benchmark ratios using individual market plan bids only, rather than a 50/50 blend of individual market plan bids and Employer Group Waiver Plan bids from the previous year. [\$10.7 billion in savings over 10 years]

***Improve the Valuation of Physician Services to Set Rates***

This proposal targets CMS's approach to valuing Relative Value Units in the Physician Fee Schedule. The Budget includes \$5 million in discretionary Program Management funding to initiate efforts to develop independent assessments of service costs that would improve accuracy of payments to physicians and other health care professionals. [No budget impact]



## Medicare

### FY 2019 Medicare Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Medicare Legislative Proposals</b>			
<b>Drug Pricing and Payment Improvements</b>			
<b>Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management</b>			
Require Medicare Part D Plans to Apply a Substantial Portion of Rebates at the Point of Sale	1,785	15,113	42,160
Establish a Beneficiary Out-of-Pocket Maximum in the Medicare Part D Catastrophic Phase	377	2,863	7,359
Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap	(1,490)	(17,320)	(47,020)
Increase Medicare Part D Plan Formulary Flexibility	(280)	(2,145)	(5,517)
Eliminate Cost-Sharing on Generic Drugs for Low-Income Beneficiaries	(30)	(150)	(210)
<b>Other Drug Pricing and Payment Improvements</b>			
Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries	-	(110)	(300)
Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates	-	-	-
Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs	**	**	**
Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B	**	**	**
Modify Payment for Drugs Hospitals Purchased through the 340B Discount Program and Require a Minimum Level of Charity Care for Hospitals to Receive a Payment Adjustment Related to Uncompensated Care	**	**	**
Reduce Wholesale Acquisition Cost Based Payments	**	**	**
<b>Address Opioids</b>			
Require Plan Participation in a Program to Prevent Prescription Drug Abuse in Medicare Part D	(10)	(50)	(100)
Provide Comprehensive Coverage of Substance Abuse Treatment in Medicare	**	**	**
<b>Reform of Delivery and Payment Systems</b>			
Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts /1	-	30	180
Modify Medicare Payments to Hospitals for Uncompensated Care /2	-	(50,620)	(138,410)
Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care	(780)	(20,620)	(80,190)
Reduce Medicare Coverage of Bad Debts	(400)	(12,400)	(37,030)
Pay All Hospital-Owned Physician Offices Located Off-Campus at the Physician Office Rate	(1,240)	(11,960)	(33,980)
Reform and Expand Durable Medical Equipment Competitive Bidding	-	(2,250)	(6,480)
Address Excessive Hospital Payments by Reducing Payment when a Patient is Quickly Discharged to Hospice	(70)	(510)	(1,260)
Cancel Funding from the Medicare Improvement Fund	-	(193)	(193)

## Medicare

### FY 2019 Medicare Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Reform of Delivery and Payment Systems (continued)</b>			
Expand Basis for Beneficiary Assignment for Accountable Care Organizations	-	(40)	(140)
Allow Accountable Care Organizations to Cover the Cost of Primary Care Visits to Encourage Use of the Accountable Care Organizations Providers	-	(40)	(60)
Expand the Ability of Medicare Advantage Organizations to Pay for Services Delivered via Telehealth	-	-	-
Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization	**	**	**
Require Prior Authorization When Physicians Order Certain Services Excessively to Their Peers	**	**	**
<b>Simplify Government-Imposed Provider Burdens in Medicare</b>			
Repeal the Independent Payment Advisory Board	-	1,579	29,482
Eliminate the Reporting Burden and Arbitrary Requirements for the Use of Electronic Health Records	-	-	-
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment	-	-	-
Simplify and Eliminate Reporting Burdens Associated with the Merit-based Incentive Payment System	-	-	-
Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models	**	**	**
<b>Improve the Medicare Appeals System</b>			
Provide Additional Resources for Medicare Appeals /3	111	556	1,111
Change the Medicare Appeal Council's Standard of Review	-	-	-
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals	-	-	-
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review	-	-	-
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold	-	-	-
Expedite Procedures for Claims with No Material Fact in Dispute	-	-	-
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	-	-	-
<b>Medicare Interactions</b>			
Reduce Fraud, Waste, and Abuse in Medicare	(42)	(358)	(907)
Medicare-Medicaid Enrollee Proposals (Medicare Impact)	(38)	(277)	(693)
Reform Graduate Medical Education Payments (Medicare Impact)	(13,310)	(82,460)	(195,040)
Reform Medical Liability (Medicare Impact)	(88)	(6,233)	(30,703)
Change Conditions on First Generic Exclusivity to Spur Access and Competition	(118)	(728)	(1,786)
Other Interactions	190	2,193	5,996
<b>Subtotal, Medicare Legislative Proposals</b>	<b>(15,434)</b>	<b>(186,129)</b>	<b>(493,731)</b>



## Medicare

### FY 2019 Medicare Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Medicare Administrative Proposals</b>			
Implement a More Accurate Payment System for Home Health	-	(5,530)	(16,670)
Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters	(110)	(3,280)	(11,110)
Eliminate Excessive Payment to Medicare Advantage Employer Group Waiver Plans by Basing Payment on Competitive Individual Market Plan Bids	(530)	(4,130)	(10,690)
Improve the Valuation of Physician Services to Set Rates	-	-	-
<b>Subtotal, Medicare Administrative Proposals</b>	<b>(640)</b>	<b>(12,940)</b>	<b>(38,470)</b>
<b>Total, Medicare FY 2019 Budget Proposals</b>	<b>(16,074)</b>	<b>(199,069)</b>	<b>(532,201)</b>
** Budget impact unavailable as of the publication date of the FY 2019 President's Budget.			
1/ Memorandum: Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts Proposal (Non-Add)			
Medicare Impact	-	30	180
General Revenue Treasury Impact	-	2,966	11,285
<b>Total Impact</b>	<b>-</b>	<b>2,996</b>	<b>11,465</b>
2/ Memorandum: Modify Medicare Payments to Hospitals for Uncompensated Care Proposal (Non-Add)			
Medicare Impact	-	(50,620)	(138,410)
General Revenue CMS Impact	-	28,470	68,870
<b>Total Impact</b>	<b>-</b>	<b>(22,150)</b>	<b>(69,540)</b>
3/ The annual mandatory appropriation for this proposal is \$127 million per year; this display shows the Medicare proposed law impact net of Part B premiums.			

## Program Integrity



<i>dollars in millions</i>	2017	2018	2019	2019 +/-2018
<b>Health Care Fraud and Abuse Control Discretionary</b>	725	725	770	+45
<b>Health Care Fraud and Abuse Control Mandatory /1 /2</b>	1,270	1,298	1,377	+79
<b>Total, Budget Authority</b>	<b>1,995</b>	<b>2,023</b>	<b>2,147</b>	<b>+124</b>
1/ The FY 2017 and FY 2018 mandatory base includes sequester reductions. 2/ Does not include Deficit Reduction Act funding for the Medicaid Integrity Program, which is discussed in this chapter but is in the State Grants and Demonstrations account.				

The Fiscal Year (FY) 2019 Budget strengthens the integrity and sustainability of Medicare and Medicaid by investing in activities that prevent fraud, waste, and abuse and promotes quality and efficient delivery and financing of health care. For FY 2019, the Budget assumes \$2.1 billion in total mandatory and discretionary investments in the Health Care Fraud and Abuse Control program.

### HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM

The FY 2019 Budget proposes to build on recent progress by increasing support for the Health Care Fraud and Abuse Control program through both mandatory and discretionary funding streams.

#### **Discretionary Health Care Fraud and Abuse Control Account**

The Budget requests \$770 million in discretionary Health Care Fraud and Abuse Control funding, \$45 million above the FY 2018 Continuing Resolution. The Budget requests \$316 million in base discretionary funds plus a

discretionary cap adjustment of \$454 million, which is consistent with the Budget Control Act of 2011. The discretionary funding is allocated to CMS program integrity activities at \$604.4 million, the Department of Justice \$78.4 million, and the HHS Office of Inspector General \$87.2 million.

Recent investments in Health Care Fraud and Abuse Control have shifted fraud and abuse activities away from the “pay-and-chase” model and toward front-end prevention efforts. The Health Care Fraud and Abuse Control investment also supports efforts to reduce the Medicare and Medicaid improper payment rates that balance fraud and abuse protections with limiting burden on providers.

#### **Mandatory Health Care Fraud and Abuse Control Account**

The \$1.4 billion in mandatory base funds for FY 2019 are financed from the Medicare Part A Trust Fund. The funding is allocated to: the Medicare Integrity Program and the Health Care Fraud and Abuse Control Account,

### Health Care Fraud and Abuse Control Multi-Year Investment and Savings (in millions)

	2019	2020	2021	2022	2023	2019 -2023	2019 -2028
Mandatory Funding	1,377	1,403	1,422	1,455	1,489	7,146	15,119
Discretionary Funding	770	797	825	850	876	4,118	8,927
<b>Total Program Level /1</b>	<b>2,147</b>	<b>2,200</b>	<b>2,247</b>	<b>2,305</b>	<b>2,365</b>	<b>11,264</b>	<b>24,046</b>
<i>Savings from Discretionary Cap Adjustment Investment /2</i>	-910	-975	-1,041	-1,106	-1,146	-5,178	-11,602

1/ Total Program Levels may not add due to rounding.

2/ Reflects savings already assumed in current law, as well as savings attributable to the new discretionary investment request above current law. Savings are not scoreable under PAYGO.

which is divided annually among the HHS Office of Inspector General, other HHS agencies, the Department of Justice, and the Federal Bureau of Investigation. These dollars fund comprehensive efforts to combat health care fraud, waste, and abuse, including prevention-focused activities, improper payment reduction, provider education, data analysis, audits, investigations, and enforcement.

#### PROGRAM HIGHLIGHT

### Key Program Integrity Initiatives

- **Medicaid Data Systems:** Both the Office of Inspector General and the Government Accountability Office have highlighted inadequacies in Medicaid data and data systems as a significant program integrity concern for Medicaid. The Budget invests in Medicaid data systems to address these concerns and help states to better fulfill their responsibilities to address fraud, waste, and abuse in Medicaid.
- **Medicare Program Integrity:** The Budget enhances and transforms CMS efforts to prevent fraud, waste, and abuse in Medicare by promoting activities that better target oversight of truly bad actors, while minimizing burden on compliant providers. Specifically, the Budget improves Medicare prescription drug reporting and payment accuracy and strengthens and streamlines provider screening and enrollment.
- **Partnerships to Address Fraud and Abuse:** The Budget continues to support law enforcement efforts at the HHS Office of Inspector General and the Department of Justice to detect and prosecute health care fraud and abuse. Additionally, the Budget includes both a continued investment and clarified legislative authorities for the Healthcare Fraud Prevention Partnership, a public-private partnership dedicated to addressing fraud and abuse across all health care payers.

### Return on Investment

Program integrity efforts are proven cost effective. There are three key ways in which returns-on-investment from program integrity activities are measured. First, mandatory Medicare Integrity Program prevention and detection efforts have yielded a return-on-investment is \$12.4 to 1, and the Medicare Integrity Program has yielded a consistent return of over \$10 billion in savings annually.

Second, the three-year rolling average return-on-investment for Health Care Fraud and Abuse Control law enforcement activities is \$5 to 1. In FY 2016 alone, \$3.3 billion was recovered, including \$1.7 billion returned to the Medicare Trust Funds and \$235.2 million in Federal Medicaid recoveries returned to the Treasury.

Third, CMS actuaries conservatively project that, for every new dollar spent by HHS to combat health care fraud, about \$2 is saved or avoided.

### MEDICAID INTEGRITY PROGRAM

The Medicaid Integrity Program was established by the Deficit Reduction Act of 2005, which appropriated \$75 million in FY 2009 and for each year thereafter. The Patient Protection and Affordable Care Act later increased appropriations for FY 2011 and future years by inflation.

States have the primary responsibility for combating fraud, waste, and abuse in the Medicaid program, but the Medicaid Integrity Program plays an important role supporting state efforts, including through contracting with eligible entities to carry out activities such as reviews, audits, identification of overpayments, education activities, and technical support to states. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded through the Health Care Fraud and Abuse Control Program.

In connection with the Medicaid Integrity Program, the Medicaid Financial Management and Oversight Project provides funding specialists, including accountants and financial analysts, who work with states to improve CMS's financial oversight of Medicaid and the Children's Health Insurance Program (CHIP). In 2017, these funding specialists partnered with states to avert \$457 million in questionable reimbursements and recovered \$647 million in questionable costs.

### 2019 LEGISLATIVE PROPOSALS

#### Medicare

#### ***Suspend Coverage and Payment for Questionable Part D Prescriptions and Incomplete Clinical Information***

This proposal provides the Secretary authority to suspend coverage and payment for drugs when those prescriptions present an imminent risk to patients or when they are prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential. In addition, the proposal provides the Secretary authority to require additional clinical information on certain Part D prescriptions, such as diagnosis and incident codes, as a condition of coverage. [\$420 million in savings over 10 years]

***Prevent Abuse of Medicare Coverage when Another Source has Primary Responsibility for Prescription Drug Coverage***

Although health plans offered by employers and unions are required by Medicare secondary payer-related law to report enrollment information on certain active employees, there is no requirement for other group health plans that offer a prescription drug benefit to report their plan enrollees with drug coverage to HHS or the Part D plan sponsors. This proposal extends mandatory reporting requirements to include prescription drug coverage. This extension ensures that all prescription drug coverage provided by group health plans that is primary to Medicare coverage is communicated to HHS and to Part D sponsors, thereby permitting sponsors to comply with the statutory Medicare secondary payer requirements. [\$410 million in savings over 10 years]

***Prevent Fraud by Enforcing Reporting of Enrollment Changes through Civil Monetary Penalties for Providers and Suppliers Who Fail to Update Enrollment Records***

Currently, providers and suppliers are required to update enrollment records to remain in compliance with the Medicare program. This proposal allows penalties if providers and suppliers fail to update their records, providing an additional incentive to report the most current information and help reduce program vulnerability to fraud. [\$32 million in collections over 10 years]

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

This proposal allows the Secretary to assess an administrative penalty on providers for claims that have not been properly documented involving high-risk, high-cost items or services. The proposal only applies when there is insufficient documentation and would not apply to the determination of whether a fully-documented, ordered item or service was reasonable and necessary. The penalty would be \$50 per Part B item/service and \$100 per Part A service. [No budget impact]

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

This proposal allows the Secretary to enforce an exception to Medicare's reasonable assurance period in cases of patient harm or neglect. The reasonable assurance period currently allows providers and suppliers who have been terminated from participation

in Medicare for not complying with Federal requirements to re-enter the program after a preliminary showing of compliance, even under circumstances that conflict with Medicare's minimum reenrollment bar and put beneficiaries at an increased risk of patient harm. [No budget impact]

***Require Clearinghouses and Billing Agents Acting on Behalf of Medicare Providers and Suppliers to Enroll in the Program***

This proposal expands provider screening authorities by establishing a registration process for clearinghouses and billing agents that act on behalf of Medicare providers and suppliers. This proposal would also allow CMS to obtain organizational information from clearinghouses and billing agents. It is estimated that this proposal would yield \$165 million in additional collections over ten years to be spent on provider and supplier screening. [No budget impact]

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

Currently, CMS has authority to require prior authorization for specified Medicare fee-for-service items and services. This proposal extends that authority to all Medicare fee-for-service items and services, specifically those items that are at high risk for fraud, waste, and abuse. By allowing prior authorization on additional items and services, CMS can ensure in advance that the correct payment goes to the right provider for the appropriate service, and avoid future audits on those payments. [Budget impact not available]

**Medicaid**

***Streamline the Medicaid Terminations Process***

This proposal enhances the existing Medicaid provider terminations statute by defining appeals periods such that State Medicaid Agencies will report terminations after the first appeal rather than waiting until all appeals have been exhausted, establishing reporting requirements for rescissions and reinstatements of terminated Medicaid providers, and establishing a requirement to check the centralized Termination Notification Database before enrolling providers. [No budget impact]

### ***Expand Medicaid Fraud Control Unit Review to Additional Care Settings***

The Budget proposes to allow Medicaid Fraud Control Units to receive federal matching funds for the investigation or prosecution of abuse and neglect in non-institutional settings, such as home-based care, in which a beneficiary may be harmed in the course of receiving health care services. The current limitation on federal matching was established in 1978, at a time when Medicaid services were typically provided in institutional settings, so current restrictions do not reflect the shift in delivery and payment for health services to in-home and community based settings. [Budget impact not available]

### ***Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments***

The Budget proposes to require states to implement claims edits to automatically deny unusual Personal Care Services payments, such as payments for duplicative services, for services provided by Personal Care Service attendants who did not meet state qualification requirements, and for services rendered to individuals no longer eligible for Medicaid. This proposal addresses concerns and recommendations from the HHS Office of Inspector General. [Budget impact not available]

## **Medicare and Medicaid**

### ***Allow Revocation and Denial of Provider Enrollment Based on Affiliation with a Sanctioned Entity***

This proposal expands the current authority to revoke or deny individuals and entities from Medicare enrollment if they are affiliated with a sanctioned entity. Specifically, this proposal would allow the Secretary to take administrative actions against entities that have owners, managing employees, officers, and/or directors that were affiliated with previously sanctioned Medicare entities. This proposal would prevent these individuals from being able to evade Medicare revocation by “reinventing” themselves under a new business’s corporate umbrella. [\$53 million in savings over 10 years]

### ***Alter the Open Payments Reporting and Publication Cycle***

This proposal changes the annual publication date for the Open Payments data from June 30th to October 1st. This change would reduce burden for both industry and providers and improve data accuracy by allowing more time for data submission and review. [No budget impact]

### ***Clarify Authority for the Healthcare Fraud Prevention Partnership***

This proposal establishes explicit authority for the Healthcare Fraud Prevention Partnership and its activities. Currently, the Partnership operates under the authority established for the Health Care Fraud and Abuse Control Program, which allows for data sharing to address fraud and abuse in health insurance. By providing explicit authority, the Partnership will be able to clearly define the rules and responsibilities of its members and expand the scope of allowable activities, to address the full spectrum of fraud and abuse in the healthcare sector, such as efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse. [No budget impact]

### ***Consolidate Provider Enrollment Screening for Medicare, Medicaid, and CHIP***

This proposal requires providers who receive Federal funding and who are enrolling in Medicare, Medicaid, or CHIP to use centralized CMS screening as necessary under federal law. Regulations currently allow State Medicaid Agencies to rely on CMS screening, but providers are still subject to duplicative screening in many instances as multiple state and Federal programs and managed care plans may screen a single provider. State Medicaid Agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening. [No budget impact]

### ***Publish the National Provider Identifier for Covered Recipients in the Open Payments Program***

This proposal allows CMS to publish the National Provider Identifier of covered recipients on the public Open Payments website. Adding this identifier to the published data made on the Open Payments website will make it easier for data users to connect Open Payments records with covered recipient information, allowing greater access and transparency of the data. This addition will not make public any data that is not already currently available to the general public. [No budget impact]

## **Address Opioids**

### ***Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Agency to Terminate Provider Prescribing Authority***

This proposal allows the Secretary to work with the Drug Enforcement Agency (DEA) to revoke a provider’s DEA Certificate of Registration after CMS revokes a provider’s

Medicare enrollment based on a pattern of abusive prescribing via a newly established mandatory reporting requirement. Under this proposal, CMS will be required to report all revocation actions to DEA that are based totally or in part on abusive prescribing, and the DEA would be able to use this data to establish revocation of a provider's certification of registration. [Budget impact not available]

#### ***Track High Prescribers and Utilizers of Prescription Drugs in Medicaid***

In connection with other efforts to address the opioid abuse crisis, the Budget proposes to require states to monitor high-risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. States will have flexibility to choose one or more drug classes and must develop or review and update their care plans to reduce utilization and remediate any preventable episodes to improve Medicaid integrity and beneficiary quality of care. [Budget impact not available]

### **2019 ADMINISTRATIVE PROPOSALS**

#### **Medicare**

#### ***Address Excessive Billing for Durable Medical Equipment that Requires Refills or Serial Claims***

This proposal uses Medicare demonstration authority to test 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 time period. [Budget impact not available]

#### ***Address Overutilization and Billing of Durable Medical Equipment, Prosthetics, and Orthotics by Expanding Prior Authorization***

This proposal expands prior authorization to additional items and services that are at high risk for improper payments. In FY 2016, CMS finalized a regulation that established a master list of items that are both high-cost and high-risk for improper payments and therefore could be subject to prior authorization. This proposal would expand the number of items on the list subject to prior authorization. [Budget impact not available]

#### **Medicaid**

#### ***Establish Unique Identifiers for Personal Care Service Attendants***

Most states do not currently assign unique identifiers to personal care service attendants, making it difficult to track their activities or to verify claims in ways that adequately address concerns about fraud, waste, and abuse in personal care services. HHS will reduce fraud and abuse among personal care service attendants by requiring states assign unique identifiers to personal care service attendants that will be listed on claims along with dates that attendants performed services in question. [Budget impact not available]



## Program Integrity



### FY 2019 Program Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Program Integrity Legislative Proposals</b>			
<b>Medicare</b>			
Suspend Coverage and Payment for Questionable Part D Prescriptions and Incomplete Clinical Information	-30	-190	-420
Prevent Abuse of Medicare Coverage when Another Source has Primary Responsibility for Prescription Drug Coverage	-10	-140	-410
Prevent Fraud by Enforcing Reporting of Enrollment Changes through Civil Monetary Penalties for Providers and Suppliers Who Fail to Update Enrollment Records /1	-2	-13	-32
Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation	-	-	-
Ensure Providers that Violate Medicare's Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Medicare Program	-	-	-
Require Clearinghouses and Billing Agents Acting on Behalf on Medicare Providers and Suppliers to Enroll in the Program	-	-	-
Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste, and Abuse	**	**	**
<b>Medicaid</b>			
Streamline the Medicaid Terminations Process	-	-	-
Expand Medicaid Fraud Control Unit Review to Additional Care Settings	**	**	**
Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments	**	**	**
<b>Medicare &amp; Medicaid</b>			
Allow Revocation and Denial of Provider Enrollment Based on Affiliation with a Sanctioned Entity	-	-18	-53
<i>Medicare [non-add]</i>	-	-15	-45
<i>Medicaid [non-add]</i>	-	-3	-8
Alter the Open Payments Reporting and Publication Cycle	-	-	-
Clarify Authority for the Healthcare Fraud Prevention Partnership	-	-	-
Consolidate Provider Enrollment Screening for Medicare, Medicaid, and CHIP	-	-	-
Publish the National Provider Identifier for Covered Recipients in the Open Payments Program	-	-	-
<b>Address Opioids</b>			
Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Agency to Terminate Provider Prescribing Authority	**	**	**
Track High Prescribers and Utilizers of Prescription Drugs in Medicaid	**	**	**
<b>Subtotal, Savings Program Integrity Legislative Proposals</b>	<b>-42</b>	<b>-361</b>	<b>-915</b>
Subtotal, Medicare Impact	-42	-358	-907
Subtotal, Medicaid Impact	-	-3	-8

## Program Integrity



### FY 2019 Program Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b><i>Program Integrity Administrative Proposals</i></b>			
Address Excessive Billing for Durable Medical Equipment that Requires Refills or Serial Claims	**	**	**
Address Overutilization and Billing of Durable Medical Equipment, Prosthetics, and Orthotics by Expanding Prior Authorization	**	**	**
Establish Unique Identifiers for Personal Care Service Attendants	**	**	**
<b>Subtotal, Administrative Proposals</b>	<b>**</b>	<b>**</b>	<b>**</b>
** Budget impact unavailable as of the publication date of the FY 2019 President's Budget. 1/ This proposal reflects new revenue collections to the Medicare Part A Trust Fund.			

## Medicaid



<i>dollars in millions</i>	2017	2018	2019	2019 +/-2018
<b>Current Law</b>				
Benefits /1	355,142	381,125	398,763	+17,638
State Administration	19,539	20,963	21,479	+516
<b>Total Net Outlays, Current Law /2</b>	<b>374,681</b>	<b>402,088</b>	<b>420,241</b>	<b>+18,153</b>
<b>Proposed Law</b>				
Legislative Proposals	-	-1,700	-8,209	-6,509
<b>Total Net Outlays, Proposed Law /2</b>	<b>374,681</b>	<b>400,388</b>	<b>412,033</b>	<b>+11,645</b>
1/ Includes outlays from the Vaccines for Children Program, administered by the Centers for Disease Control and Prevention. Total reflects administrative policies assumed in the baseline. 2/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120.				

Note: Totals may not add due to rounding.

Medicaid is the primary source of medical assistance for millions of low-income and disabled Americans. In Fiscal Year (FY) 2017, more than one in five individuals were enrolled in Medicaid for at least one month during the year, and in FY 2018, nearly 75 million people on average will receive health care coverage through Medicaid under current law.

### HOW MEDICAID WORKS

States design, implement, and administer their own Medicaid programs based on general guidelines established by the Federal Government. The Federal Government matches state expenditures on medical assistance based on the Federal Medical Assistance Percentage, which can be no lower than 50 percent. In FY 2018, the Federal share of current law Medicaid outlays is expected to be approximately \$402.1 billion.

Without reforms, the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary estimates total Federal and state Medicaid benefits spending will be approximately \$1.1 trillion by FY 2028, comprising 3.4 percent of the Nation's gross domestic product.

Currently, states are required to cover individuals who meet certain minimum categorical and financial eligibility standards. Medicaid beneficiaries include children; pregnant women; adults in families with dependent children; the aged, blind, and/or disabled; and individuals who meet certain minimum income eligibility criteria that vary by category. States also have the flexibility to extend coverage to higher income groups, including medically needy individuals through waivers and amended state plans. Medically needy individuals are those individuals who do not meet the income standards of the categorical eligibility groups but incur large medical expenses and would otherwise qualify for Medicaid.

Under Medicaid, states must cover certain medical services and are provided the flexibility to offer additional benefits to beneficiaries. Medicaid also covers most of the costs of providing long-term care services. Medicare and private health insurance often furnish only limited coverage of these benefits.

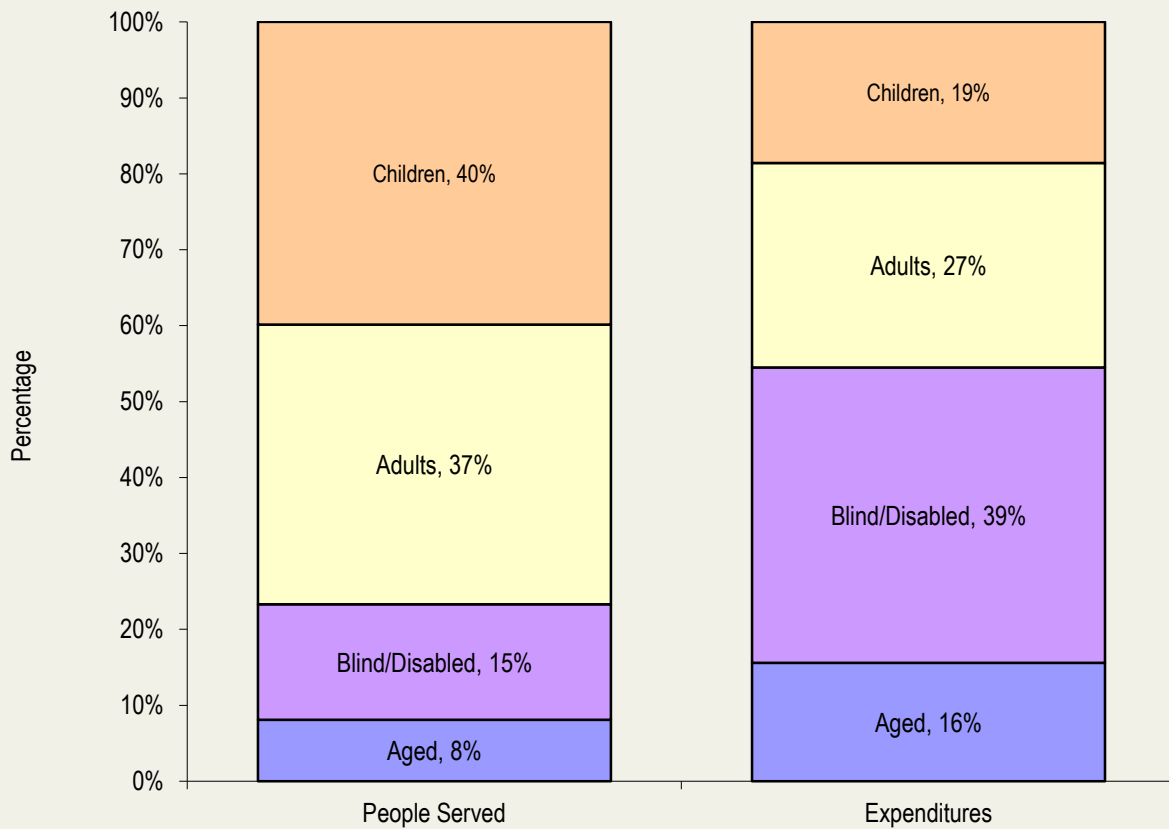
### Medicaid Enrollment

(person-years in millions, excludes U.S. Territories)

	2017	2018	2019	2019 +/- 2018
Aged 65 and Over	5.8	6.0	6.2	+0.2
Blind and Disabled	10.6	10.7	10.9	+0.1
Children	28.2	29.7	32	+2.3
Adults	27.7	28.1	28.5	+0.4
<b>Total /1</b>	<b>72.4</b>	<b>74.6</b>	<b>77.7</b>	<b>+3.1</b>

Source: CMS Office of the Actuary estimates.

1/ Totals may not add due to rounding.

**FY 2016—Percentage of Medicaid Beneficiaries vs. Federal Medical Assistance Expenditures by Eligibility Group /1 /2**

Source: CMS Office of the Actuary

1/ Estimates of expenditures by eligibility group in FY 2016 are projected based on prior year data and may change as more data becomes available. Totals and components exclude Disproportionate Share Hospital expenditures, territorial enrollees and expenditures, and financial adjustments.

2/ Percentages may not add to 100% due to rounding.

## 2019 LEGISLATIVE PROPOSALS

The FY 2019 Budget provides additional flexibilities to states, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. In total, the Budget includes net savings to Medicaid of \$1,438.8 billion over 10 years. Of this total, the Budget includes \$1,389.2 billion in savings to Medicaid related to enactment of the Repeal and Replace Obamacare proposal (see the CMS Health Reform chapter for more information).<sup>1</sup>

### State Medicaid Flexibility Proposals

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

Currently, states are required to obtain waiver authority to charge copayments above the nominal statutory amounts for non-emergency use of the emergency department. 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 health care resources. [\$1.3 billion in savings over 10 years]

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

This proposal would provide states the option to apply asset tests to populations determined eligible by the Modified Adjusted Gross Income (MAGI) standard, such as able-bodied adults. States currently use asset tests in determining eligibility for aged, blind, and disabled Medicaid beneficiaries. The Budget proposes greater flexibility for states to expand asset tests to MAGI populations so states can refocus Medicaid on the truly low-income. [\$2.1 billion in savings over 10 years]

#### ***Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers***

This proposal reduces burdensome Federal reviews by giving states the option to grandfather the managed care authorities in waivers and demonstration

<sup>1</sup> Note: Some of the savings from proposals discussed in this chapter would be reduced if enacted in conjunction with the Repeal and Replace Obamacare proposal. As such, due to this interaction, the net Medicaid savings proposed in the Budget is a subset of gross savings and is non-additive.

## PROGRAM UPDATE

### A New Vision for the Future of Medicaid

On November 7, 2017, CMS outlined a vision for the future of Medicaid “to reset the Federal-State relationship and restore the partnership, while at the same time modernizing the program to deliver better outcomes for the people we serve.” The Administration also supports providing states more freedom to design innovative programs through Section 1115 demonstrations that align with the core objectives of the Medicaid program, including:

1. Improving access to high-quality, person-centered services that produce positive health outcomes for individuals;
2. Promoting efficiencies that ensure Medicaid’s sustainability for beneficiaries over the long term;
3. Supporting coordinated strategies to address certain health determinants that promote upward mobility, greater independence, and improved quality of life among individuals;
4. Enhancing alignment between Medicaid policies and commercial health insurance products to facilitate smoother beneficiary transition; and
5. Advancing innovative delivery system and payment models to strengthen provider network capacity and drive greater value for Medicaid.

More information about Section 1115 demonstrations is available at the following URL: <https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html>

programs under their state plans as long as there are no substantive changes to the waiver or demonstration program and it has been renewed at least once. [No budget impact]

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

Medicaid managed care has become common and widespread in states, and it no longer makes sense to impose the burden on states to submit paperwork for re-approval of Medicaid managed care waivers every five years for programs involving dual-eligible individuals and every two years for 1915(b) waivers involving all other Medicaid eligibility groups. This proposal eliminates the time limit for 1915(b) waivers to give the Secretary the flexibility to determine the appropriate approval timeframe for all enrolled populations. [No budget impact]

### Refocusing Medicaid Eligibility on the Most Needy

#### ***Reduce the Maximum Allowable Home Equity for Medicaid Eligibility***

This proposal removes states’ authority to substitute a higher home equity limit than the statutory minimum.

This approach better prioritizes long-term care coverage through Medicaid for lower-income individuals who do not have significant assets that could be liquidated to cover their cost of health care. [No budget impact]

#### ***Require Documentation of Satisfactory Immigration Status Before Receipt of Medicaid Benefits***

This proposal requires individuals to prove their eligibility for Medicaid before they receive Medicaid coverage funded by scarce Federal resources. Currently, states are required to enroll individuals that claim they have, but cannot immediately provide documentation of citizenship or satisfactory immigration status for a reasonable opportunity period. After that period, the individuals must submit evidence indicating citizenship or a satisfactory immigration status. This proposal allows states to elect whether to provide Medicaid coverage for a reasonable opportunity period, but prohibits Federal payments for medical assistance during this period. [\$2.2 billion in savings over 10 years]

#### **PROGRAM UPDATE**

#### **Promoting Community Engagement and Work among Medicaid Beneficiaries**

It is important that Medicaid address the needs of the working-age population, particularly through work or other community engagement activities. Research has shown that targeting certain health determinants, such as productive work and community engagement, may improve health outcomes.

On January 11, 2018, the Administration announced its intention to support Section 1115 demonstrations that promote work or community engagement activities (e.g., volunteering, educational activities, or job training) for working-age, able-bodied adults, and that link such requirements to improved health and well-being. Such programs may also be designed to help individuals and families rise out of poverty and attain independence.

More information about Section 1115 demonstrations and opportunities to promote work and community engagement among Medicaid beneficiaries is available at the following URL: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf>

#### ***Define Lottery Winnings and Other Lump-Sum Payments as Income for Medicaid Eligibility***

To ensure that Medicaid funding is available for those who need it most, this proposal requires states to count lottery winnings, inheritances, and settlement

payments from certain legal judgments as income for purposes of Medicaid eligibility over a period of time, rather than counting such payments only in the month in which the payment is received as states do under current law. [\$50 million in savings over 10 years]

#### ***Other Medicaid Proposals***

#### ***Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage***

This proposal includes a new statutory demonstration authority to allow up to five states more flexibility in negotiating prices with manufacturers, rather than participate in the Medicaid Drug Rebate Program, and to make drug coverage decisions that meet state needs. Participating states will be required to include an appeals process so beneficiaries can access non-covered drugs based on medical need. [\$85 million in savings over 10 years]

#### ***Prohibit Medicaid Payments to Public Providers in Excess of Costs***

This proposal limits Medicaid reimbursement for health care providers that are operated by a unit of government to an amount that does not exceed the provider's cost of providing services to Medicaid beneficiaries. This will avoid misuse of funds by preventing states from circumventing Medicaid matching requirements. [Budget impact not available]

#### ***Continue Medicaid Disproportionate Share Hospital Allotment Reductions***

State Medicaid Disproportionate Share Hospital (DSH) allotments have been reduced between FY 2018 and FY 2025 under current law. The Budget includes a proposal to continue Medicaid DSH allotment reductions at \$8 billion per year from FY 2026 through FY 2028. [\$19.5 billion in savings over 10 years]

#### ***Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates***

This proposal clarifies the Medicaid definition of brand and over-the-counter drugs as well as drugs approved under a biologics license application by codifying existing regulations to ensure appropriate Medicaid drug rebates. [\$319 million in savings over 10 years]



### ***Require Coverage of All Medication Assisted Treatments in Medicaid***

This proposal requires that state Medicaid programs cover all Food and Drug Administration-approved Medication Assisted Treatments (MAT) for opioid use disorder, including associated counseling and other costs. These up-front investments in expanded MAT treatment are expected to reduce total Medicaid expenditures over time as more individuals recover from opioid use disorder. [\$865 million in savings over 10 years]

#### **NEW INITIATIVE**

### **Medicaid Drug Coverage Reform Demonstration**

As part of an Administration-wide effort to address the high costs of prescription drugs and provide states more purchasing flexibility, this proposal includes a new statutory demonstration authority allowing up to five states to test a closed formulary under which they negotiate prices directly with manufacturers, rather than participating in the Medicaid Drug Rebate Program.

In addition, the demonstration would exempt prices negotiated under the demonstration from best price reporting.

Given the interest among stakeholders to identify opportunities in outcomes-based purchasing (i.e. value-based purchasing) drug models, adhering to best price reporting can be a barrier for manufacturers to enter these models. This approach provides a pathway for testing changes to Medicaid drug coverage without the constraints in existing Medicaid authorities.

### **LEGISLATIVE PROPOSALS FOR MEDICARE-MEDICAID ENROLLEES**

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

Under current law, marketing materials provided by Dual Eligible Special Needs Plans to beneficiaries have to go through separate state and CMS review processes. This proposal allows for joint state and CMS review, building on CMS's experience with joint review

conducted under current demonstration authority. The proposal lowers administrative burden on participating plans and enhances their ability to provide a uniform message to beneficiaries. [No budget impact]

### ***Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans***

This proposal provides HHS with the authority to streamline the appeals communication requirements imposed on private and non-profit health plans that integrate payment and services for Medicare-Medicaid enrollees. The proposal enhances beneficiary communications so they do not receive conflicting instructions based on differing Medicare and Medicaid requirements, and improves care coordination for a population with complex and high-cost medical needs. [No budget impact]

### ***Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries***

The Social Security Act currently requires that CMS maintain a Special Enrollment Period (SEP) for full-benefit dually eligible beneficiaries. Effective plan year 2019, this proposal narrows the applicability of the SEP by specifying that the intent is to promote integration of Medicare and Medicaid coverage and to allow individuals to make alternative choices following auto-assignment into a Part D plan. This allows CMS to apply the same annual election process for both dually eligible and non-dually eligible beneficiaries, but preserve the ability for dually eligible beneficiaries to use an SEP to opt into integrated care programs or to change plans following auto-assignment. Efficient use of the Part D SEP for full-benefit dual eligible beneficiaries reduces aggressive marketing targeted to low-income beneficiaries, improves incentives to make investments in and provide care coordination for high-cost, often vulnerable beneficiaries, and reduces the administrative burden on health plans from beneficiary fluctuations between plans numerous times throughout the year. [No budget impact to Medicaid]

**MULTI-AGENCY PROPOSALS*****Repeal and Replace Obamacare***

The Administration supports the Graham-Cassidy-Heller-Johnson legislation, with additional modifications to reform the Medicaid program, by giving states the flexibility they need to achieve better health outcomes for patients while putting Medicaid on a more sustainable fiscal trajectory through per capita caps or block grants beginning in FY 2020 (see the Health Care Reform chapter for a proposal description). [\$1.4 trillion in Medicaid savings over 10 years]

***Reform Graduate Medical Education Payments***

The Budget includes a proposal to consolidate and better target Federal spending for Graduate Medical Education (see the Health Care Reform chapter for a proposal description). [\$21.2 billion in Medicaid savings over 10 years]

***Reform Medical Liability***

The Budget includes a set of proposals to reform medical liability, which will reduce medical malpractice costs and the practice of defensive medicine, while supporting states' efforts to reduce Medicaid costs (see the Health Care Reform chapter for proposal descriptions). [\$57 million in net Medicaid savings over 10 years<sup>2</sup>]

***Change Conditions on First Generic Exclusivity to Spur Access and Competition***

This proposal makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity. [Budget impact not available]

***Reduce Fraud, Waste, Abuse, and Improper Payments in Medicaid***

The Budget includes a number of Medicaid program integrity proposals that strengthen the Department's and states' ability to fight fraud, waste, and abuse in the Medicaid program and to reduce improper payments (see the Program Integrity chapter for descriptions of these proposals). [\$8 million in Medicaid savings over 10 years]

<sup>2</sup> Savings accounts for the interaction with the proposal to Repeal and Replace Obamacare.

**NEW INITIATIVE****Medicaid and CHIP State Scorecard**

On November 7, 2017, the Administration announced that, for the first time, CMS will create a state-by-state Medicaid and CHIP Scorecard. This multi-year initiative will help to refocus the Medicaid and CHIP programs on achieving positive health outcomes by tracking the extent to which states achieve tangible results that will improve the lives of beneficiaries. This initiative will also bring more transparency and accountability to the Medicaid and CHIP programs—so taxpayers can see when their hard-earned tax dollars are being spent appropriately and sustainably. Finally, the Medicaid and CHIP Scorecard will also give states an opportunity to demonstrate their progress to the Nation and to more easily see what changes have already been successfully implemented by other states. Funding for this initiative is discussed in the Program Management chapter.

**2019 ADMINISTRATIVE PROPOSALS*****Require Minimum Standards in Medicaid State Drug Utilization Review Programs***

The Medicaid statute requires that each state develop a Drug Utilization Review program targeted in part at reducing clinical abuse and misuse. CMS currently does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Under this proposal, HHS will set minimum standards for Drug Utilization Review programs, in part to help increase oversight of opioid prescriptions/dispensing in Medicaid. [\$245 million in savings to Medicaid assumed over 10 years]

***Make Medicaid Non-Emergency Medical Transportation Optional***

Under current regulations, states are required to provide Non-Emergency Medical Transportation to all Medicaid beneficiaries. The Budget commits to using regulatory authority to change provision of this benefit from mandatory to optional. [No budget impact]

***Improve Data Collection on Medicaid Supplemental Payments***

To improve the transparency and oversight of Medicaid supplemental payments, the Budget commits to issue a regulation requiring more complete and timely provider-level data on supplemental payments, including the financing of such payments. This approach also includes enhanced review of supplemental payment methodologies. [No budget impact]



## Medicaid

### FY 2019 Medicaid Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>State Medicaid Flexibility Proposals</b>			
Increase the Limit on Medicaid Copayments for Non-Emergency Use of the Emergency Department	-60	-530	-1,290
Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations	-50	-760	-2,050
Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers	-	-	-
Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers	-	-	-
<b>Subtotal Outlays, State Medicaid Flexibility Proposals</b>	<b>-110</b>	<b>-1,290</b>	<b>-3,340</b>
<b>Refocusing Medicaid Eligibility on the Most Needy</b>			
Reduce the Maximum Allowable Home Equity for Medicaid Eligibility	-	-	-
Require Documentation of Satisfactory Immigration Status Before Receipt of Medicaid Benefits	-170	-950	-2,190
Define Lottery Winnings and Other Lump-Sum Payments as Income for Medicaid Eligibility	-3	-20	-50
<b>Subtotal Outlays, Refocusing Medicaid Eligibility on the Most Needy</b>	<b>-173</b>	<b>-970</b>	<b>-2,240</b>
<b>Other Medicaid Proposals</b>			
Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage	-	-35	-85
Prohibit Medicaid Payments to Public Providers in Excess of Costs	**	**	**
Continue Medicaid Disproportionate Share Hospital Allotment Reductions	-	-	-19,470
Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates	-26	-135	-319
Require Coverage of All Medication Assisted Treatments in Medicaid	35	-145	-865
<b>Subtotal Outlays, Other Medicaid Proposals</b>	<b>9</b>	<b>-315</b>	<b>-20,739</b>
<b>Medicare-Medicaid Enrollee Proposals</b>			
Allow for Federal/State Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials	-	-	-
Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans	-	-	-
Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries	-	-	-
<b>Subtotal Outlays, Medicare-Medicaid Enrollee Proposals</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Multi-Agency Proposals</b>			
Repeal and Replace Obamacare (Medicaid Impact) /1	-2,885	-429,395	-1,389,235
Reform Graduate Medical Education Payments (Medicaid Impact) /1	-1,600	-9,000	-21,200
Medical Liability Reform (Medicaid Impact) /1 /2	-57	-57	-57
Change Conditions on First Generic Exclusivity to Spur Access and Competition (Medicaid Impact) /3	**	**	**
Cut Fraud, Waste, Abuse, and Improper Payments (Medicaid Impact) /4	-	-3	-8
Extend Special Immigrant Visa Program (Medicaid Impact) /5	7	67	128
Extend Children's Health Insurance Program (CHIP) through 2019 with Reforms (Medicaid Impact) /6	-3,400	-7,000	-7,000
<b>Subtotal Outlays, Multi-Agency Proposals</b>	<b>-7,935</b>	<b>-445,388</b>	<b>-1,417,372</b>

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Gross Outlays, Legislative Proposals</b>	<b>-8,209</b>	<b>-447,963</b>	<b>-1,443,691</b>
<b>Outlay Effect of Interactions /7</b>	<b>-</b>	<b>1,197</b>	<b>4,856</b>
<b>Net Outlays, Legislative Proposals /7</b>	<b>-8,209</b>	<b>-446,766</b>	<b>-1,438,835</b>
<b>Medicaid Administrative Proposals</b>			
Require Minimum Standards in Medicaid State Drug Utilization Review Programs	-20	-105	-245
Make Medicaid Non-Emergency Medical Transportation Optional	-	-	-
Improve Data Collection on Medicaid Supplemental Payments	-	-	-
<b>Subtotal Outlays, Medicaid Administrative Proposals (non-add) /8</b>	<b>-20</b>	<b>-105</b>	<b>-245</b>
<b>Total Outlays, Medicaid Budget Proposals (non-add)</b>	<b>-8,229</b>	<b>-446,871</b>	<b>-1,439,080</b>
<p>** Budget impact unavailable as of the publication date of the FY 2019 President's Budget.</p> <p>1/ See Health Care Reform chapter for proposal description.</p> <p>2/ Savings accounts for the interaction with the proposal to Repeal and Replace Obamacare.</p> <p>3/ See Medicare and Food and Drug Administration chapters for proposal description.</p> <p>4/ This reflects the Medicaid impact of the "Allow Revocation of Medicare Enrollment Based on Affiliation with a Sanctioned Entity" proposal. See Program Integrity chapter for proposal description.</p> <p>5/ This proposal is included in the State Department's FY 2019 Budget Request.</p> <p>6/ See Children's Health Insurance Program chapter for proposal description. Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120.</p> <p>7/ The gross Medicaid savings from all proposals in this package would be reduced if enacted in conjunction with the Repeal and Replace Obamacare proposal. As such, due to this interaction, the net Medicaid savings proposed in the Budget is a subset of gross savings and is non-additive.</p> <p>8/ These administrative actions are assumed to take effect in FY 2019 under current law.</p> <p><b>Note: Totals may not add due to rounding.</b></p>			



## Children's Health Insurance Program

<i>dollars in millions</i>	2017	2018	2019	2019 +/- 2018
<b>Current Law</b>				
Children's Health Insurance Program (CHIP)	16,224	12,620	5,724	-6,985
Child Enrollment Contingency Fund	27	198	0	-198
<b>Total Outlays, Current Law /1</b>	<b>16,251</b>	<b>12,818</b>	<b>5,724</b>	<b>-7,094</b>
<b>Proposed Law</b>				
CHIP Legislative Proposals /1 /2	-	4,500	5,700	+1,200
<b>Total Outlays, Proposed Law</b>	<b>16,251</b>	<b>17,318</b>	<b>11,424</b>	<b>-5,894</b>
1/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120. 2/ This score reflects the impact on CHIP. The net Federal cost of the proposal is \$2.5 billion over 10 years, which reflects impacts to CHIP (\$13.2 billion) and interactions with Medicaid (-\$7.0 billion) and other Federal programs and accounts (-\$3.7 billion). See the Medicaid chapter for the Medicaid impact.				

The Children's Health Insurance Program (CHIP) was originally created under the Balanced Budget Act of 1997. On January 22, 2018, Congress passed and the President signed the HEALTHY KIDS Act, as included in the FY 2018 Continuing Resolution (P.L. 115-120), which extended CHIP funding for six years. Since September 1999, every state, the District of Columbia, and all five territories have approved CHIP plans.

### HOW CHIP WORKS

CHIP is a partnership between the Federal Government and states and territories to help provide low-income children under age 19 with health insurance coverage so they can access health care. In general, CHIP reaches children whose families have incomes too high to qualify for Medicaid but too low to afford private health insurance.

States with an approved CHIP plan are eligible to receive an enhanced Federal matching rate, which will range from 65 to 85 percent. Beginning in FY 2016, and effective through FY 2019, each state's enhanced Federal matching rate increased by up to 23 percentage-points to cover between 88 and 100 percent of total costs for child health care services and program administration, drawn from a capped allotment.

States have a high degree of flexibility in designing their programs. They can implement CHIP by expanding Medicaid, creating a separate program, or combining both approaches. As of December 2017,

there were 14 Medicaid expansion programs, two separate programs, and 40 combination programs among the states, District of Columbia, and territories.

In FY 2017, the Centers for Medicare & Medicaid Services (CMS) Office of the Actuary estimated that 9.4 million individuals received health insurance funded through CHIP allotments at some point during the year. Approximately 6.7 million individuals were enrolled in CHIP on average throughout the year.

A Child Enrollment Contingency Fund was established for states that predict a funding shortfall based on higher than expected enrollment. The Contingency Fund is invested in interest bearing securities of the United States. Payments from the fund are currently authorized through FY 2023.

### RECENT PROGRAM DEVELOPMENTS

On January 22, 2018, Congress passed and the President signed the HEALTHY KIDS Act, which included an extension of CHIP funding and authorized the Child Enrollment Contingency Fund for six years through FY 2023. This legislation also extended CHIP Express Lane Eligibility, the qualifying state option, and the expansion allotment adjustment.

### Financing

The HEALTHY KIDS Act phases down the 23 percentage-point increase in the CHIP enhanced Federal match rate to 11.5 percentage points in

FY 2020 before returning to the traditional CHIP match rate from FYs 2021 to 2023.

### ***Eligibility and Coverage***

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

Prior to the enactment of the HEALTHY KIDS Act, states were required to maintain the same eligibility levels for all children covered under Medicaid and CHIP as of March 30, 2010 through September 30, 2019. Under current law, this maintenance of effort requirement only applies to children in families with incomes up to 300 percent of the Federal Poverty Level from FYs 2020 to 2023.

### ***Enrollment and Retention Outreach***

The Outreach and Enrollment Program provided grants and established a national campaign to improve outreach and enrollment to children who are eligible for, but not enrolled in Medicaid and CHIP. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) provided new funding and extended the Outreach and Enrollment Program for two years through FY 2017. Current law extends the Outreach and Enrollment Program and provides an additional \$120 million for six years through FY 2023. Outlay totals for Outreach and Enrollment Grants are reflected in the State Grants and Demonstrations chapter.

### ***Improving Quality***

Children's Health Insurance Program Reauthorization Act (CHIPRA) provided \$225 million over five years for activities that improve child health quality in Medicaid and CHIP, and 18 States (across 10 grants) participated in CHIPRA Quality Demonstrations to test ways to strengthen the quality of and access to children's health care through a variety of health care delivery and measurement approaches at both the provider and patient levels. The Protecting Access to Medicare Act

of 2014 allocated \$15 million of Adult Health Quality funding for the pediatric quality measures program, and MACRA provided an additional \$20 million in new funding for the program. Current law provides an additional \$90 million for FYs 2018 to 2023 for child health quality activities.

## **2019 LEGISLATIVE PROPOSALS**

### ***Extend Children's Health Insurance Program through 2019 with Reforms***

Notwithstanding the recent extension of CHIP for six years, due to the timing of the production and release of the President's Budget, the Budget includes a proposal to extend funding for CHIP and the Child Enrollment Contingency Fund through FY 2019. Baseline estimates will be updated at the Mid-Session Review.

The estimates of the President's Budget are based on the following policy assumptions, including an extension of funding for CHIP and the Child Enrollment Contingency Fund through FY 2019. The Budget also proposes a series of reforms that rebalance the State-Federal partnership and increase state flexibility.

As part of cross-cutting health reforms, this proposal ends the 23 percentage-point increase in the enhanced Federal match rate and the current law maintenance of effort requirement beginning in FY 2019 that were included in Obamacare.

This funding extension also caps the level at which states could receive the CHIP enhanced Federal matching rate at 250 percent of the Federal Poverty Level beginning in FY 2019, to return the focus of CHIP to low-income children who need it most.

Under current law, states are required to transition children ages 6 to 18 in families with incomes between 100 and 133 percent of the Federal Poverty Level from CHIP to Medicaid. The Budget proposes allowing states to move these children back into CHIP.



## Children's Health Insurance Program



### FY 2019 CHIP Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>CHIP Proposals</b>			
Extend Children's Health Insurance Program through 2019 with Reforms /1	5,700	13,200	13,200
<i>CHIP Impact</i>	5,700	13,200	13,200
<i>Medicaid Impact (non-add)</i>	-3,400	-7,000	-7,000
<i>Other Federal Impacts (non-add)</i>	-2,860	-3,685	-3,685
Extend the Child Enrollment Contingency Fund through FY 2019	0	0	0
<b>Total Outlays, CHIP Proposals /1 /2</b>	<b>5,700</b>	<b>13,200</b>	<b>13,200</b>
<p>1/ This score reflects the impact on CHIP. The net Federal cost of the proposal is \$2.5 billion over 10 years, which reflects impacts to CHIP (\$13.2 billion) and interactions with Medicaid (-\$7.0 billion) and other Federal programs and accounts (-\$3.7 billion).</p> <p>2/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120.</p>			

Note: Totals may not add due to rounding.



## State Grants and Demonstrations

<i>dollars in millions</i>	2017	2018	2019	2019 +/-2018
<b>Current Law Budget Authority</b>				
Medicaid Integrity Program /1	78	80	87	+7
Money Follows the Person Demonstration	-	-	-	-
Money Follows the Person Evaluations	-	-	-	-
Demonstration Program to Improve Community Mental Health Services	-	-	-	-
Children's Health Insurance Program (CHIP) Outreach and Enrollment Grants /2	-	-	-	-
Incentives for Prevention of Chronic Diseases in Medicaid	-	-	-	-
<b>Total, Current Law Budget Authority</b>	<b>78</b>	<b>80</b>	<b>87</b>	<b>+7</b>
<b>Current Law Outlays /3</b>				
Medicaid Integrity Program /1	82	81	86	+5
Money Follows the Person Demonstration	393	487	483	-4
Money Follows the Person Evaluations	1	1	-	-1
Demonstration Program to Improve Community Mental Health Services	9	3	2	-1
CHIP Outreach and Enrollment Grants /2	16	10	6	-4
Incentives for Prevention of Chronic Diseases in Medicaid /4	2	1	1	-
<b>Total, Current Law Outlays</b>	<b>503</b>	<b>583</b>	<b>578</b>	<b>-5</b>
1/ Budget authority for the Medicaid Integrity Program is adjusted annually by Consumer Price Index for All Urban Consumers and outlays include some spending from prior year budget authority. This program is also described in the Program Integrity chapter. 2/ Does not reflect the Children's Health Insurance Program (CHIP) funding extension through FY 2023, as the Budget was finalized prior to the enactment of P.L. 115-120. 3/ The following programs/laws were excluded from the Current Law Outlays table (because outlays were less than \$1 million): Ticket to Work and Work Incentives Improvement Act, Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens, and the Medicaid Emergency Psychiatric Demonstration. 4/ Outlays are from prior year budget authority.				

The State Grants and Demonstrations account funds a diverse set of program activities, including activities that were authorized in the Patient Protection and Affordable Care Act, the Children's Health Insurance Program Reauthorization Act (CHIPRA), and the Deficit Reduction Act of 2005. Such activities include strengthening Medicaid program integrity, supporting enrollment of children into Medicaid and the Children's Health Insurance Program (CHIP) through funding for outreach activities, and promoting prevention and wellness by providing grants to states to prevent chronic diseases.

### **Medicaid Integrity Program**

The Medicaid Integrity Program was established by the Deficit Reduction Act of 2005, which appropriated \$75 million in Fiscal Year (FY) 2009 and for each year thereafter. Congress later increased appropriations for FY 2011 and future years by inflation.

States have the primary responsibility for combating fraud, waste, and abuse in the Medicaid program, but the Medicaid Integrity Program plays an important role supporting state efforts, including through contracting with eligible entities to carry out activities such as agency reviews, audits, identification of overpayments, education activities, and technical support to states. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded through the Health Care Fraud and Abuse Control program.

Please refer to the Program Integrity chapter for additional information.

### **Money Follows the Person (MFP) Demonstration**

This demonstration, extended through FY 2016, helps states support individuals to achieve independence. While there have been no recent appropriations for

this program, states are continuing to operate this demonstration since 2007, and have demonstrated positive outcomes. States that are awarded competitive grants receive an enhanced Medicaid matching rate to help eligible individuals transition from a qualified institutional setting to a qualified home or community-based setting.

The latest MFP demonstration Report to Congress noted that through 2013, MFP participants that transitioned to home and community-based long-term services and supports generated \$978 million in reduced Medicare and Medicaid costs in the first year after the transition (\$1,003 million in cost savings to state Medicaid programs and \$25 million in additional costs to Medicare).

#### ***CHIP Outreach and Enrollment Grants***

Through grants and a national campaign, the Outreach and Enrollment Program improves outreach and enrollment to children who are eligible for, but not enrolled in Medicaid and CHIP, including children who

are American Indian or Alaska Native. Funding is aimed at educating families about the availability of free or low-cost health coverage under Medicaid and CHIP, identifying children likely to be eligible for these programs, and assisting families with the application and renewal process. The HEALTHY KIDS Act extends the Outreach and Enrollment Program and provides an additional \$120 million for six years through FY 2023.

#### ***Demonstration Program to Improve Community Mental Health Services***

Section 223 of the Protecting Access to Medicare Act created this demonstration program for states to implement between FYs 2017 and 2019. The program provides an enhanced Federal Medicaid match rate for certified community behavioral health clinics with the aim of improving access to behavioral health services for Medicaid beneficiaries. In December of 2016, HHS selected eight states to participate in the two-year demonstration program to improve access to high-quality behavioral health services.

## Program Management



<i>dollars in millions</i>	2017	2018	2019	2019 +/- 2018
<b>Discretionary Administration</b>				
Program Operations	2,816	2,806	2,402	-404
Federal Administration	733	728	703	-25
Survey and Certification	397	395	421	+26
Research	20	20	18	-2
<b>Subtotal, Discretionary Budget Authority</b>	<b>3,966</b>	<b>3,948</b>	<b>3,544</b>	<b>-404</b>
<b>Mandatory Administration /1</b>				
Medicare Improvements for Patients and Providers Act	3	3	3	-
Protecting Access to Medicare Act (2014)	6	6	10	+4
Improving Medicare Post-Acute Care Transformation (2014)	20	17	19	+2
Medicare Access and CHIP Reauthorization Act	196	152	115	-37
21 <sup>st</sup> Century Cures Act	18	0	0	-
<b>Subtotal, Mandatory Administration</b>	<b>243</b>	<b>178</b>	<b>147</b>	<b>-31</b>
<b>Reimbursable Administration</b>				
Medicare and Medicaid Reimbursable Administration /2	579	499	794	+295
Exchange-Related Reimbursable Administration /1	1,141	1,232	1,000	-232
Risk Corridors /3	98	11,513	0	-11,513
<b>Subtotal, Reimbursable Administration (no Risk Corridor)</b>	<b>1,720</b>	<b>1,731</b>	<b>1,794</b>	<b>-63</b>
<b>Subtotal, Reimbursable Administration (with Risk Corridor)</b>	<b>1,818</b>	<b>13,244</b>	<b>1,794</b>	<b>-11,450</b>
<b>Total Program Management Program Level, Current Law (no Risk Corridor)</b>	<b>5,929</b>	<b>5,857</b>	<b>5,485</b>	<b>-372</b>
<b>Total Program Management Program Level, Current Law (with Risk Corridor)</b>	<b>6,027</b>	<b>17,370</b>	<b>5,485</b>	<b>-11,885</b>
<b>Proposed Law</b>				
Survey and Certification Revisit and Complaint Investigation Fee	0	0	14	+14
Rebase National Medicare & You Education Program User Fee	0	0	30	+30
Program Management Implementation Funds (mandatory)	0	0	200	+200
Fully Fund the Risk Corridors Program /4	0	812	0	-812
<b>Subtotal, Proposed Law</b>	<b>0</b>	<b>812</b>	<b>244</b>	<b>-568</b>
<b>Total Program Management Program Level, Proposed Law (no risk corridor)</b>	<b>5,929</b>	<b>5,857</b>	<b>5,729</b>	<b>-128</b>
<b>Total Program Management Program Level, Proposed Law (with risk corridor)</b>	<b>6,027</b>	<b>18,182</b>	<b>5,729</b>	<b>-12,453</b>
1/ Includes user fees charged to issuers in Federally-facilitated Exchanges, State-based Exchanges using the Federal platform, and risk adjustment. 2/ Includes 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, recovery audit contractors, and provider enrollment fees. 3/ Reflects collections of \$98 million in FY 2017 and \$25 million in FY 2018. Additionally, FY 2018 includes \$11,488 million from the FY 2019 Budget proposal to provide a mandatory appropriation to fully fund the Risk Corridors Program. 4/ Reflects legislative proposal to fully fund the Risk Corridors Program, including exempting the program from sequestration.				

Note: Totals may not add due to rounding.

The FY 2019 discretionary budget request for CMS Program Management is \$3.5 billion, a decrease of \$404 million below the FY 2018 Continuing

Resolution level. This request will enable CMS to continue to effectively administer Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

The FY 2019 Budget reflects CMS's key priorities, which: strengthen the integrity and sustainability of Medicare and Medicaid by investing in activities to prevent fraud, waste, and abuse; empower states and provide them with greater flexibility; modernize programs to address the changing needs of the people we serve; and leverage innovation and technology to drive better care for millions of Americans.

## BUDGET ACCOUNT SUMMARIES

### Program Operations

The Program Operations request is \$2.4 billion, a decrease of \$404 million below the FY 2018 Continuing Resolution level. The Program Operations account funds essential payment, information technology, and outreach activities necessary to administer Medicare, Medicaid, CHIP, Exchanges and other private insurance programs. Top priority activities for FY 2019 include:

- **Ongoing Medicare Contractor Operations:** Approximately 39 percent, or \$936 million, of the FY 2019 Program Operations request supports ongoing Medicare contractor operations. This workload includes processing 1.3 billion Medicare Part A and B claims, enrolling providers in the Medicare program, handling provider reimbursement services, processing 2.5 million first-level appeals, responding to provider inquiries, educating providers about the program, and administering the participating physicians/supplier program.
- **Medicare Appeals:** The Budget includes \$91 million to timely process about 393,000 appeals at the second level of appeals.
- **Information Technology Systems and Support:** The Budget includes \$397 million for information technology systems and other support, including cybersecurity, allowing the agency to protect the valuable consumer health data of millions of Americans from outside threats. Additionally, CMS will continue a pilot begun in FY 2018 to make seniors' health data more accessible to beneficiaries and their providers.

- **Medicaid and CHIP Operations:** The Budget requests \$100 million to fund administrative activities to improve Medicaid and CHIP program operations, including the modernization of data systems and ongoing work to develop a scorecard for state Medicaid and CHIP programs that will track the extent to which states achieve tangible results that improve the lives of beneficiaries.
- **Exchanges:** The Budget includes \$135.2 million in requested budget authority for the Exchanges, including \$122.7 million in Program Operations activities for eligibility, call center operations, and information technology activities. In addition, CMS anticipates collecting approximately \$1.0 billion in user fee revenues to support Exchange activities. The total estimated program level, including all sources, is \$1.2 billion to fund critical Exchange functions and allow for the wind down of the Federal Exchange, consistent with the Budget's Repeal and Replace proposal.

PROGRAM HIGHLIGHT		
Survey and Certification Frequencies Program Level		
Type of Facility	2018	2019
Long-Term Care Facilities (statutory)	Every Year (100%)	Every Year (100%)
Home Health Agencies (statutory)	Every 3 Years (33%)	Every 3 Years (33%)
Hospice (statutory)	Every 3 Years (33%)	Every 3 Years (33%)
Non-Accredited Hospitals	--	Every 5 Years (20%)
Accredited Hospitals	0.4% Sample Per Year	1.0% Sample Per Year
ESRD Facilities	--	Every 5 Years (20%)
Ambulatory Surgical Centers	--	Every 5 Years (20%)
Community Mental Health Centers and Rural Health Clinics	--	Every 12 Years (8%)
Outpatient Physical Therapy, Outpatient Rehabilitation, Portable X-Ray	--	Every 12 Years (8%)

**Federal Administration**

For FY 2019, the Budget requests \$703 million for CMS Federal administrative costs, \$25 million below the FY 2018 Continuing Resolution level.

At this level of staff, CMS will be able to support core Medicare, Medicaid, and CHIP operations.

**Survey and Certification**

The FY 2019 Survey and Certification request is \$421 million, a \$26 million increase over the FY 2018 Continuing Resolution level. The increased funding level is needed to maintain non-statutory survey frequency levels due to growing numbers of participating facilities and increasing costs to conduct surveys.

CMS expects states to complete over 20,300 initial surveys and re-certifications and over 58,000 visits in response to complaints in FY 2019. Over 90 percent of the program level request will go to State survey agencies or Federal direct survey costs. Surveys include mandated Federal inspections of long-term care facilities (i.e., nursing homes), home health agencies, hospices, as well as 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.

The Budget also proposes to levy a fee for survey and certification revisits that occur as a result of deficiencies found during initial certification, recertification, or substantiated complaint surveys, in addition to fees for substantiated complaint surveys at the highest levels of deficiency. The fee would provide CMS with an increased ability to revisit poor performers, while creating an incentive for facilities to correct deficiencies and ensure quality of care. IHS facilities would be exempt from the fee. The Budget assumes a six-month lag for collecting fees in the initial year of operation and \$14.1 million in revenue in FY 2019.

## PERFORMANCE HIGHLIGHT

**Reducing Unnecessary Antipsychotic Drug Use in Nursing Homes**

The CMS survey and certification budget aims to improve dementia care in nursing homes by decreasing the percentage of long-stay nursing home residents receiving an antipsychotic medication. Antipsychotic medications have common and dangerous side effects when misused to treat the behavioral and psychological symptoms of dementia. In calendar year 2011, 23.9 percent of long-stay nursing home residents received an antipsychotic medication. In calendar year 2016, CMS met its target of 16.7 percent. CMS set the calendar year 2019 target rate at 15.5 percent.

**Research**

For FY 2019, the Budget requests \$18 million for Research—a \$2 million decrease below the FY 2018 Continuing Resolution level—to maintain the Medicare Current Beneficiary Survey and other research databases which support Medicare payment systems.

**CROSSCUTTING SUMMARIES****National Medicare Education Program**

The total FY 2019 program level for the National Medicare Education Program is \$423.8 million, including \$281.2 million in budget authority. Beneficiary education remains a top priority of CMS to ensure that beneficiaries have accurate and up-to-date information on their coverage options and covered benefits.

Of the total program level, \$307.7 million, or nearly 73 percent, supports the 1-800-MEDICARE call center, which provides beneficiaries with access to customer service representatives who are trained to answer questions regarding the Medicare program. The request will support approximately 26.3 million calls with an average-speed-to-answer of less than five minutes. Beneficiaries can also use 1-800-MEDICARE to report fraud allegations.

The request also includes \$60.5 million for beneficiary materials, the majority of which will fund the *Medicare & You* handbook.



**2019 LEGISLATIVE PROPOSALS*****Rebase National Medicare & You Education Program User Fee***

Effective FY 2019, this proposal allows CMS to assess an increased amount of user fees from Medicare Advantage and Part D plans to more equitably support outreach activities in the National Medicare & You program. [\$30 million in additional collections in FY 2019]

***Change Medicare Beneficiary Education Requirements***

This proposal provides the Secretary with increased flexibility to determine how to efficiently and effectively communicate Medicare benefits information included in the Medicare & You Handbook with beneficiaries, including providing information online as opposed to hard copy. [No budget impact]

***Improve Safety and Quality of Care by Requiring Accreditation Organizations to Publicly Report Medicare Survey and Certification Reports***

Effective FY 2019, hospital accreditation organizations that have deeming authority would be required to publicly report their survey findings for hospitals in a format as specified by the Secretary. [No budget impact]

***Tailor the Frequency of Skilled Nursing Facility Surveys to More Efficiently Use Resources and Alleviate Burden for Top Performing Nursing Homes***

Effective FY 2019, 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

## PROGRAM HIGHLIGHT

**National Medicare & You Education Program (NMEP)  
FY 2019 Program Level  
(dollars in millions)**

Activity	2018	2019
Beneficiary Materials (e.g., Handbook)	57.1	60.5
1-800-MEDICARE and Beneficiary Claims Contact Center	279.8	307.7
Internet	26.3	27.3
Community-Based Outreach	2.4	2.1
Program Support Services/National Ad Campaign	40.6	26.2
<b>Total, NMEP Program Level /1</b>	<b>406.2</b>	<b>423.8</b>

1/ Includes funding from Program Management, user fees, and Quality Improvement Organizations.

quality improvement for poor performing facilities.  
[No budget impact]

***Provide CMS Program Management Implementation Funding***

The Budget provides \$200 million over 10 years for CMS to implement all the CMS legislative proposals included in the Budget. [\$200 million in costs over 10 years]

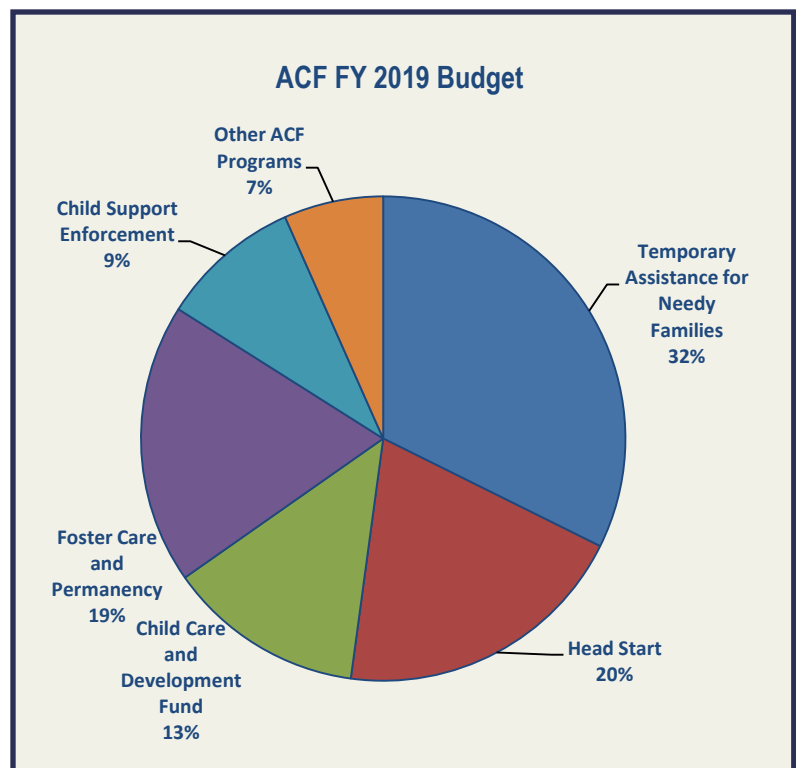
## Administration for Children and Families: Overview



<i>dollars in millions</i>	2017 /1	2018 /2	2019
<b>Mandatory</b>			
Budget Authority	35,087	35,001	31,929
<b>Discretionary</b>			
Budget Authority	19,702	19,144	15,317
<b>Total, ACF Budget Authority</b>	<b>54,789</b>	<b>54,145</b>	<b>47,246</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions. 2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).			

*The Administration for Children and Families promotes the economic and social well-being of children, youth, families, and communities, focusing particular attention on populations such as children in low-income families, refugees, and Native Americans.*

The FY 2019 Budget request for the Administration for Children and Families (ACF) is \$47.2 billion. ACF works in partnership with states and communities that provide critical assistance to families and children while helping them achieve a path to success. ACF's Budget supports enabling more parents to find work and achieve self-sufficiency, lifting their families out of poverty and promoting the school readiness of their children. This effort includes helping families facing financial crises or economic insecurity, thereby combatting child poverty; supporting low-income working families with access to quality child care; improving outcomes for children and families involved in the child welfare system; increasing child support payments; and continuing to support early care and education programs. Funds are also included for programs that serve runaway and homeless youth and victims of domestic violence, dating violence, and human trafficking.



## Administration for Children and Families: Discretionary



dollars in millions	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Early Care and Education Programs</b>				
Head Start	9,225	9,190	9,275	+ 85
Preschool Development Grants /3	250	248	--	-248
Child Care and Development Block Grant (discretionary)	2,856	2,837	3,006	+ 169
<b>Subtotal, Early Care and Education Programs</b>	<b>12,331</b>	<b>12,275</b>	<b>12,281</b>	<b>+ 6</b>
<b>Programs for Vulnerable Populations</b>				
Runaway and Homeless Youth Programs	119	118	119	+ 1
Child Abuse Prevention Programs	98	97	98	+ 1
Child Welfare Programs	325	324	326	+ 2
Chafee Education & Training for Foster Youth	43	43	43	--
Adoption and Guardianship Incentives	38	38	38	--
Native Americans Programs	52	52	52	--
Family Violence Prevention and Services Programs	159	158	159	+ 1
Promoting Safe and Stable Families (discretionary)	60	59	60	+ 1
Personal Responsibility Education Program /4	0	0	75	+ 75
Abstinence Education /4	0	0	75	+ 75
Health Profession Opportunity Grants /4	0	0	85	+ 85
<b>Subtotal, Programs for Vulnerable Populations</b>	<b>892</b>	<b>889</b>	<b>1,130</b>	<b>+ 241</b>
<b>Refugee Programs</b>				
Transitional and Medical Services	490	487	354	-133
Unaccompanied Alien Children	1,415	942	1,148	+ 206
<i>Contingency Fund Score (non-add)</i>	0	0	100	+ 100
Refugee Support Services	203	201	161	-40
Other Programs	34	34	29	-4
<b>Subtotal, Refugee Programs</b>	<b>2,141</b>	<b>1,663</b>	<b>1,692</b>	<b>+ 29</b>
<b>Discontinued Programs</b>				
Low Income Home Energy Assistance Program	3,390	3,367	--	-3,367
Community Services Block Grant	708	710	--	-710
Other Community Services Programs	27	27	--	-27
<b>Subtotal, Discontinued Programs</b>	<b>4,125</b>	<b>4,105</b>	<b>--</b>	<b>-4,105</b>
<b>Other ACF Programs</b>				
Social Services Research & Demonstration	6	6	6	--
Disaster Human Services Case Management	2	2	2	--
Federal Administration	204	204	205	+1
<b>Subtotal, Other ACF Programs</b>	<b>213</b>	<b>212</b>	<b>213</b>	<b>+1</b>
<b>Total Discretionary Budget Authority /4 /5</b>	<b>19,702</b>	<b>19,144</b>	<b>15,317</b>	<b>-3,827</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions. 2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-96), including any funding anomalies and directed or permissive transfers (where applicable). 3/ Funds were transferred to the Department of Education to provide continuation awards for the final year of pre-existing grants. 4/ Program previously received mandatory funding and is discussed in the "ACF Mandatory" chapter. 5/Totals do not include a \$20 million reduction due to a change in mandatory programs for 2017 and 2018 created by the difference between the OMB and CBO baseline assumptions on the mandatory portion of the Promoting Safe and Stable Families (PSSF) account. 6/ Totals may not sum due to rounding.				

The Administration for Children and Families (ACF) provides support to families, refugees, survivors of domestic violence, and many other populations in their efforts to achieve self-sufficiency and economic independence, as well as care for those most in need. The Fiscal Year (FY) 2019 Budget requests \$15.3 billion, a decrease of \$3.8 billion relative to the FY 2018 Continuing Resolution.

## **SUPPORTING FAMILIES AND SELF-SUFFICIENCY**

The FY 2019 Budget continues to invest in funding for two early care and education programs: Head Start and Child Care. These programs offer a two-generation strategy toward upward economic mobility that allows parents and guardians to pursue self-sufficiency while helping their children receive care and education.

### ***Head Start***

The FY 2019 Budget provides \$9.3 billion for Head Start, which includes \$22 million for a cost-of-living adjustment and maintains current funding levels for other parts of the program. Overall, the program is expected to serve 861,000 children at the proposed funding level. In addition, the FY 2019 Budget seeks to reduce the burden of operating these programs by simplifying reporting requirements for Head Start grantees that receive both traditional Head Start funding and funding to operate Early Head Start Expansion and Early Head Start-Child Care Partnerships.

### ***Child Care***

The request increases funding for the Child Care and Development Block Grant by \$169 million above the FY 2018 Continuing Resolution for a total discretionary investment of \$3 billion. The FY 2019 Budget also provides new incentives for states to recover improper child care payments and eliminates the requirement for a national child care hotline, which duplicates the hotlines required of every state. Because health and safety violations or suspected child abuse and neglect at child care centers are handled at the state or local level, the national reporting hotline creates a new federal role and slows down the response to situations where a child may be in danger while requiring families to recount their concerns to multiple agencies.

## **SERVING VULNERABLE CHILDREN AND FAMILIES**

Ensuring that children, survivors of abuse, youth experiencing homelessness, and other at-risk

populations have the services they need continues to be an important goal of the Administration, and the FY 2019 Budget preserves funding for these programs.

### ***Runaway and Homeless Youth***

The most recent national count of individuals and families experiencing homelessness conducted by the Department of Housing and Urban Development identified more than 40,000 young people under age 25 who were not accompanied by a family member and living in a car, on the street, or in a shelter, plus nearly 10,000 more individuals who were caring for a young child and experiencing similar situations. These youth and families are at heightened risk for exploitation, victimization, and other long-lasting, negative outcomes. To respond to the needs of these youth and the millions more who experience homelessness, the FY 2019 Budget continues to provide a \$119 million investment in emergency shelter, transitional housing, and street outreach programs. This investment is anticipated to support more than 600 programs across the country.

### ***Child Abuse Prevention Programs***

ACF provides funding to states and tribes to improve their ability to investigate reports of child abuse and provide training for child protective workers and mandatory reporters. State formula funds are also used to expand community-based efforts to strengthen families and prevent child abuse. ACF also provides competitive research and demonstration funds to expand the evidence base for child welfare programs and investigate the causes, prevention, identification, and treatment of child abuse and neglect. The Budget requests \$98 million for these programs, an increase of \$1 million above the FY 2018 Continuing Resolution.

### ***Child Welfare Programs***

ACF provides formula grants to help state and tribal public welfare agencies expand services, such as by supporting at-risk families and, when appropriate, allowing children to remain with their families or return to them in a timely manner. Funds also support safety and consistent placement for children in foster care and permanency for children in adoptive families. Competitive funding is provided to remove barriers to adoption, especially for the adoption of children with special needs. The Budget provides \$326 million for these activities, an increase of \$2 million above the FY 2018 Continuing Resolution.

***Native Americans***

ACF's Administration for Native Americans promotes economic independence by providing competitive grant funding for community-based projects, and training and technical assistance to Federally recognized Tribes, American Indian and Alaska Native organizations, Native Hawaiian organizations, and Native populations throughout the Pacific Basin. The majority of funding is provided for social and economic development projects. For example, a grant provided to a partnership between the Oregon Native American Business and Entrepreneurial Network, a non-profit Native American business network; two Federally recognized Tribes; and a Native Hawaiian organization, moved people from dependence to independence through the creation or expansion of 55 businesses and 268 full and part-time jobs. Funds also support the preservation of native languages and the environmental protection of tribally controlled lands. The FY 2019 Budget includes \$52 million to support these activities, the same level as the FY 2018 Continuing Resolution.

***Family Violence Prevention and Services***

The FY 2019 Budget requests \$159 million for Family Violence Prevention and Services Programs, including \$8 million for the National Domestic Violence Hotline. With this funding, an estimated 244,000 victims will receive shelter services, and nearly 2.7 million crisis hotline calls will be answered. In addition, the Budget revises the set-asides for Federal administration to ensure efficient operations and requests the authority to lengthen the project period for pilot projects testing specialized services for abused parents and their children. This will maximize the opportunity to learn from these important projects and provide time for robust implementation that can yield significant impacts.

**REFUGEES, ENTRANTS, AND UNACCOMPANIED ALIEN CHILDREN*****Refugees and Other New Arrivals***

ACF provides services to refugees and other eligible new arrivals, such as those granted asylum, to facilitate their successful transition to life in the United States and to help them to attain economic independence. Services are provided through state refugee offices, state and local governments, and a network of national, state, and local non-profit organizations.

The Budget includes \$354 million for transitional and medical services, sufficient to continue to provide eight months of cash and medical benefits to an estimated 119,000 new arrivals, including 45,000 refugees, though the President has not yet determined the 2019 refugee admissions ceiling. Other services for refugees include case management, English as a Foreign Language classes, and job readiness and employment services. The FY 2019 Budget continues to propose that the English Language and job readiness/employment services be consolidated into a single refugee supportive services program to achieve greater efficiencies and reduce the administrative burden on states.

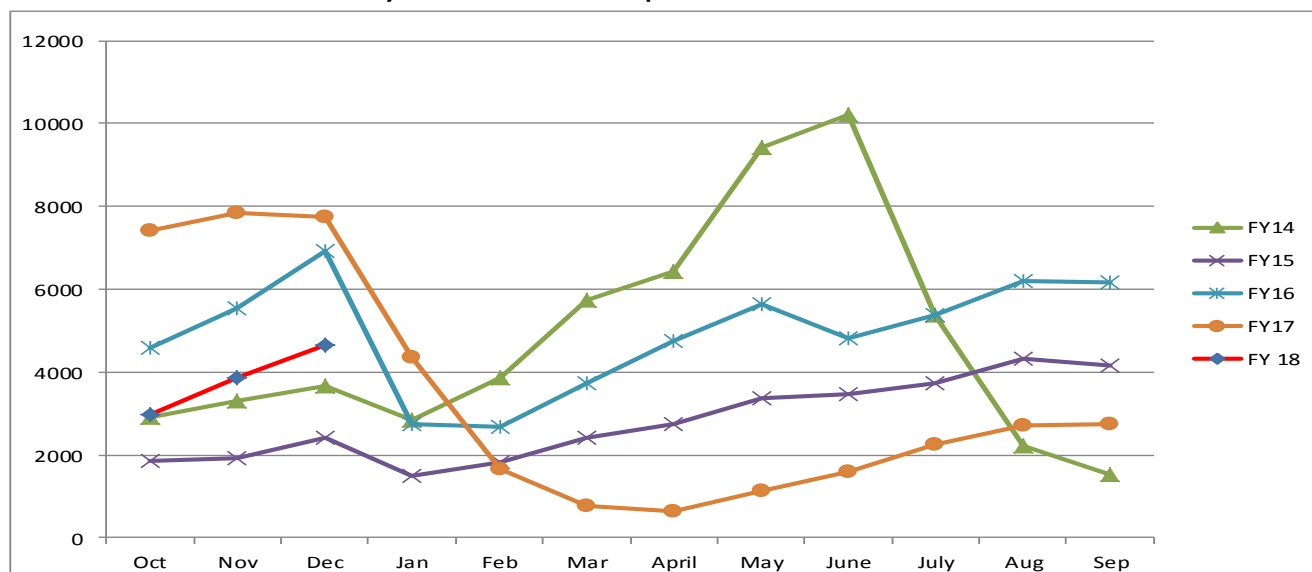
Other programs identify and provide support for victims of human trafficking and provide medical and psychological services for survivors of torture. The FY 2019 Budget includes a legislative proposal to better enable adult victims of trafficking to access refugee benefits while simultaneously improving efficiency and reducing the risk of improper payments.

***Unaccompanied Alien Children***

ACF is legally required to take custody of all unaccompanied alien children (UAC) referred to the Office of Refugee Resettlement by U.S. immigration authorities. Most UAC are apprehended by Customs and Border Protection at the southwest border. They remain in ACF-funded shelters until they can be released to an appropriate sponsor, usually a parent or other close relative, while their immigration cases proceed.

The majority of UAC in ACF's custody are cared for through a network of state-licensed care providers which facilitate medical and mental health care, access to legal services, opportunities for recreation, and five days a week of structured education in basic academic areas. In deciding to release a child to sponsors, ACF considers the child's best interests, taking into consideration danger to self, danger to the community, and risk of flight. The number of UAC requiring shelter fluctuates. Referrals declined rapidly in January of 2017 and remained at historically low levels through the spring. Referrals began increasing in the summer of 2017, but referral levels during the fall were still lower than they had been during the comparable period in the past two years.

Monthly Referrals of Unaccompanied Alien Children to ACF Care



The Budget requests \$1.1 billion in base budget authority for the UAC program, an increase of \$206 million above the FY 2018 Continuing Resolution. This additional funding would be used to meet potential increased demand for the program in the near-term, while also reflecting the successful deterrence of UAC migration to the United States from the Administration's border enforcement efforts. Given the inherent uncertainty about the shelter capacity ACF will need in FY 2019, the Budget includes a contingency fund that will trigger \$200 million in additional resources if capacity needs are higher than anticipated.

## DISCONTINUED PROGRAMS

### *Low Income Home Energy Assistance Program (LIHEAP)*

LIHEAP is unable to demonstrate strong performance outcomes. Furthermore, utility companies and state and local governments provide significant heating and cooling assistance, and the majority of states prohibit utilities from discontinuing a household's energy in periods of severe weather. The FY 2019 Budget continues to propose that no funding be included for LIHEAP, consistent with the FY 2018 Budget.

### *Community Services Programs*

The FY 2019 Budget discontinues funding for the Community Services Block Grant (CSBG), Community Economic Development, and Rural Community Facilities Programs for a savings of \$735 million. Currently, grantees can continue receiving CSBG funds

even if they have not demonstrated strong performance. The formula for distribution is not directly tied to local agency performance. Furthermore, CSBG accounts for only five percent of total funding received by the local agencies that receive these funds.

The Budget proposes the discontinuation of the Community Economic Development or Rural Community Facilities programs, as other Federal programs provide similar services.

## EVALUATION AND INNOVATION

### *Research and Demonstration*

Through evaluation and the use of data and evidence, ACF and our partners are able to improve the effectiveness of existing programs. While some ACF programs have dedicated research and evaluation funding, many do not. The FY 2019 Budget includes \$6.5 million for Social Services Research and Demonstration funds. These funds can be used to study programs without dedicated research and evaluation funding, as well as for cross-cutting studies.

### *Federal Administration*

The Budget provides \$205 million to cover staffing and other administrative costs for the majority of ACF's programs. Administrative expenses include office space, program management and oversight, and the development and maintenance of information technology.



## Administration for Children and Families: Mandatory



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Current Law Budget Authority</b>				
Child Care Entitlement to States /3	2,917	2,917	2,917	-
Child Support Enforcement and Family Support	4,311	4,326	4,322	-4
Children's Research and Technical Assistance /4	34	35	37	+2
Foster Care and Permanency	8,357	8,468	8,738	+270
Promoting Safe and Stable Families (mandatory only) /5	461	322	345	+23
Social Services Block Grant	1,662	1,588	1,700	+112
Temporary Assistance for Needy Families (TANF)	16,737	16,737	16,739	+2
TANF Contingency Fund	608	608	608	-
<b>Subtotal, TANF (non-add)</b>	<b>17,345</b>	<b>17,345</b>	<b>17,347</b>	<b>+2</b>
<b>Total, Current Law Budget Authority</b>	<b>35,087</b>	<b>35,001</b>	<b>35,406</b>	<b>+405</b>
<b>Proposed Law Budget Authority</b>				
Child Care Entitlement to States /3	2,917	2,917	3,216	+299
Child Support Enforcement and Family Support	4,311	4,326	4,398	+72
Children's Research and Technical Assistance /4	34	35	37	+2
Foster Care and Permanency	8,357	8,468	8,756	+288
Promoting Safe and Stable Families (mandatory only) /5	461	322	385	+63
Social Services Block Grant /6	1,662	1,588	-	-1,588
Temporary Assistance for Needy Families (TANF)	16,737	16,737	15,137	-1,600
TANF Contingency Fund	608	608	-	-608
<b>Subtotal, TANF (non-add)</b>	<b>17,345</b>	<b>17,345</b>	<b>15,137</b>	<b>-2,208</b>
<b>Total, Proposed Law Budget Authority</b>	<b>35,087</b>	<b>35,001</b>	<b>31,929</b>	<b>-3,072</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions. 2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable). 3/ The Child Care Entitlement to States contains mandatory funding for the Child Care Development Fund, which also includes discretionary funding from the Child Care Development Block Grant. 4/ The FY 2019 budget authority amount in this display for the Children's Research and Technical Assistance account does not include restored reimbursable authority (due to sequestration from the prior fiscal year). 5/ The 2019 total for Promoting Safe and Stable Families (PSSF) reflects the proposal to fund Abstinence Education and the Personal Responsibility Education Programs through the ACF discretionary budget, with a proposed reauthorization for each program in FY 2019. In addition, there is a discretionary appropriation of \$60 million for PSSF in FY 2017, \$59 million in FY 2018, and \$60 million proposed in FY 2019. Totals do not include a \$20 million reduction due to a change in mandatory programs for 2017 and 2018 created by the difference between the OMB and CBO baseline assumptions on the mandatory portion of the PSSF account. 6/ The 2019 total reflects the proposal to fund Health Profession Opportunity Grants through the ACF discretionary budget.				

The Fiscal Year (FY) 2019 Budget requests \$31.9 billion in budget authority for the Administration for Children and Families (ACF) mandatory programs. ACF serves individuals and families in need of assistance and promotes work and self-sufficiency through mandatory programs, including Child Care Entitlement to States, Child Support Enforcement, Foster Care, Adoption Assistance, Guardianship, Independent Living, Promoting Safe and Stable Families, and Temporary Assistance for Needy Families.

### CHILD CARE ENTITLEMENT TO STATES

The Budget requests a total of \$6.2 billion in budget authority for the Child Care and Development Fund, including \$3.2 billion in budget authority for the Child Care Entitlement to States, an increase of \$2.3 billion in mandatory budget authority over 10 years. This request will ensure that Federal mandatory funding for HHS child care programs is maintained across the ten-year window, taking into account the interactions with proposals for the Temporary Assistance for Needy

Families program, and the Social Services Block Grant. This investment will leverage approximately \$1.8 billion in additional state support for child care over ten years.

#### **CHILD SUPPORT ENFORCEMENT AND FAMILY SUPPORT PROGRAMS**

The Child Support Program is a joint Federal, state, tribal, and local partnership that operates under title IV-D of the Social Security Act with the vision that children can count on their parents for the financial, medical, and emotional support they need to be healthy and successful even when they live in different households. The program functions in 54 States and territories, and 63 tribes. The Federal child support program seeks to ensure financial and emotional support for children from both parents by locating non-custodial parents, establishing paternity, and establishing and enforcing child support orders. The Budget requests \$4.4 billion in budget authority in FY 2019 for Child Support Enforcement and Family Support Programs.

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. These proposals are estimated to save \$679 million over 10 years, which includes combined savings of \$387 million in the Supplemental Security Income and the Supplemental Nutrition Assistance Programs.

As part of the Administration's commitment to promoting work and self-sufficiency, the Budget includes a proposal that will help noncustodial parents engage in work activities. The proposal will enable noncustodial parents to provide for their children, and offers families a pathway towards economic independence.

In addition, the Budget achieves \$793 million in net savings over 10 years for a technology enhancement and replacement fund to acquire model child support systems and applications and make them available to states. This proposal plans to maximize reusable technology to create savings and cost-efficiencies for states and the Federal Government and provide better service delivery to child support customers. The proposal leverages reusable technology to provide a cost-effective solution to the widespread and pressing

issue of replacing aging child support systems. With this solution state child support agencies will be able to serve a larger number of families, providing them improved customer service, greater transparency, and more efficient processing of child support payments, all while saving Federal taxpayers' money.

#### **PROGRAM HIGHLIGHT**

##### **Child Support Highlights**

The Child Support Program continues to make strong gains in establishing child support orders and increasing child support collections. In FY 2016:

- Child Support collections increased to \$28.8 billion.
- Child support orders were established for 86 percent of child support cases, which exceeded the performance target of 85 percent.
- For every dollar invested in the program, \$5.33 in child support was collected, which exceeded the performance target of \$5.00.
- The Tribal Child Support Program oversaw 59 comprehensive tribal IV-D programs, and an additional four start-up tribal programs.

#### **CHILDREN'S RESEARCH AND TECHNICAL ASSISTANCE**

The FY 2019 President's Budget includes \$37 million in Children's Research and Technical Assistance, devoted to training and technical assistance (\$12 million) and operating the Federal Parent Locator Service (\$25 million).

The Budget proposes to extend access to the National Directory of New Hires, a component of the Federal Parent Locator System, to multiple agencies to improve efficiencies and strengthen program integrity. Also, the Budget will use access to the National Directory of New Hires to support statistical activities, evaluation, and workforce program administration and evaluation.

## NEW INITIATIVE

**National Directory of New Hires and Program Integrity**

The National Directory of New Hires provides employment and unemployment insurance information that enables state child support agencies to be more effective in locating noncustodial parents and establishing and enforcing child support orders. The National Directory of New Hires can also be used to increase the efficiency and effectiveness of other Federal programs through data matching.

The Budget contains a suite of National Directory of New Hires access proposals that support program integrity efforts within other Federal agencies. These proposals will require the Department of Health and Human Services to review each agency's information security position before any data is provided and require the Department to generate a public report on the use of National Directory of New Hires data.

**FOSTER CARE AND PERMANENCY**

The Budget requests \$8.8 billion for the Foster Care, Adoption Assistance, Guardianship Assistance, and Independent Living programs, an increase of \$288 million over FY 2018. These programs, authorized by title IV-E of the Social Security Act, support safety and permanency for children separated from their families and prepare older foster youth for independence.

Funding goes primarily to states as a reimbursement for board and care payments for children in foster care who are eligible for title IV-E funding, to payments related to adoption and guardianship, and to the Chafee Foster Care Independence Program, which offers assistance to current and former foster youth up to age 21 in obtaining education, employment, and life skills for upward economic mobility, and to related administrative costs. The program is also available to tribal agencies with an approved title IV-E plan to help strengthen their child welfare systems.

The Budget includes a new proposal to create a flexible funding option for states and tribes to expand allowable uses of foster care maintenance and administration payments (excluding training and information systems payments, adoption assistance and guardianship programs, and the Chafee Foster Care Independence Program). Unlike the existing

system, in which Federal funds can only be used to reimburse the costs of foster care, adoption and guardianship payments, the flexible funding option would allow Federal foster care funds to be used for any of the purposes or services authorized for child welfare spending under titles IV-B and IV-E of the Social Security Act, empowering states to invest broadly in services that promote permanency and stability for children. The flexible funding option would also remove the burdensome and prescriptive title IV-E eligibility requirements and the need to participate in eligibility reviews and certain plan requirements while continuing to monitor performance through Child and Family Services Reviews, for which participating states will be eligible for performance incentives. The proposal to provide title IV-E funds through a flexible funding option is cost-neutral; the performance incentives component adds a 10-year cost of \$110 million.

**PROMOTING SAFE AND STABLE FAMILIES**

The Budget includes \$385 million for the mandatory portion of the Promoting Safe and Stable Families program for FY 2019. These funds provide formula grants to states to provide services to families, address child safety at home, and provide supportive services for reunifying and adoptive families. Funding also supports grants to state and tribal courts in improving the handling of child welfare proceedings, and Regional Partnership Grants, a competitive grant program that reduces the risk of children being removed from their parents' homes due to parental substance abuse.

The Budget reauthorizes Promoting Safe and Stable Families (title IV-B of the Social Security Act) through FY 2023 at \$385 million per year. This includes an expansion of the Regional Partnership Grants program by \$40 million per year with a five-year reauthorization, for a total cost of \$200 million. This expansion will enable Regional Partnership Grants to reach more communities, especially rural communities, to help address the impact of opioid abuse on children and families.

This account includes two other programs: the Personal Responsibility Education Program and Abstinence Education. The Personal Responsibility Education Program provides formula grants to states to educate adolescents on pregnancy prevention, sexually transmitted diseases, and adulthood preparation subjects such as relationship skills and financial literacy.

Abstinence Education provides formula grants to states to support programs that present ways teens can develop healthy and positive relationships and promote reasons to delay sexual activity. Projects 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 minority groups with disparities in teen birth rates. The Budget reauthorizes both programs through FY 2019 at the current levels of \$75 million per year for each program. The Budget also proposes certain cost-neutral policy changes within the programs. For Abstinence Education, the Budget reduces the matching requirement, adding a program integrity set-aside, and allowing local entities to compete for funds not accepted by states. For the Personal Responsibility Education Program, the Budget doubles the set-aside for the Tribal Personal Responsibility Education Program to \$6.5 million. Support for these programs, previously funded in this account, is requested in ACF's discretionary budget.

#### NEW INITIATIVE

### Child Welfare: Performance and Prevention

The Budget's proposals for Child Welfare are intended to improve the performance of the child welfare system overall, and to prevent child maltreatment and entry into foster care. For participating states, the flexible funding option for foster care maintenance and administration will lift the burden of carrying out title IV-E eligibility determinations, allowing states to devote resources to strengthening and stabilizing families to keep children living safely at home, to improving outcomes for children in foster care, and to supporting families who adopt or assume legal guardianship of children in foster care who are unable to return home.

Similarly, the proposal to expand Regional Partnership Grants extends the reach of this program to serve more children, families, and communities grappling with the impact of substance use disorders, including opioid abuse, on child welfare. Results from the first round of Regional Partnership Grants showed that the majority of children served had timely reunifications with their parents and a low rate of re-entry into foster care. A funding increase will allow this important and promising program to expand beyond the 19 States it currently serves, especially to reach rural areas reporting high rates of opioid abuse.

### SOCIAL SERVICES BLOCK GRANT

The FY 2019 Budget eliminates funding for the Social Services Block Grant for a savings of \$1.7 billion in FY 2019 and \$17 billion over 10 years. The Social Services Block Grant provides funding that is duplicative of resources available through other Federal programs and has not demonstrated its effectiveness in reducing dependency on welfare or supporting self-sufficiency. As a 2011 U.S. Government Accountability Office report pointed out, the Social Services Block Grant is fragmented, provides duplicative or overlapping services, and has limited accountability. The grant essentially offers a no-strings-attached approach to taxpayer funds. Eliminating the grant aligns with the Administration's goal of supporting welfare programs that effectively help low-income families move to independence through paid employment. Furthermore, the proposal represents the Administration's commitment to focus limited taxpayer dollars on program outcomes, not inputs, to ensure they are effectively helping low-income families.

Recognizing that the Social Services Block Grant is sometimes used to provide rapid and flexible funding for disaster relief, the Budget maintains the grant's authorization for possible future use in emergencies. The Budget also proposes to continue the Health Profession Opportunity Grants program through FY 2019. Support for this program, previously funded in this account, is requested in ACF's discretionary budget.

### TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

The Temporary Assistance for Needy Families (TANF) block grant was created to provide states, territories, and eligible tribes the opportunity to design programs that help families transition from welfare to self-sufficiency. As a result, the statute gives states, territories, and tribes tremendous flexibility in determining how to use their TANF dollars to meet their citizen's needs and get them back on their feet.

The Budget proposes \$15.1 billion for the Temporary Assistance for Needy Families State and Territory Family Assistance Grants, which reflects a 10 percent reduction from the FY 2018 level. This funding level builds on the successes of welfare reform and re-focuses TANF Families as an effective anti-poverty program that promotes economic independence.

Despite its successes, the TANF program could perform better in moving low-income families from welfare to work. Recent data shows that states are spending less on work, education, and training activities that can help families achieve economic independence. In FY 2016, 26 States spent less than 30 percent of their TANF and maintenance of effort funds on work, education, and training, and work supports and child care; and 44 States spent less than 15 percent on work, education, and training. Furthermore, many states have taken advantage of provisions in the law that allows them to reduce their level of effort in engaging TANF recipients in work. For example, in FY 2016, 20 States had reduced their required work participation rate target for all families from 50 percent to zero percent through the caseload reduction credit. To address these issues, the Budget includes a legislative proposal that strengthens the program's focus on work and self-sufficiency for low-income families and ensures that states invest in work activities that will benefit low-income families.

The Budget also includes the Welfare to Work Projects proposal that offers five-to-seven States the opportunity to streamline funding from Federal antipoverty programs and design comprehensive plans to deliver coordinated and effective services to

low-income families. Participating states will have to tailor programs to their constituent's needs, and reduce burdens and inefficiencies that result from overlapping and at times conflicting program requirements. Ultimately, this proposal will create a portfolio of rigorously planned and evaluated demonstrations that will cultivate evidenced-based strategies grounded in the values of work and personal responsibility. This approach will allow increased flexibility for participating states to tailor programs to their constituents' needs, reduce burdens and inefficiencies due to overlapping program requirements, and allow us to learn from their experiences.

The Budget again proposes to eliminate the TANF Contingency Fund, saving more than \$6 billion dollars over 10 years. This proposal advances the Administration's goal of increasing the effectiveness and efficiency of Federal benefit spending programs. The Administration looks forward to working with Congress to ensure TANF resources are targeted to families that are temporarily in need of additional support while maintaining welfare reform's emphasis on recipients progressing to self-sufficiency through unsubsidized employment.



### Using Human Services Programs to Encourage Self-Sufficiency

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) was built on the principle that work and personal responsibility are key to reducing long-term government dependence and achieving economic security. Since the enactment of PRWORA, both the Temporary Assistance for Needy Families (TANF) and the child support enforcement program have fostered economic security and stability for low-income families with children through services like support order enforcement, short-term cash assistance, and a range of services to promote work. However, much of the progress experienced after the enactment of welfare reform has been slowed due to the unforeseen consequences of policies, and complex program rules have moved the focus of the programs away from work. More than 20 years later, it is time to revive a vision for a safety net that encourages state and local innovation and promotes the principle that gainful employment is the best pathway to economic self-sufficiency and family well-being. The Administration is committed to changing the culture of dependence that contributes to cycles of poverty within the Nation. The first step in fulfilling this commitment was rescinding a policy that encouraged waivers from TANF work requirements. The next step will be working with Congress to enact key reforms to the TANF program that will help states improve employment outcomes. For example, to ensure sufficient TANF investments in work promotion activities, the Budget proposes adding a requirement that states spend at least 30 percent of Federal TANF and state maintenance-of-effort funds on: work, education, and training activities; work supports, including child care; and assessment/service provision for TANF eligible families. The Budget also proposes strengthening TANF's primary performance measure related to work engagement by: replacing the caseload reduction credit with an employment credit that rewards states for moving TANF recipients to work; collapsing the two work participation rates into one standard rate, thereby eliminating the "marriage penalty"; and allowing states to count partial credit towards the work participation rate to incentivize participation among all TANF recipients.

True welfare reform cannot focus solely on the TANF program; it must also encompass the other loose confederation of safety-net programs. While these single-purpose programs deliver crucial services to help low-income Americans, they reflect a complex and bureaucratic system that lacks a holistic approach to serving the needs of low-income Americans and that fails to consistently promote economic independence. To address this problem, the Budget proposes to support partnerships between states, localities, and other Federal agencies through new Welfare to Work Projects. These demonstrations will allow for the redesign of public assistance programs so that they provide an integrated approach to reducing poverty and government dependency and promoting personal responsibility. State applications must demonstrate how the proposed innovative approaches and coordinated service delivery will achieve outcomes related to fostering employment, reducing welfare dependency, and promoting child well-being. These demonstrations will be rigorously evaluated and will serve to build the evidence base of best practices for helping low-income individuals and families achieve self-sufficiency.

Finally, the Administration will encourage states to reform how their local child support agencies engage with noncustodial parents. The child support program is highly successful at collecting child support from noncustodial parents who are employed but has little success among those with barriers to sustained employment. Unfortunately, current law allows states to order work activities only for noncustodial parents who owe overdue support for a child receiving assistance from the TANF program. In order to ensure that states have the flexibility necessary to engage work-capable adults in work, the Budget proposes to give states the authority to order any noncustodial parent who owes overdue support into work activities and to provide limited Federal funding for those work activities through title IV-D. Significant evaluation evidence shows that work programs for unemployed noncustodial parents increase employment rates and in turn consistent child support payments. This proposal reflects an evidence-based approach to promoting personal responsibility, empowering noncustodial parents to provide for their children, and allowing families to avoid government dependence.



## Administration for Children and Families: Mandatory



### FY 2019 ACF Mandatory Outlays

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Current Outlays</b>				
Child Care Entitlement to States /3	2,905	3,010	2,943	-67
Child Support Enforcement and Family Support	4,075	4,206	4,258	+52
Children's Research and Technical Assistance	46	43	52	+9
Foster Care and Permanency	7,712	8,266	8,597	+331
Promoting Safe and Stable Families (mandatory only) /4	411	445	385	-60
Social Services Block Grant	1,606	1,621	1,718	+97
Sandy Supplemental /5	55	-	-	-
Temporary Assistance for Needy Families (TANF)	15,974	16,331	16,511	+180
TANF Contingency Fund	567	626	609	-17
<b>Subtotal, TANF (non-add)</b>	<b>16,541</b>	<b>16,957</b>	<b>17,120</b>	<b>+163</b>
<b>Total, Current Law Outlays</b>	<b>33,351</b>	<b>34,548</b>	<b>35,073</b>	<b>+525</b>
<b>Proposed Law Outlays</b>				
Child Care Entitlement to States /3	2,905	3,010	3,165	+155
Child Support Enforcement and Family Support	4,075	4,206	4,334	+128
Children's Research and Technical Assistance (mandatory only)	46	43	52	+9
Foster Care and Permanency	7,712	8,266	8,615	+349
Promoting Safe and Stable Families (mandatory only) /4	411	445	398	-47
Social Services Block Grant /6	1,606	1,621	307	-1,314
Sandy Supplemental /5	55	-	-	-
Temporary Assistance for Needy Families (TANF)	15,974	16,331	15,356	-975
TANF Contingency Fund	567	626	64	-562
<b>Subtotal, TANF (non-add)</b>	<b>16,541</b>	<b>16,957</b>	<b>15,420</b>	<b>-1,537</b>
<b>Total, Proposed Law Outlays</b>	<b>33,351</b>	<b>34,548</b>	<b>32,291</b>	<b>-2,257</b>
<p>1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.</p> <p>2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).</p> <p>3/ The Child Care Entitlement to States contains mandatory funding for the Child Care Development Fund, which also includes discretionary funding from the Child Care Development Block Grant.</p> <p>4/ The total for Promoting Safe and Stable Families includes the transfer of the Abstinence Education and the Personal Responsibility Education Programs to the ACF discretionary budget, with a proposed reauthorization for each program in FY 2019. In addition, there is a discretionary appropriation of \$60 million for Promoting Safe and Stable Families in FY 2017, \$59 million in FY 2018, and \$60 million proposed in FY 2019.</p> <p>5/ The Disaster Relief Appropriations Act of 2013 provided \$500 million in funding for Social Services Block Grant to aid in the recovery from Hurricane Sandy.</p> <p>6/ The proposed law reflects the proposed reauthorization of the Health Profession Opportunity Grants and its transfer to the ACF discretionary budget.</p>				



## Administration for Children and Families: Mandatory

### FY 2019 ACF Mandatory Legislative Proposals

<i>dollars in millions</i>	2019	2019 -2023	2019 -2028
<b>Proposed Law Outlays</b>			
Increase the Child Care Entitlement to States	222	1,110	2,220
Strengthening Child Support Enforcement and Establishment /1	-23	-265	-679
Technology Enhancement and Replacement Fund	63	-33	-793
Get Noncustodial Parents to Work /2	5	34	97
<b>Subtotal, Child Support (non-add) /3</b>	<b>45</b>	<b>-263</b>	<b>-1,375</b>
Permitting Access to Treasury, USDA, and the Railroad Retirement Board	-	-	-
Interaction with Zero-Fund the Social Services Block Grant	18	105	220
Create Child Welfare Flexible Funding Option	-	23	110
Reform Title IV-E Adoption Assistance Savings Provisions	-	-	-
Provide Tribal Access to the Federal Parent Locator Service	-	-	-
<b>Subtotal, Foster Care and Permanency (non-add)</b>	<b>18</b>	<b>128</b>	<b>330</b>
Reauthorize Promoting Safe and Stable Families /4	-	-	-
Expand Regional Partnership Grants	13	168	200
<b>Subtotal, Promoting Safe and Stable Families (non-add)</b>	<b>13</b>	<b>168</b>	<b>200</b>
Zero-Fund Social Services Block Grant	-1,411	-8,160	-16,660
<b>Subtotal, Social Services Block Grant (non-add)</b>	<b>-1,411</b>	<b>-8,160</b>	<b>-16,660</b>
Reduce Temporary Assistance for Needy Families (TANF)	-1,155	-7,240	-15,240
Welfare to Work Projects	-	-	-
TANF Technical Improvements	-	-	-
Eliminate the TANF Contingency Fund	-545	-2,977	-6,017
<b>Subtotal, TANF (non-add)</b>	<b>-1,700</b>	<b>-10,217</b>	<b>-21,257</b>
<b>Total Outlays, ACF Legislative Proposals</b>	<b>-2,813</b>	<b>-17,234</b>	<b>-36,542</b>
1/ The Strengthening Child Support Enforcement and Establishment proposals outlays in this table incorporate estimated savings from the Supplemental Nutrition Assistance Program (\$249 million over 10 years) and the Supplemental Security Income program (\$138 million over 10 years), which will result from this proposal. The outlays include the cost of \$293 million over 10 years from Federal Offsetting Collections. 2/ Proposal incorporates estimated savings from the Supplemental Nutrition Assistance Program (\$119 million over 10 years) and the Supplemental Security Income program (\$16 million over 10 years). This proposal includes the cost of \$45 million over 10 years from Federal Offsetting Collections. 3/ Subtotals adjusted to account for rounding. 4/ Reauthorizing the underlying Promoting Safe and Stable Families program through FY 2023 does not score. However, the proposal to add \$40 million per year to the Regional Partnership Grants program within Promoting Safe and Stable Families costs \$200 million over ten years. Totals do not include a \$20 million reduction due to a change in mandatory programs for 2017 and 2018 created by the difference between the OMB and CBO baseline assumptions on the mandatory portion of the PSSF account.			

## Administration for Community Living



<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Health and Independence Services</b>				
Home & Community-Based Supportive Services	349	348	350	2
Nutrition Services	833	832	838	6
Native American Nutrition & Supportive Services	31	31	31	--
Preventive Health Services	20	20	25	5
Chronic Disease Self-Management /3	8	7	--	-7
Falls Prevention /3	5	5	--	-5
Aging Network Support Activities	10	10	9	-1
<b>Subtotal, Health and Independence</b>	<b>1,257</b>	<b>1,252</b>	<b>1,253</b>	<b>1</b>
<b>Caregiver Services</b>				
Family Caregiver Support Services	150	150	151	1
Native American Caregiver Support Services	8	8	8	--
Alzheimer's Disease Program /4	19	19	19	--
Lifespan Respite Care	3	3	3	--
<b>Subtotal, Caregiver Services</b>	<b>176</b>	<b>175</b>	<b>181</b>	<b>6</b>
<b>Protection of Vulnerable Older Adults</b>				
Long Term Care Ombudsman Program	16	16	16	--
Prevention of Elder Abuse & Neglect	5	5	5	--
Senior Medicare Patrol Program (HCFAC)	18	18	18	--
Elder Rights Support Activities	14	14	12	-2
<b>Subtotal, Protection of Vulnerable Older Adults</b>	<b>52</b>	<b>52</b>	<b>51</b>	<b>-2</b>
<b>Disability Programs, Research and Services</b>				
Partnerships for Innovation, Inclusion, and Independence	--	--	--	--
State Councils on Developmental Disabilities	73	73	56	-17
Developmental Disabilities Protection and Advocacy	39	38	39	--
Projects of National Significance	10	10	1	-9
University Centers for Excellence in Developmental Disabilities	39	38	33	-6
Nat'l Institute on Disability, Independent Living, & Rehab. Research /5	104	103	--	-103
Independent Living	101	100	96	-4
Traumatic Brain Injury	9	9	9	--
Limb Loss Resource Center	2	2	--	-2
Paralysis Resource Center	7	7	--	-7
<b>Subtotal, Disability Programs, Research and Services</b>	<b>383</b>	<b>381</b>	<b>234</b>	<b>-148</b>
<b>Consumer Information, Access and Outreach</b>				
Voting Access for People With Disabilities (Help America Vote Act)	5	5	5	--
Aging and Disability Resource Centers	6	6	6	--
State Health Insurance Assistance Program	47	47	--	-47
Assistive Technology	34	34	32	-2
Medicare Improvements for Patients and Providers Act Programs	35	38	38	--
<i>Discretionary Budget Authority</i>	--	--	38	38
<i>Current Law Mandatory</i>	35	--	--	--
<i>Proposed Law Mandatory</i>	--	38	--	--
<b>Subtotal, Consumer Information, Access and Outreach</b>	<b>131</b>	<b>133</b>	<b>81</b>	<b>-52</b>

<i>dollars in millions</i>	2017/1	2018/2	2019	2019 +/-2018
<b>Other Programs, Total, and Less Funds From Other Sources</b>				
Program Administration	40	40	38	-2
<b>Total, Program Level</b>	<b>2,040</b>	<b>2,033</b>	<b>1,837</b>	<b>-197</b>
Less Funds from Other Sources/6	81	81	18	-63
<b>Total, Budget Authority</b>	<b>1,959</b>	<b>1,953</b>	<b>1,819</b>	<b>-134</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ The FY 2019 Budget consolidates the Chronic Disease Self-Management and Falls Prevention Programs into the Preventive Health Service Program.				
4/ The FY 2019 Budget consolidates ACL's Alzheimer's Disease activities into a single grant program.				
5/ The FY 2019 Budget consolidates the National Institute on Disability, Independent Living, and Rehabilitation Research program from ACL to NIH.				
6/Source of funds displayed consistent with prior year presentations and the assumptions for the FY 2019 Budget.				

*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) helps older adults and people with disabilities to live independently and gain access to community-based supportive services. ACL's programs provide services that empower people with disabilities, older adults, and their families and caregivers to live and participate in community settings with equal opportunities for independence. In addition, ACL also invests in innovation and education to improve the quality and availability of these services for older adults and people with disabilities.

The Fiscal Year (FY) 2019 Budget requests \$1.8 billion for ACL, which is \$197 million below the FY 2018 Continuing Resolution. The Budget prioritizes funding for direct service programs that focus on ensuring that both older adults and people with disabilities are able to live in the community with the supports they need to remain independent. In addition, ACL's request creates flexibility for states to allocate resources to meet state-specific challenges and needs and decreases duplication of services.

#### **HELPING SENIORS STAY HEALTHY AND INDEPENDENT**

The growth in the number and proportion of older adults is unprecedented in the history of the United States. In 2015, there were nearly 67 million people aged 60 or older. By 2030, that number is expected to reach almost 94 million, and people aged 65 and older will account for roughly 20 percent of the United States population. The Budget maintains funding for essential

nutrition and community-based services to help older Americans stay healthy, independent, and active in their communities. The Budget also includes a new general provision to maximize funding flexibility for states to use Older American Act funding, which includes Nutrition Services, Home and Community-Based Services, Family Caregiver Support Services, and Preventive Health Services Programs. This flexibility will allow states to direct funding to activities that are most needed in their communities.

#### ***Nutrition Services Programs***

The Budget requests \$838 million for Nutrition Services, which is \$6 million above the FY 2018 Continuing Resolution. ACL's nutrition programs provide healthy meals and other related services to approximately 2.4 million older adults every year. These programs are provided in congregate facilities such as senior centers, and through delivery to seniors who are homebound due to illness, disability, or geographic isolation.

#### ***Home and Community-Based Supports***

The Budget also includes a total of \$375 million for Home and Community Based Supportive Services and Preventive Health Services, \$8 million above the FY 2018 Continuing Resolution. The Home and Community-Based Supportive Services Program supports through formula grants to states a variety of activities that help older adults and people of all ages with disabilities to live independently and avoid costlier care settings. Among other services, the Budget

request supports 45.5 million hours of personal care, homemaker, and chore services, as well as 10.3 million hours of adult care. Providing a variety of supportive services that meet the diverse needs of older adults and individuals with disabilities enables them to stay and remain healthy in their homes and communities.

The Preventive Health Services Program focuses on the prevention of chronic disease and disability by providing formula grants to states and territories to support evidence-based interventions. The FY 2019 Budget request consolidates the Falls Prevention Program and the Chronic Disease Self-Management Program into the Preventive Health Service Program. With this consolidation, states will have more flexibility to direct funding based on local needs.

#### **Other Aging Programs**

The Budget provides a total of \$40 million, the same level as the FY 2018 Continuing Resolution, for two other health and independence services: the Native American Nutrition and Supportive Services at \$31 million and the Aging Network Support Activities at \$9 million. These programs provide services such as adult day care, referral and outreach, transportation, and nutrition services to help postpone the need for expensive institutional services and allow Native Americans to remain in their community for as long as possible.

The FY 2019 Budget shifts mandatory funding for the following programs to discretionary funding: Aging and Disability Resource Centers, Area Agencies on Aging, the National Center for Benefits Outreach and Enrollment, and the State Health Insurance Assistance Program. The Budget proposes \$38 million for these programs, which provide grants to states to fund outreach activities targeted to low-income and rural populations to provide beneficiary education and enrollment assistance for Medicare.

#### **CAREGIVER AND FAMILY SUPPORT SERVICES**

Informal caregivers provide over \$500 billion worth of services every year that would otherwise likely need to be provided in an institutional setting. Research has shown that coordinated support services can enable caregivers to provide care longer, which avoids or delays the need for costly institutional care services that might otherwise be paid through Medicaid and Medicare. The Budget includes \$162 million, \$1 million above the FY 2018 Continuing Resolution, to fund three

programs designed to support family and informal caregivers.

#### **PROGRAM HIGHLIGHT**

##### **Home and Community-Based Supportive Services**

The Home and Community-Based Supportive Services (HCBSS) program funds a variety of services that enable seniors and individuals with disabilities to stay and remain healthy in their homes and communities. The FY 2019 Budget provides a total of \$350 million, which is \$2 million above the FY 2018 Continuing Resolution. The services provided to seniors through the HCBSS program include transportation, case management, and referrals; in-home services such as personal care and homemaker assistance; and community services such as adult day care and physical fitness programs. In FY 2016, through the HCBSS program, seniors received over 40.8 million hours of assistance to perform activities of daily living, 23.7 million rides to doctor's office, pharmacies' and senior centers, and engaged in 3.6 million hours of case management services.

The National Family Caregiver Support Program and the Native American Caregiver Support Services Program work in conjunction with state and community-based programs to provide coordinated support services such as counseling, respite care, and training. In the last national survey, over one-fifth of caregivers who participate in these programs indicated that without the services they receive, the care recipient would be living in a nursing home.

In FY 2019, the Family Caregiver Support Program will serve approximately 855,000 family caregivers. In addition to these efforts, the Lifespan Respite Care Program supports the development and expansion of coordinated systems of accessible, community-based respite care services for family caregivers of children or adults with special needs.

#### **Alzheimer's Disease**

The FY 2019 Budget maintains funding for Alzheimer's Disease activities at \$19 million, the same level as the FY 2018 Continuing Resolution. Alzheimer's Disease is the sixth leading cause of death in the United States. An estimated 5.3 million Americans age 65 and older are living with Alzheimer's Disease and other dementias, and nearly 14 million Americans may be diagnosed by 2050. The Budget consolidates ACL's Alzheimer's Disease activities into a single grant program to provide greater flexibility to States,

Territories, and Tribes, which are best equipped to identify and address the needs of their communities.

## **IMPROVING THE LIVES OF PEOPLE WITH DISABILITIES**

As many as 57 million people with all types of disabilities live in the community, as of 2015, and between 3.9 and 5.3 million Americans of all ages are living with intellectual disabilities. ACL works with States, Territories, communities, and non-profit organizations, to improve access to community-based care, which in turn enables individuals with disabilities to live independently.

### ***Protection and Advocacy***

The Budget requests \$39 million, the same level as the FY 2018 Continuing Resolution, to maintain funding for the Developmental Disabilities Protection and Advocacy Program. Protection and Advocacy Systems protect the legal and human rights of all persons with developmental disabilities. Research indicates that children with disabilities are four to ten times more likely to experience abuse or neglect than children without a disability.

### ***State Councils on Developmental Disabilities***

The Budget also requests \$56 million, which is \$17 million below the FY 2018 Continuing Resolution, to continue funding for State Councils on Developmental Disabilities, a nationwide network charged with identifying and addressing the most pressing needs of people with developmental disabilities in their state or territory. State Councils focus on developmental disabilities that are lifelong, significant, and require ongoing support from existing and innovative services that improve the quality of life of those with developmental disabilities. These services will help them achieve independence, productivity, integration, self-determination and inclusion in the community. ACL will work with grantees to identify ways to improve efficiencies in the State Councils.

### ***Independent Living***

ACL's Independent Living programs help people of all ages, with all types of disabilities, live independently. Independent Living Programs work to coordinate services provided to individuals with disabilities, conduct resource development activity, and foster working relationships among centers for independent living. The FY 2019 Budget provides a total of

\$96 million, which is \$4 million below the FY 2018 Continuing Resolution. ACL's Centers for Independent Living serve about 250,000 people with disabilities with tools, resources, and support to promote equal opportunities for independence, including going to school, working, living in the community, and making daily decisions about life. Since its inception in 2008, the Veteran-Directed Home-and Community-Based Services program has enabled more than 6,700 veterans live in their own homes, rather than in nursing homes.

### ***National Institute on Disability, Independent Living, and Rehabilitation Research***

The Budget transfers the National Institute on Disability, Independent Living, and Rehabilitation Research to the National Institutes of Health (NIH), which complements existing NIH research portfolios addressing disabilities and aging. The Budget provides \$95 million for these activities, which is \$8 million below the FY 2018 Continuing Resolution.

### ***Other Disability Programs***

The Budget requests \$34 million, which is \$15 million below the FY 2018 Continuing Resolution, for other disability programs, research and services. The Budget provides \$33 million for University Centers for Excellence in Developmental Disabilities, which is \$6 million below the FY 2018 Continuing Resolution, and \$1 million for Projects of National Significance, \$9 million below the FY 2018 Continuing Resolution, in order to prioritize funding for direct services such as senior meals, caregiver support, and Centers for Independent Living.

The Budget also includes \$9 million, the same level as the FY 2018 Continuing Resolution, to continue funding the Traumatic Brain Injury Program, which supports grant programs that provide rehabilitation, counseling, and vocational services to individuals with Traumatic Brain Injury.

## **RESPONSIBLE STEWARDSHIP AND DELIVERY OF SERVICES**

The Budget proposes to discontinue funding for programs whose activities could be carried out with other existing funding streams to deliver services more efficiently including the Limb Loss and Paralysis Resource Centers. Resources for individuals living with paralysis will continue to be available through other HHS programs, such as Centers for Independent Living



and Assistive Technology, which provide resources to people with all types of significant disabilities.

***Federal Administration***

The Budget includes \$38 million, \$2 million below the FY 2018 Continuing Resolution, for program

management and support activities. This funding carries out ACL's mission by ensuring adequate support for oversight and program integrity activities.

## Office of the Secretary, General Departmental Management



<i>dollars in millions</i>	2017	2018/1	2019	2019 +/- 2018
Budget Authority	460	458	290	-168
Public Health Service Evaluation Funds	65	65	53	-12
Health Care Fraud and Abuse Control Program	7	7	10	+3
Proposed Mandatory Funding—Departmental Appeals Board	--	--	2	+2
Proposed User Fee Collections—Departmental Appeals Board	--	--	2	+2
<b>Total, Program Level /2</b>	<b>532</b>	<b>530</b>	<b>357</b>	<b>-173</b>
Additional Opioids Allocation/3			125	+125
<b>TOTAL with Additional Opioids Allocation /3</b>	<b>532</b>	<b>530</b>	<b>482</b>	<b>-48</b>
1/ Reflects the FY 2018 Annualized Continuing Resolution level, including the across the board reduction and directed transfers. 2/ This table does not include funding or Full-time Equivalents for the Pregnancy Assistance Fund. 3/ This funding is part of the \$10 billion proposal to combat the opioid epidemic and address serious mental illness.				

*The General Departmental Management budget line supports the Secretary's role as chief policy officer and general manager of the Department.*

The Budget supports the Secretary's role in administering and overseeing the organization, programs, and activities of the Department. These efforts are carried out through 11 Staff Divisions within the Office of the Secretary. The Fiscal Year (FY) 2019 President's Budget requests a program level of \$357 million for General Departmental Management, \$173 million below the funding level provided in the FY 2018 Continuing Resolution.

The FY 2019 Budget supports ongoing and critical priorities, including the Global Health Security Agenda, the HHS Pain Management Best Practices Inter-Agency Task Force, and the Departmental Appeals Board. The Budget also supports the Administration's focus on promoting religious freedom through the work of the Center for Faith-Based and Neighborhood Partnerships to connect the work of HHS with faith and community organizations, as well as the Conscience and Religious Freedom Division within the Office for Civil Rights. The Budget does not include funding for new grants in the Office of the Assistant Secretary for Health.

### GLOBAL HEALTH SECURITY AGENDA

The Global Health Security Agenda is a multilateral and multisector initiative to establish capacity to prevent, detect, and respond to, biological threats. The Office of Global Affairs (OGA) maintains a leadership role on the Global Health Security Agenda for the United States, focusing on political, diplomatic, and coordination issues. Global Health Security Agenda activities are carried out by a number of Departments and Agencies, most notably by CDC, the United States Agency for International Development, the Department of Defense, and the Department of State. OGA interfaces with the multi-country Global Health Security Agenda Steering Group, Alliance, and other international partners and supports engagement on Global Health Security Agenda by HHS and other principals.

OGA, along with other government and international partners, will finalize the development of Global Health Security Agenda 2.0 and support its launch during FY 2019.

**OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH**

The Office of the Assistant Secretary for Health (OASH) serves as the senior advisor for public health and science to the Secretary and coordinates public health policy and programs across the Staff and Operating Divisions of HHS. OASH oversees several public health offices, including the Office of the Surgeon General and the United States Public Health Service Commissioned Corps.

OASH is addressing the enormous challenges presented by the opioid epidemic, which touches so many Americans, especially those in rural and underserved populations. These challenges include prescribing practices, increased rates of suicide and accidental opioid overdose, and persistent needs for comprehensive and science-based pain treatment approaches.

**ADDRESSING THE OPIOID EPIDEMIC**

The Pain Management Best Practices Inter-Agency Task Force, authorized by the Comprehensive Addiction and Recovery Act of 2016, is charged with reviewing, identifying gaps in, and making recommendations to update pain management best practices (including for prescribing pain medication and managing chronic and acute pain). HHS is convening the Task Force, in which several components of HHS, the Departments of Veterans Affairs and Defense, and the Office of National Drug Control Policy will participate. The Task Force will:

- Determine whether there are gaps or inconsistencies in pain management best practices among Federal agencies;
- Propose recommendations on addressing gaps or inconsistencies;
- Provide the public with an opportunity to comment on any proposed recommendations; and
- Develop a strategy for disseminating information about best practices.

In addition, the Budget provides \$125 million to the Office of the Secretary to fight the opioid crisis. This funding includes \$100 million for a media campaign and \$25 million to support a robust evaluation to strengthen the evidence of the impact of Medication-Assisted Treatment on reducing overdose deaths. HHS will encourage agency-wide collaboration in this important initiative. When accounting for these

resources, the total for General Department Management is \$482 million, which is a decrease of \$48 million below the FY 2018 Continuing Resolution.

**OFFICE OF MINORITY HEALTH**

The Budget includes \$54 million for the Office of Minority Health, \$2 million below the FY 2018 Continuing Resolution. The Office of Minority Health will continue to lead, coordinate, and collaborate on minority health activities across the Department, including leadership in coordinating policies, programs, and resources to support the HHS Disparities Action Plan and the National Partnership for Action to End Health Disparities.

**OFFICE ON WOMEN'S HEALTH**

The Budget includes \$28 million for the Office on Women's Health, \$3 million below the FY 2018 Continuing Resolution. The Office on Women's Health will continue to lead, coordinate, and collaborate on women's health activities across the Department. The Office on Women's Health will continue targeted grants for women's health and support the advancement of women's health programs with other government organizations and with consumer and health professional groups.

**DEPARTMENTAL APPEALS BOARD**

The Budget includes \$22 million for the Departmental Appeals Board, with \$18 million in discretionary budget authority, \$2 million in proposed mandatory funding, and \$2 million in proposed user fee collections. This level is an increase of \$11 million above the FY 2018 Continuing Resolution. The Departmental Appeals Board provides high-quality adjudication and other conflict resolution services in administrative disputes involving HHS, including Medicare appeals. The Budget increase for FY 2019 will provide additional support to the Medicare Appeals Council to keep pace with the growing number of Medicare appeals. The Council provides the final administrative review of claims for entitlement to Medicare, individual claims for Medicare coverage, and claims for payment filed by beneficiaries or health care providers and suppliers.

## **OFFICE OF SURGEON GENERAL & U.S. 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 oversees the United States Public Health Service Commissioned Corps (Corps), which consists of over 6,500 uniformed public health professionals who work alongside their equivalent civilian counterparts performing the same day jobs but often receiving higher total compensation. The Commissioned Corps receives military-like benefits, but has not been incorporated into the Armed Forces since 1952 and generally does not meet DOD's criteria for the military compensation system. Further, the Corps' mission assignments and functions have not evolved in step with the public health needs of the Nation. It is time for that to change. HHS is committed to providing the best public health services and emergency response at the lowest cost, and is undertaking a comprehensive look at how the Commissioned Corps is structured. The specific recommendations and plans resulting from this

analysis will be released in the months to come, and could range from phasing out unnecessary Corps functions to reinventing the Corps into a smaller, more targeted cadre focused on providing the most vital public health services and emergency response. The goal of this proposal is to modernize how the Government employs public health professionals and how HHS responds to public health emergencies, saving Federal funds and reducing duplication while safeguarding the well-being of the Nation.

## **OTHER GENERAL DEPARTMENTAL MANAGEMENT**

The Budget includes \$253 million for the remainder of the activities supported by General Departmental Management in the Office of the Secretary. The Budget funds leadership, policy, legal, and administrative guidance to Department components and includes funding to continue ongoing programmatic activities, including strengthening program integrity by reducing fraud, waste, and abuse.



## Office of the Secretary, Opioids and Serious Mental Illness

<i>dollars in millions</i>	2017	2018/1	2019	2019 +/- 2018
<b>Opioids and Serious Mental Illness Initiative</b>	--	--	10,000	+10,000
1/ Reflects the FY 2018 Annualized Continuing Resolution level, including the across the board reduction and directed transfers.				

### THE OPIOID CRISIS AND SERIOUS MENTAL ILLNESS INITIATIVE

As the President remarked in his State of the Union address, 64,000 Americans – 174 Americans per day – died as a result of drug overdoses in FY 2016.

The FY 2019 Budget proposes a \$10 billion historic investment to combat the opioid epidemic and address serious mental illness. Funding this proposal in the Office of the Secretary will facilitate department-wide collaboration on this important initiative. Coordination by the Office of the Secretary will also better enable the Department to focus on evidence-based practices and the unique needs of women and minority populations across the investment.

These funds will expand efforts to prevent opioid abuse, and help Americans seeking treatment to access overdose-reversing drugs, treatment, and recovery support services. It will build on the Department's five-point strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted therapies (MAT);
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

As reflected in this document, the Budget proposes an initial allocation for \$3 billion of this funding across HHS. This initial allocation provides \$1.2 billion in SAMHSA, including \$1 billion to expand State Targeted Response (STR) to the Opioid Crisis Grants, as well as new funding for reducing injection drug use, purchasing naloxone for first responders, drug courts, and services for pregnant and post-partum women.

In HRSA, the initial allocation provides \$550 million to address substance abuse, including opioid abuse, in high risk communities, and for health centers activities, including quality improvement payments for community health centers that implement evidence-based models to address behavioral health, including opioid addiction, issues in the communities they serve.

Further, the initial allocation provides \$175 million in CDC to expand support to States through the Prescription Drug Overdose Prevention program, and to expand state surveillance capacity. The initial allocation also includes \$750 million in NIH to support and supplement existing efforts with a public-private collaborative research initiative on opioid abuse, and to advance opioid-, serious mental illness-, and pain-related research.

The initial allocation includes \$150 million in IHS for grants to expand opioid abuse prevention, treatment, and recovery support in Indian Country, and \$10 million in FDA to complement ongoing activities to support health professionals in more optimally delivering MATs, and to accelerate the development of generic versions of opioid drug products with abuse deterrent formulas.

Finally, the initial allocation provides \$125 million in the Office of the Secretary to support HHS-wide activities to launch a nation-wide digital and mass media campaign to raise awareness about opioids and reduce drug demand, and to support a robust evaluation to strengthen the evidence of the impact of MAT on reducing overdose deaths.

The remaining \$7 billion will be available for transfer across the Department to support additional work to address the opioid crisis and serious mental illness, including establishing a new grant program for Certified Community Behavioral Health Clinics that provide services to individuals suffering from serious mental illness.

## Office of the Secretary, Office of Medicare Hearings and Appeals



<i>dollars in millions</i>	2017	2018 /1	2019	2019 +/- 2018
Budget Authority	107	107	112	+5
Proposed Mandatory Funding	--	--	125	+125
Proposed User Fee Collections	--	--	4	+4
Recovery Audit Collections	--	--	10	+10
<b>Total Program Level</b>	<b>107</b>	<b>107</b>	<b>251</b>	<b>+144</b>
1/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				

*The Office of Medicare Hearings and Appeals provides a forum for the adjudication of Medicare appeals for beneficiaries and other parties. This mission is carried out by a cadre of Administrative Law Judges exercising decisional independence under the Administrative Procedures Act with the support of a professional, legal, and administrative staff.*

The Fiscal Year (FY) 2019 Budget requests \$251 million for the Office of Medicare Hearings and Appeals (OMHA), an increase of \$144 million over the funding provided in the FY 2018 Continuing Resolution. The increase outlined in the FY 2019 Budget request is comprised of an increase of \$5 million in discretionary budget authority, \$125 million in proposed mandatory funding, \$4 million in proposed user fee collections, and access to \$10 million in Recovery Audit collections. The Budget request also includes a legislative package to address the Medicare appeals backlog.

OMHA administers hearings and appeals nation-wide for the Medicare program. OMHA began processing cases on July 1, 2005. Since then, it has received approximately 1.8 million appeals for Medicare Parts A, B, C, and D, as well as for Medicare entitlement and eligibility. In FY 2011, OMHA began receiving additional appeals resulting from the Recovery Audit Program administered by the Centers for Medicare & Medicaid Services. The incoming workload for OMHA has been significant. OMHA has used best efforts to resolve incoming appeals timely, but appeal receipt volume has continued to exceed annual adjudication capacity. The appeal receipt volume has been: FY 2014—474,000; FY 2015—240,000; FY 2016—184,000; and FY 2017—113,000. Annual adjudication capacity was 87,000 appeals in FY 2014, 79,000 appeals in FY 2015, 87,000 appeals in FY 2016, and 85,000 appeals in FY 2017.

Current law requires that Medicare appeals at OMHA be heard within 90 days after receipt of a request for a hearing from an appellant. OMHA has not been able to

meet the 90-day time frame for case adjudication, despite OMHA's best efforts to maximize its adjudication capacity within its budget. It currently takes approximately 1,100 days for OMHA to adjudicate a non-beneficiary appeal.

### PROGRAM HIGHLIGHT

#### Improving the Medicare Appeals Process

The Department has a strategy to improve the Medicare appeals process by investing new resources to increase adjudication capacity and implement new strategies to alleviate the current backlog. The strategies include taking administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process and proposing legislative reforms that provide additional funding and new authorities to address the appeals volume.

HHS has undertaken—and continues to explore—new administrative actions expected to have a favorable impact on the Medicare appeals backlog.

To address these challenges, OMHA has taken a number of administrative actions to reduce the pending appeals workload. For example, OMHA will continue to pursue alternative dispute resolution as an alternative to an Administrative Law Judge hearing. In addition, OMHA will continue to make statistical sampling an option available to appellants, which has the potential to resolve large numbers of cases based on representative samples. OMHA will continue to



utilize technology, such as video telephone and teleconference hearings, to offer appellants access to multiple hearing venues and services. While helpful, these initiatives alone are insufficient to keep up with the appeal volume, which continues to increase.

The Budget will increase adjudicatory capacity by adding 106,000 additional dispositions per year. The

requested resources are critical for OMHA to respond to the backlog of unheard appeals while maintaining the quality and accuracy of its decisions. These resources are also essential to provide timely hearings for Medicare appellants.

For more information about the Medicare appeals legislative proposals, please see the Medicare chapter.



## Office of the Secretary, Office of the National Coordinator for Health Information Technology

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
Budget Authority	60	60	38	-22
<b>Program Level</b>	<b>60</b>	<b>60</b>	<b>38</b>	<b>-22</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-56), including any CR extensions, applicable funding anomalies, and directed or permissive transfers (where applicable).				

*To help lower health care costs, empower consumer choice, and improve provider satisfaction, ONC will work to make health information more accessible, decrease the documentation burden, and support electronic health records' usability.*

The Office of the National Coordinator for Health Information Technology (ONC) leads the Government's efforts to ensure that electronic health information is available and can be shared safely and securely to improve the health and care of all Americans and their communities. ONC's work is pivotal to achieving interoperability, encouraging market competition, advancing patient access to their electronic records, combating information blocking, and bringing innovative easy-to-use products into the hands of users.

In Fiscal Year (FY) 2019, ONC will focus on the interoperability of health information and provider burden reduction. The FY 2019 Budget prioritizes policy, rulemaking, standards development and implementation, and certification efforts to fulfill ONC's commitment to achieving a nation-wide interoperable health system. In a landscape of large health care delivery networks and hundreds of thousands of smaller providers, achieving interoperability among various health information technology (IT) systems while addressing burdens felt by providers is vital to creating a safe and secure health IT infrastructure that improves health and health care for all Americans.

The FY 2019 Budget for ONC is \$38 million, \$22 million below the FY 2018 Continuing Resolution. The Budget continues ONC's commitment to reducing provider burden and advancing interoperability through existing programs while also implementing new activities required by the 21st Century Cures Act.

### NEW INITIATIVE

#### 21st Century Cures Act: Health IT Advisory Committee

As required by the 21st Century Cures Act, ONC is transitioning its current Health IT Policy and Health IT Standards Federal Advisory Committees—established by the Health Information Technology for Economic and Clinical Health Act—to a single Health IT Advisory Committee (HITAC). This committee will play a critical role in ONC's policy development and the advancement of standards, implementation specifications, and certification criteria to support interoperability across the care continuum. Through the work of the HITAC, ONC is able to work directly with relevant stakeholder groups to more quickly understand steps that can be taken to advance interoperability and support key health IT goals.

One of the first efforts of the Health IT Advisory Committee will be to provide feedback on the draft Trusted Exchange Framework released by ONC as part of our implementation of section 4003 of the 21st Century Cures Act. The feedback of the HITAC will help ONC evaluate the draft framework and develop an effective final framework and the associated common agreement called for by Congress.

### POLICY DEVELOPMENT AND COORDINATION

ONC will continue to administer the policy and rulemaking activities that are required by the 21st Century Cures Act, Medicare Access and CHIP Reauthorization Act, and the Health Information Technology for Economic and Clinical Health Act. ONC will also work to meet the needs of providers, patients, payers, public health entities, and researchers who rely

on health IT as well as other stakeholders and policy makers at the Federal and state level to advance the safe and secure movement of health information.

ONC will further its goal of reducing provider burden by continuing to work with the Centers for Medicare & Medicaid Services to decrease documentation requirements and support new business models for payment. ONC will also encourage the development of software applications that promote intuitive and functional health IT tools for patients and clinicians. This includes engaging with stakeholders and Federal partners to develop a set of goals and strategies that leverage health IT to reduce provider, administrative, and regulatory burden.

The FY 2019 Budget will support a single Health IT Advisory Committee as directed by the 21st Century Cures Act. Similar to the previous Health IT Policy and Health IT Standards Federal Advisory Committees, the new committee will help ONC better understand the needs of patients and providers, inform policies critical to interoperability, and advance standards and specifications that support interoperability. This committee plays a critical role in ONC's work to develop policy development and standards to promote interoperability across the care continuum and determine where more focused industry coordination is necessary.

Throughout FY 2017 and FY 2018, ONC engaged with stakeholders to develop a trusted exchange framework as directed by the 21st Century Cures Act. In FY 2019, ONC will focus on implementation of the framework and a common agreement, including working with the private sector to identify technical needs to support interoperable health information exchange across disparate networks.

#### **STANDARDS, INTEROPERABILITY, AND CERTIFICATION**

In FY 2019, ONC will advance nationwide health IT interoperability through implementation of the requirements of the 21st Century Cures Act, including conditions of certification. ONC will also coordinate standards development and implementation, and ensure that the governance of our nation's health data supports equity, scalability, integrity and sustainability of information sharing for everyone in the United States. Achieving interoperability will lead to consumers who have an informed choice in their health care.

ONC will continue to support collaborative initiatives to accomplish accelerated and coordinated standards work. In FY 2019, ONC's standards development work will include a focus on summary care records, application programming interface standards, continued implementation testing, pilots, and collaboration with industry stakeholders.

ONC will coordinate with industry stakeholders to improve the standardization, implementation, and use of open application programming interfaces. ONC will collaborate with health IT developers and standards development organizations to focus on data and security standards for these interfaces, health care providers to understand implementation challenges, and consumer-advocacy groups to include perspectives from patients and caregivers. These overall efforts will focus on the ways in which modern computing via standardized application programming interfaces can be leveraged to enhance patients access to their health data, improve clinical workflow, and enable market competition.

#### **PROGRAM HIGHLIGHT**

##### **Privacy of Health IT and Patient Access to Health Information**

Patient trust in the privacy and security of health data is a core requirement of an interoperable health system. ONC ensures this requirement is met by advising on health information privacy, security, and data stewardship policies. Key components of this involve working with the HHS Office for Civil Rights to show how the Health Insurance Portability and Accountability Act (HIPAA) and other privacy laws and regulations support, rather than impede, information flow in an electronic environment. ONC also develops and supports approaches that ensure information is shared electronically and is kept secure. In accordance with the access provisions of section 4006 of the 21st Century Cures Act, ONC works with the Office for Civil Rights to develop education materials and guidance for providers and policymakers on how HIPAA enables data sharing.

The FY 2019 Budget will support the ongoing maintenance of standards conformance test tools, ONC Health IT Certification Program administration and oversight, and the ongoing support of the Certified Health IT Product List, which provides detailed information on each certified product and open data access on each product. ONC will continue to refine

and enhance the testing tools necessary for certification and work with the industry to coordinate the development of test methods to ensure products conform to the technical standards. ONC will enhance tools and test methods with a greater focus toward interoperability and basic standards conformance. These efforts will help ensure certified products interoperate and provide individuals and health care

providers with the functionality needed to coordinate care and implement care delivery transformation.

In FY 2019, ONC will continue the cost reductions included in the FY 2018 Budget related to information technology, space, staff training, and agency travel. ONC will continue to seek additional administrative and operational efficiencies.

## Office of the Secretary, Office for Civil Rights



<i>dollars in millions</i>	2017	2018 /1	2019	2019 +/- 2018
<b>Program Level</b>	<b>39</b>	<b>39</b>	<b>31</b>	<b>-8</b>
1/ Reflects the annualized level of the Continuing Resolution (Public Law 115-96) that ends January 19, 2018, including the across the board reduction, the 21st Century Cures Act, and directed transfers.				

*The Office for Civil Rights is the Department's chief law enforcer and regulator of civil rights, conscience and religious freedom, and health information privacy and security.*

The Fiscal Year (FY) 2019 Budget request for the Office for Civil Rights (OCR) is \$31 million, \$8 million below the FY 2018 Continuing Resolution level. The Budget supports OCR's essential programmatic focus 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, and access, privacy, and security protections for individually identifiable health information. To carry out 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 health information privacy laws. OCR will use civil monetary settlement funds to support Health Insurance Portability and Accountability Act (HIPAA) enforcement activities.

Case receipts are expected to further rise in FY 2019. In FY 2017, OCR received approximately 30,166 complaints, a 23 percent increase over the 24,523 complaints received in FY 2016. OCR resolved 28,431 cases and reduced a case backlog from an average of six months to 30 days.

### CIVIL RIGHTS

#### **General Authorities**

OCR works to safeguard individuals' access to health care, health coverage, and human services without discrimination. In particular, OCR enforces Federal anti-discrimination laws with respect to race, color, national origin, disability, age, and sex in various programs that receive financial assistance from, or are conducted by, the Department.

The OCR Director chairs the HHS Language Access Steering Committee, which coordinates departmental

efforts to improve access for limited English proficient individuals to HHS programs. OCR also works with HHS components to ensure that HHS programs provide effective communication to individuals with disabilities.

During FY 2019, OCR will continue to address a broad range of critical civil rights issues that address compliance topics and are of paramount importance to the American people. As examples, in FY 2017, in addition to major voluntary resolution agreements, from statewide child welfare national origin protections to non-discrimination on the basis of HIV/AIDS, OCR developed a number of civil rights guidance documents and outreach to stakeholders, including:

- Issuing guidance to ensure civil rights compliance in emergency response and recovery efforts following the challenging 2017 hurricane season; ensuring health care services and health coverage offered through electronic technology are accessible to all individuals, including those with auditory or visual disabilities; and partnering with the HHS Administration on Children and Families and the United States Department of Justice to safeguard the civil rights of parents, prospective parents, and children in the child welfare system, including issuing joint guidance on compliance with title VI of the Civil Rights Act of 1964.
- Leveraging relationships with health care providers, associations, colleges and universities, and industry stakeholders. For example, during FY 2017, OCR staff taught a civil rights compliance curriculum to more than a thousand students at 14 universities to help them understand how providing equal access to

patients is required by law and necessary to ensure effective health care.

## HEALTH INFORMATION PRIVACY AND SECURITY

### *General Authorities*

OCR administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules. OCR seeks to ensure covered entities understand and comply with their obligations and to increase individuals' awareness of their HIPAA rights and protections. OCR accomplishes this 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.

In FY 2019, OCR will continue its robust and comprehensive HIPAA program efforts to maintain and improve upon the solid enforcement achievements from 2017:

- Issued multiple guidance documents explaining (1) how providers can share health information with family and friends, especially in response to the opioid crisis, as well as during and after natural disasters and mass shootings; (2) how to effectively respond to cybersecurity threats, including issuing resources to illustrate the steps HIPAA-covered entities or business associates should take in response to a cyber-related security incident; and (3) how to improve understanding, by the public and regulated entities, of the right to access health information, including through a Medscape module on the HIPAA right of individual access as part of the National Institutes of Health's "All of Us" initiative.
- Launched a revised HIPAA Breach Reporting Tool that provides transparency to the public and the regulated community about breaches of protected health information.

During FY 2017, OCR entered into settlement agreements that include corrective action plans with

10 covered entities encompassing hundreds of hospitals, health care provider and delivery systems, and group health insurance companies across the country for privacy and security violations. OCR ultimately recovered more than \$20 million in settlements and civil monetary penalties. As provided for by the Health Information Technology Economic Clinical Health Act, OCR utilizes such collections to support HIPAA enforcement activities and is required to maintain an audit program.

By the end of 2017, OCR audited 166 covered entities and 41 business associates. These audits focused on the HIPAA Security Rule risk analysis and risk management provisions, the HIPAA Breach Notification Rule requirements to notify individuals and HHS of breaches of health information, and the HIPAA Privacy Rule requirements to provide individuals with access to their health information. Individual reports were sent to each audited entity.

## CONSCIENCE AND RELIGIOUS FREEDOM

In FY 2017, OCR took active steps to support the Administration's priority to vigorously enforce Federal laws' robust protections for religious freedom, in accordance with Executive Order 13798, "Promoting Free Speech and Religious Liberty." In FY 2018, OCR established a new Conscience and Religious Freedom Division to ensure protection of conscience and religious freedom rights of individuals and entities working in health care and human services.

The Conscience and Religious Freedom Division provides a centralized point within HHS to coordinate, oversee, and ensure compliance with Federal laws protecting conscience and the free exercise of religion and prohibiting coercion and religious discrimination. Examples of such laws include the Religious Freedom Restoration Act of 1993; the Church, Coats-Snowe, and Weldon Amendments; and section 1553 of the Affordable Care Act.





## Office of Inspector General

<i>dollars in millions</i>	2017	2018 /2	2019	2019 +/- 2018
Discretionary Appropriation/1	82	81	80	-1
Health Care Fraud and Abuse Control (HCFAC) Program Collections	10	11	12	+1
Discretionary HCFAC	82	82	87	+5
Mandatory HCFAC	186	190	208	+18
<b>Total Funding, All Sources/3</b>	<b>359</b>	<b>365</b>	<b>388</b>	<b>+23</b>
1/ Includes the \$1.5 million required transfer from the Food and Drug Administration appropriation in FY 2017 and FY 2018 Continuing Resolution. 2/ Reflects the annualized level of the Continuing Resolution (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable). 3/ Funding amounts may not sum to totals because of rounding.				

*The mission of the Office of Inspector General is to protect the integrity of Department of Health and Human Services programs as well as the health and welfare of the people they serve.*

The President's Fiscal Year (FY) 2019 Budget requests \$388 million for the Office of Inspector General (OIG), \$23 million above the FY 2018 Continuing Resolution. These funds will enable OIG to target oversight efforts and ensure efficient and effective use of resources within the Department's programs.

OIG's areas of oversight fall into two broad categories:

- Public Health and Human Services Oversight.
- Medicare and Medicaid Oversight.

### PUBLIC HEALTH AND HUMAN SERVICES OVERSIGHT

OIG uses funding from its discretionary budget authority to conduct program integrity and enforcement activities for HHS programs and operations. OIG will continue to review activities for any evidence of fraud, waste, and abuse, and oversee new and emerging issues related to HHS's international and domestic response to public health concerns and new cyber security threats facing the Department.

The FY 2019 Budget request for Public Health and Human Services Oversight is \$80 million, which will support the following investments to strengthen the integrity of HHS programs including:

- **Indian Health Services:** OIG will continue providing oversight to promote quality of care, safety, and program integrity in the Indian Health Service.

- **Grants Oversight:** OIG will continue to focus on grant oversight of high risk grant programs, including grants for services to children and substance abuse grant funding provided under the 21st Century Cures Act for opioid abuse prevention and treatment programs. OIG will continue to provide training and education to prevent grant fraud, waste, and abuse.
- **Privacy and Security:** OIG will increase oversight and investigative response to threats from computer hacking groups intent on compromising systems and releasing sensitive data. OIG conducts general security control audits of information and technology supporting HHS programs and conducts network and web application penetration testing to assess HHS's network security to determine vulnerability.
- **Public Health Emergencies:** OIG will continue oversight of HHS grants for emergency preparedness and make recommendations to prevent fraud, waste, and abuse.

### MEDICARE AND MEDICAID OVERSIGHT

Through its oversight work, OIG saves taxpayer dollars and works to ensure that patients receive medically appropriate care in the Nation's largest health care programs—Medicare and Medicaid. OIG relies on principles of prevention, detection, and enforcement to address fraud, waste, and abuse in these programs.

Two key focus areas are sound fiscal management of the programs and ensuring that beneficiaries receive quality care.

OIG protects these programs and their beneficiaries using a multidisciplinary approach and through important partnerships, including with the Department of Justice and State Medicaid Fraud Control Units (MFCUs). Many fraudulent providers cheat both Medicare and Medicaid and the beneficiaries who rely on these programs. OIG fraud-fighting and patient protection activities often have cross-cutting impacts. The Health Insurance Portability and Accountability Act established the Health Care Fraud and Abuse Control (HCFAC) Program to combat fraud, waste, and abuse in health care and provides funds to OIG dedicated to activities relating to Medicare and Medicaid. Overall, HCFAC funding constitutes the major portion of OIG's annual operating budget.

The FY 2019 President's Budget for OIG includes \$308 million for Medicare and Medicaid oversight, an increase of \$24 million over the FY 2018 Continuing Resolution.

#### PROGRAM HIGHLIGHT

##### 2017 Health Care Fraud Takedown

OIG worked with state and Federal law enforcement partners to coordinate the largest health care fraud takedown in history during July 2017. More than 400 defendants in 41 Federal districts were charged with participating in fraud schemes that involved approximately \$1.3 billion in false billings to Medicare and Medicaid. OIG also issued exclusion notices to 295 doctors, nurses, and other providers on the basis of conduct related to opioid diversion and abuse.

The FY 2019 President's Budget supports the Administration's priorities of addressing fraud, waste, and abuse in Federal health care programs. OIG's work covers issues of access and affordability, Medicare and Medicaid enrollment and spending, innovations in health care and data analytics, quality of care, and the increase in complexity and technical sophistication of fraud schemes. OIG will continue its work from FY 2018 to address fraud, waste, and abuse in prescription drugs, including abuse and diversion of opioids, while using additional funding to address fraud, waste, and abuse in home health and other noninstitutional-based services and to strengthen

oversight of Medicare Advantage and Medicaid Program Integrity.

#### ***Home Health and Other Noninstitutional-Based Services***

Services provided in a beneficiary's home or other noninstitutional settings, including home health, hospice, and other home- and community-based services, are susceptible to fraud. OIG will develop new recommendations for targeted program safeguards for beneficiaries in homes- or community-based settings and prevent fraud by bad actors while limiting the burden on legitimate providers. Through data analytics, OIG would also detect new and emerging fraud schemes, enabling us to monitor trends and evolution of known fraud schemes.

#### ***Medicaid Program Integrity***

OIG work shows persistent and serious fraud vulnerabilities in Medicaid. OIG will continue to partner with states to identify high-risk areas and providers and with MFCUs on joint criminal investigations to tackle fraud, including in home- and community-based services; personal care services; prescription drugs; and fraud affecting both Medicare and Medicaid. OIG will continue program integrity efforts that identify needed improvements and best practices in critical areas, such as provider enrollment, data availability and accuracy, and safety of care. Additional resources will also support state fraud enforcement efforts by providing MFCUs with training and technical assistance.

#### ***Medicare Managed Care***

Approximately 30 percent of Medicare beneficiaries are enrolled in Medicare Advantage (MA), a threefold increase since 2004; Centers for Medicare & Medicaid Services (CMS) estimates the FY 2017 gross improper payment rate for payments to MA plans at 8.3 percent. OIG will develop and implement a sustained, focused, and strategic initiative to combat fraud and abuse in MA. OIG will use audits, evaluations, investigations, and enforcement actions to prevent, detect, and remediate fraud, waste, and abuse in MA. These efforts will employ advanced data modeling and specialized clinical expertise (including medical record review).



## Public Health and Social Services Emergency Fund

<i>dollars in millions</i>	2017 /1	2018 /2	2019	2019 +/- 2018
<b>Assistant Secretary for Preparedness and Response (ASPR)</b>				
Preparedness and Emergency Operations	25	24	27	+2
National Disaster Medical System	50	50	50	--
Hospital Preparedness	254	253	255	+2
Medical Reserve Corps	6	6	4	-2
Biomedical Advanced Research and Development Authority	510	508	512	+3
Project BioShield	509	507	510	+3
Strategic National Stockpile /3	-	-	575	+575
Policy and Planning	15	15	15	--
Operations	31	31	31	--
<b>Subtotal, ASPR Program Level</b>	<b>1,399</b>	<b>1,393</b>	<b>1,977</b>	<b>+584</b>
<b>Other Office of the Secretary</b>				
Security and Strategic Information (OSSI) /4	7	7	8	+1
Cybersecurity /4	51	51	68	+18
<b>Subtotal, Other Office of the Secretary</b>	<b>58</b>	<b>58</b>	<b>77</b>	<b>+19</b>
<b>Pandemic Influenza</b>				
No-Year Funding	40	40	210	+170
Annual Funding /5	32	72	40	-32
<b>Subtotal, Other Office of the Secretary</b>	<b>72</b>	<b>112</b>	<b>250</b>	<b>+138</b>
<b>Total Program Level, PHSSEF</b>	<b>1,529</b>	<b>1,563</b>	<b>2,304</b>	<b>+741</b>
<b>Total Budget Authority, PHSSEF</b>	<b>1,514</b>	<b>1,563</b>	<b>2,304</b>	<b>+741</b>
1/ Reflects FY 2017 enacted, post required and permissive transfers and rescissions.				
2/ Reflects the annualized level of the Continuing Resolution (CR) (P.L. 115-96), including any applicable funding anomalies and directed or permissive transfers (where applicable).				
3/ The FY 2019 funding level reflects the transfer of the Strategic National Stockpile from CDC to ASPR.				
4/ For FY 2018 and FY 2019 totals reflect a realignment of \$1.04 million from Cybersecurity to OSSI to support the cyber threat activities carried out by OSSI.				
5/ The FY 2017 funding level for Pandemic Influenza Annual Funding includes \$15 million provided from prior-year supplemental balances.				

*The Public Health and Social Services Emergency Fund directly supports the nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and man-made threats.*

The Public Health and Social Services Emergency Fund, within the Office of the Secretary, directly supports activities across the Department to improve the Nation's ability to prepare for and respond to acts of terrorism, natural disasters, and other threats to public health. The Fiscal Year (FY) 2019 Budget includes \$2.3 billion, an increase of \$741 million above the FY 2018 Continuing Resolution, to maintain and build on the Department's capacity to address biodefense

and cybersecurity needs, and to increase the ability of state and local governments to support communities in their efforts to prevent, respond to, and recover from disasters. The Budget maintains the establishment of the Federal Emergency Response Fund, which provides the Department with a mechanism to quickly allocate resources when a public health threat arises.

## BIOTERRORISM AND EMERGENCY PREPAREDNESS

The Department of Health and Human Services (HHS) contributes to Emergency Support Function No. 6: Mass Care, Emergency Assistance, Temporary Housing and Human Services, and is the lead Federal agency to carry out Emergency Support Function No. 8: Public Health and Medical Services for the U.S. Federal Government. In this unique role, HHS leads the Federal response to public health emergencies and incidents covered by the National Response Framework. The Public Health and Social Services Emergency Fund is the Department's mechanism to carry out these functions and support cross-cutting efforts to improve the Nation's preparedness and response activities. Activities carried out by the Public Health and Social Services Emergency Fund include providing direct response to emergency situations, developing, procuring, and stockpiling medical countermeasures, bolstering state and local response capabilities, and coordinating emergency preparedness policy and planning efforts across the Department. HHS is also the lead Federal coordinating agency for the Health and Social Services Recovery Support Function under the National Disaster Recovery Framework.

## ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The Assistant Secretary for Preparedness and Response (ASPR) leads the Department's efforts in preventing, preparing for, and responding to, the adverse health effects of public health emergencies and disasters. To fulfill this role, ASPR works in partnership with other HHS agencies on a routine basis to ensure responses are coordinated and to leverage expertise across the Department. ASPR strengthens the Nation's emergency medical response and biodefense capabilities by improving the capacity of state and local governments to respond to public health threats, collaborating with public and private partners on advanced research, development, and procurement of medical countermeasures, and leading emergency response operational planning and policy development.

The FY 2019 Budget includes \$2.2 billion for ASPR, an increase of \$722 million above the FY 2018 Continuing Resolution. This funding level reflects the transfer of the Strategic National Stockpile from the Centers for Disease Control and Prevention (CDC) to ASPR. The Budget supports emergency operations planning and

maintains critical investments for pandemic influenza preparedness and response. These activities strengthen national security and fulfill a unique Federal role to protect Americans from public health incidents and emerging infectious diseases.

ASPR's Biomedical Advanced Research and Development Authority (BARDA) develops and procures medical countermeasures, including vaccines, therapeutics, and diagnostics to address chemical, biological, radiological, nuclear, and infectious disease threats, whether naturally occurring or intentional. To accomplish this mission, BARDA leverages unique public-private partnerships to support the transition of candidate medical products from early development into late-stage development and licensure. BARDA also provides clinical support services and pursues novel technologies to streamline product development and manufacturing. The Budget provides \$512 million for BARDA, which is \$3 million above the FY 2018 Continuing Resolution, to support a robust development pipeline of biodefense products that address gaps in national preparedness.

BARDA has been successful at establishing a robust pipeline of medical countermeasures, with more than 90 aggregate candidates. The FY 2019 Budget will support the advanced development of the highest priority medical countermeasures, including candidates to address threat agents, pharmaceutical based agents, agents to address viral hemorrhagic fever virus threats for Sudan and Marburg, smallpox antivirals, Ebola vaccines and therapeutics, and point-of-care and laboratory diagnostics. Additional candidates will continue to progress in the advanced research and development program, including broad spectrum antimicrobials to mitigate the primary or secondary effects of exposures to various threat agents and treatments for illnesses caused by radiation, thermal burns, and chemical agents.

The Budget provides \$510 million for Project BioShield, which is \$3 million above the FY 2018 Continuing Resolution, to support late-stage development and procurement of medical countermeasures for the Strategic National Stockpile. The Budget will build on successful development of medical countermeasures under BARDA by transitioning promising products to Project BioShield that are sufficiently mature and ready for use during a public health emergency. Project BioShield also allows BARDA to support late-stage development of products towards Food and Drug

Administration (FDA) approval. In FY 2019, Project BioShield funding will support the procurement of three new medical countermeasures, including an antibiotic to address biological pathogens and antimicrobial drug resistance; a therapeutic to minimize neurological injury resulting from exposure to chemical agents; and a countermeasure to address thrombocytopenia resulting from acute exposure to ionizing radiation. The Budget will also support sustained development and procurement of a next-generation anthrax vaccine, Ebola and smallpox vaccines and therapeutics, and treatments for burn injury.

BARDA has successfully transitioned 27 medical countermeasure candidates to Project BioShield for late-stage development and procurement, of which 14 have been delivered to the Strategic National Stockpile and 6 have achieved FDA approval. These products address a wide range of threats such as anthrax, smallpox, botulism, viral hemorrhagic fever, and chemical, radiological, and nuclear agents. BARDA anticipates an additional three products will be approved by FDA in FY 2019, in addition to three new products supported under Project BioShield. The continued success of the Project BioShield program ensures the Nation is prepared to respond to the medical consequences of public health threats to homeland security.

The Budget includes \$192 million, \$1 million above FY 2018, to support BARDA's broad spectrum antimicrobial program. Aligned with the government-wide *National Action Plan for Combating Antibiotic-Resistant Bacteria*, this program leverages public-partnerships to develop novel antibacterial products. To stimulate product innovation, BARDA and the National Institutes of Health (NIH) have established the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X). CARB-X has accelerated the efforts of numerous companies focused on developing approaches to treat drug resistant bacterial infections.

The Budget continues to propose authority to transfer resources between ASPR's advanced research and development and Project BioShield programs. This authority would enable ASPR to maximize investments across the advanced development and procurement stages.

#### PROGRAM HIGHLIGHT

##### Responding to Emerging Infectious Diseases

BARDA collaborates strategically with CDC, FDA, NIH and other Federal partners through participation in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). The PHEMCE, chaired by the ASPR, is a standing virtual enterprise that leverages expertise across the Department and supports other Federal partners to coordinate the entire life cycle associated with the development and procurement of medical countermeasures for emergency public health threats. As part of this enterprise, BARDA played a vital role in the overall HHS response to the Zika virus outbreak in 2016-2017 by utilizing annual and emergency supplemental appropriations.

Funds were used to support the development of: (1) three Zika-specific vaccine candidates that are currently under clinical evaluation for safety and efficacy; (2) six diagnostic tests to identify individuals infected by Zika virus, four of which are now available for use under an FDA-issued Emergency Use Authorization; (3) two tests to screen the blood supply for Zika virus and prevent infection by transfusion, one of which has achieved FDA approval; and, (4) a pathogen reduction technology device that inactivates Zika virus in donated blood, which is currently under clinical evaluation. These investments were instrumental for a rapid medical countermeasure development response to a highly infectious disease.

The Budget provides \$575 million for the Strategic National Stockpile, which is \$4 million above the FY 2018 Continuing Resolution, and reflects the transfer of the program from CDC to ASPR. This reorganization streamlines the medical countermeasure development and procurement enterprise and increases operational efficiencies during emergency responses by fully integrating the Stockpile with other preparedness and response capabilities. The Strategic National Stockpile is the Nation's largest repository of life-saving medical countermeasures and medical supplies. It can be rapidly deployed to support state, local, and territorial response to health security threats. This repository is the only Federal resource readily available for use in a public health emergency severe enough to cause state and local supplies to be depleted, or when unique medical supplies are required that are not commercially available. The Budget will also support continued training for responders nationwide to sustain state and local capabilities to receive and use stockpiled medical countermeasures when deployed.



## PROGRAM HIGHLIGHT

**2017 Atlantic Hurricane Season Response**

As the Department's lead agency for emergency response, ASPR coordinated HHS's preparedness and response efforts for the 2017 hurricane season, including Hurricanes Harvey, Irma, and Maria. The 2017 hurricane season was unprecedented, with three Category 4 hurricanes in the United States within four weeks.

The Secretary's Operations Center (SOC) served as the command center to coordinate HHS's efforts. The SOC coordinated the U.S. Government's public health response and recovery planning efforts, ensuring the affected states, territories, and localities were supported to save lives during the hurricanes.

In order to be able to respond immediately, ASPR pre-deployed both personnel and medical equipment assets to the impacted areas. This allowed a swift and efficient response to the hurricanes. ASPR continued to send NDMS teams, operations staff, medical equipment and supplies, and provided logistical support for the immediate response to the three hurricanes.

As of the end of 2017, ASPR supported the deployment of over 4,600 trained, professional personnel, provided medical care and support to over 36,000 patients, and dispatched over 900 tons of critical equipment and supplies.

HHS will continue to support the impacted states, territories, and localities as they recover from the 2017 Atlantic hurricane season.

The Budget provides \$255 million, which is \$2 million above the FY 2018 Continuing Resolution, for ASPR's Hospital Preparedness Program. The Hospital Preparedness Program directly supports health care coalitions, which are comprised of diverse and competitive health care organizations within a geographic location. The funding provided enables health care coalitions to prepare for, and respond to, public health threats that exceed the day-to-day capacity of their healthcare and emergency systems. In FY 2019, the Hospital Preparedness Program will continue to fund 62 awardees, including all 50 States, eight U.S. territories and freely-associated states, and four localities. Additionally, awards will continue to allocate funding based on a risk determination and link awards to performance. Incorporating risk into the funding formula ensures that resources are allocated to states and localities according to need. ASPR will ensure effective use of Federal funds by tracking recipient programmatic performance to inform future grant awards.

The FY 2019 Budget provides \$50 million to support the National Disaster Medical System, the same as in FY 2018. The National Disaster Medical System is comprised of nearly 5,000 intermittent Federal employees who are deployed in the event of a natural or manmade disaster to provide critical medical services, protect public health, and help communities recover faster. These teams are comprised of clinical and emergency medical providers. When deployed, the National Disaster Medical System teams carry out medical, veterinary, and mortuary response activities, patient movement support, definitive care, and, behavioral health support in coordination with the local health system in the impacted region(s).

The Civilian Volunteer Medical Reserve Corps supports local preparedness and response capabilities. The Medical Reserve Corps is a national network of over 200,000 volunteers organized into 1,000 community-based units across the United States. The Budget provides \$4 million for ASPR's management of the Medical Reserve Corps, which is \$2 million below the FY 2018 Continuing Resolution. ASPR's management activities include providing technical assistance to unit leaders, supporting units in volunteer recruitment, training, and retention efforts, and maintaining a platform to track and evaluate units on both their training and activities conducted through the year. Medical Reserve Corps units have supported numerous community public health missions,

participated in local and regional exercises across the Nation, and responded during emergencies when called upon by state and local response agencies.

ASPR's Preparedness and Emergency Operations plays a critical role in monitoring emerging public health threats, coordinating the Department-wide response efforts, and leading recovery efforts after an emergency has occurred. The FY 2019 Budget provides \$27 million for Preparedness and Emergency Operations, \$2 million above the FY 2018 Continuing Resolution. This targeted investment will be used to plan and carry out a National-level exercise for a biological incidence emergency. An exercise of this magnitude will incorporate HHS agencies and other Departments within the U.S. Government. Through the simulation of a biological incident, agencies will be able to test-run their response plans. The exercise increases overall preparedness as the simulated response strengthens



inter-agency coordination, identifies gaps in response plans and solutions for any such gaps, and validates successful incidence response mechanisms.

## **PANDEMIC INFLUENZA**

The FY 2019 Budget provides a total of \$250 million for pandemic influenza preparedness activities, which is \$138 million above the FY 2018 Continuing Resolution. This investment supports international pandemic preparedness, sustainment of domestic influenza vaccine manufacturing and stockpiling capacity, and advanced development of novel influenza vaccines and therapeutics. These activities are essential to responding to pandemic threats and are carried out by the ASPR as well as the Office of Global Affairs. As newly evolved strains of drug-resistant influenza viruses emerge that pose a significant threat to public health, as seen with the 2017 H7N9 avian influenza outbreak in China, the Department continues to build on previous investments in pandemic preparedness and response capacity. This funding level supports the critical need to continue advanced development of promising medical countermeasure candidates, including improved influenza vaccines and novel antiviral therapies that can address antiviral drug resistance. With investments within ASPR advanced development, these candidates are developed under existing public-private partnerships that leverage the expertise, infrastructure, and manufacturing capacity of large pharmaceutical companies. Such partnerships are being utilized in response to the new strain of the H7N9 avian influenza virus, as BARDA collaborates with Federal and private partners to meet pandemic preparedness goals by developing a new H7N9 vaccine for the National Pre-pandemic Influenza Vaccine Stockpile.

## **DEPARTMENT-WIDE INFORMATION SECURITY**

### ***Security and Strategic Information***

The Office of Security and Strategic Information (OSSI) ensures the protection of sensitive information for the Department. OSSI is tasked to identify, prioritize, assess, remediate, and protect critical infrastructure information for the health care and public health sectors. OSSI integrates and synthesizes intelligence and all source information on public health, terrorism, national security, weapons of mass destruction, and homeland security in order to support HHS's mission. The FY 2019 Budget provides \$8 million for OSSI, which is \$1 million above the FY 2018 Continuing Resolution. This funding level will allow OSSI to continue to serve clients across HHS, other U.S. Government agencies, and 18 agencies within the Intelligence Community. OSSI's activities provide policymakers with early indicators and warnings of potential national security threats. Additionally, OSSI mitigates (1) counterintelligence and insider threat risks as they relate to cyber intelligence-derived threats, protecting the Department's intellectual property, and (2) threats to the Nation's overall medical and public health supply chain and risk management.

### ***Cybersecurity***

The Cybersecurity program ensures that the Department's critical information is secure. The FY 2019 Budget provides \$68 million for the Cybersecurity program, an increase of \$18 million above FY 2018. This funding will support enterprise-wide solutions to identify, evaluate, acquire, coordinate, and deploy cybersecurity information and tools across the Department. Without the proposed increase, the Department will be unable to take action against cyber threats and to limit the impact of those events, and will be constrained in its ability to proactively engage with a range of stakeholders to provide cybersecurity solutions, workforce, and tools integration to increase visibility for enhanced threat identification and management.

## Abbreviations and Acronyms

### A

ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organizations
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
ASP	Average Sales Price
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry

### B

BARDA	Biomedical Advanced Research and Development Authority
BD2K	Big Data to Knowledge

### C

CARA	Comprehensive Addiction Recovery Act
CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CHIPRA	Children's Health Insurance Program Reauthorization Act
CMS	Centers for Medicare & Medicaid Services
CR	Continuing Resolution
CSBG	Community Services Block Grant
CY	Calendar Year

### D

DEA	Drug Enforcement Agency
DOD	Department of Defense
DSH	Medicaid Disproportionate Share Hospital

### F

FDA	Food and Drug Administration
FY	Fiscal Year

### G

GDM	General Departmental Management
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### H

HCFAC	Health Care Fraud and Abuse Control
HCBSS	Home and Community Based Support Services
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
HRSA	Health Resources and Services Administration

### I

IHS	Indian Health Service
IT	Information Technology

### L

LIHEAP	Low Income Home Energy Assistance Program
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### M

MA	Medicare Advantage
MACRA	Medicare Access and CHIP Reauthorization Act
MAGI	Modified Adjusted Gross Income
MAT	Medication-Assisted Treatment
MFCU	Department of Justice and State Medicaid Fraud Control Units
MIPS	Merit-based Incentive Payment System
MSA	Medicare Savings Accounts

### N

NGRI	Next Generation Researchers Initiative
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

## Abbreviations and Acronyms

NIOSH National Institute for Occupational Safety and Health  
 NIRSQ National Institute for Research on Safety and Quality  
 NMEP National *Medicare & You* Education Program  
 National *Medicare & You* Education Program

### O

OASH Office of the Assistant Secretary for Health  
 OCR Office for Civil Rights  
 OGA Office of Global Affairs  
 OIG Office of Inspector General  
 OMB Office of Management and Budget  
 OMHA Office of Medicare Hearings and Appeals  
 ONC Office of the National Coordinator for Health Information Technology  
 ORR Office of Refugee Resettlement  
 OS Office of the Secretary  
 OSSI Office of Security and Strategic Information

### P

PAYGO Pay-As-You-Go  
 PHEMCE Public Health Emergency Medical Countermeasures Enterprise  
 PHS Public Health Service  
 PRWORA Personal Responsibility and Work Opportunity Reconciliation Act  
 PSSF Promoting Safe and Stable Families

### S

SAMHSA Substance Abuse and Mental Health Services Administration  
 SEP Special Enrollment Period  
 SOC Secretary's Operations Center  
 SPRANS Special Projects of Regional and National Significance  
 STI Sexually-Transmitted Infections  
 STR State Targeted Response

### T

TANF Temporary Assistance for Needy Families

### U

UAC Unaccompanied Alien Children

### W

WAC Wholesale Acquisition Cost