



DEPARTMENT OF HEALTH AND HUMAN SERVICES
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PUTTING AMERICA'S HEALTH FIRST

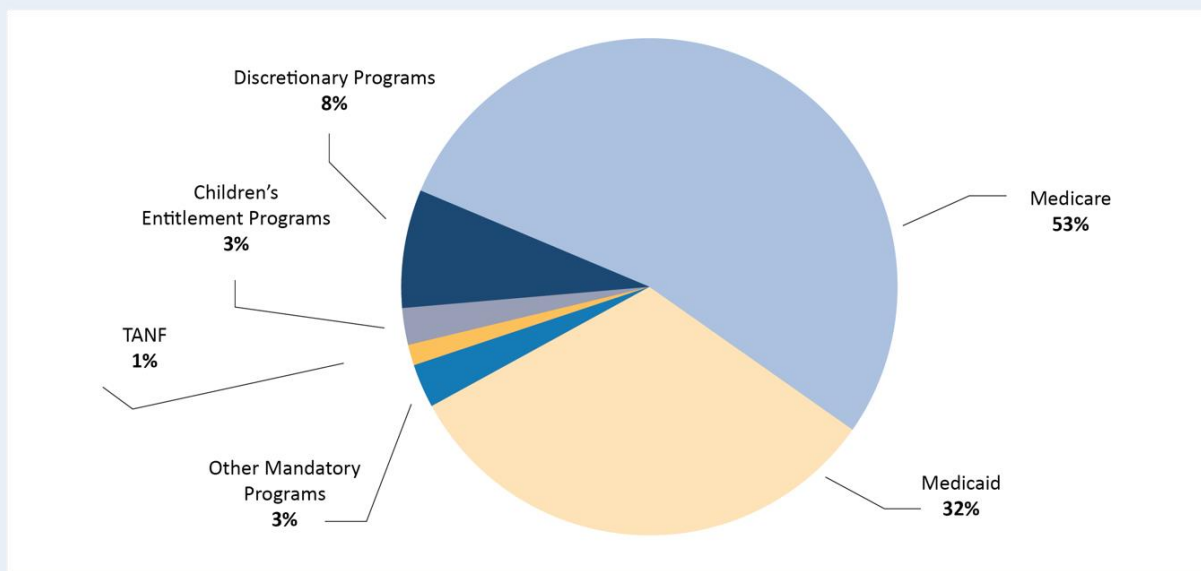
FY 2020 President's Budget for HHS

dollars in millions	2018	2019/1	2020
Budget Authority /2	1,176,503	1,274,242	1,292,523
Total Outlays	1,120,647	1,230,614	1,286,434

1/ The FY 2019 funding level reflects FY 2019 Enacted for all of HHS except for FDA, IHS, and small components of CDC and NIH, which reflect the FY 2019 Annualized CR, including any funding anomalies and directed or permissive transfers (where applicable).
 2/ The Budget Authority levels presented here are based on the Appendix, and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.

COMPOSITION OF THE FY 2020 BUDGET

\$1,286 Billion in Outlays



General Notes

Numbers in this document may not add to the totals due to rounding. Budget data in this book are presented “comparably” to the FY 2020 Budget, since the location of programs may have changed in prior years or be proposed for change in FY 2020. This approach allows increases and decreases in this book to reflect true funding changes. The FY 2019 and FY 2020 mandatory figures reflect current law and mandatory proposals reflected in the Budget.

PUTTING AMERICA'S HEALTH FIRST

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans 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) 2020 Budget supports HHS's mission by prioritizing key investments that work towards fulfilling the Administration's commitments to improve American health care, address the opioid crisis, lower the cost of drugs, and streamline federal programs. The Budget reforms the Department's programs to better serve and safeguard the American people, while prioritizing key investments within them.

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

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

Reforming the Individual Market for Insurance

The Budget proposes bold reforms to build a stronger health care system and fix the damage done by Obamacare. These reforms return the management of health care to the states, which are more capable of tailoring programs to their unique markets, increasing options for patients and providers, and promoting financial stability and responsibility, while protecting people with pre-existing conditions and high health care costs.

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

Lowering the Cost of Prescription Drugs

Putting America's health first includes improving access to safe, effective, and affordable prescription drugs. The Budget proposes to expand the Administration's work to lower prescription drug prices and reduce beneficiary out-of-pocket costs. The Administration has proposed and, in many cases, made significant strides to implement bold regulatory reforms to increase competition, improve negotiation, create incentives to lower list prices, reduce out-of-pocket

costs, improve transparency, and end foreign free-riding. Congress has already taken bipartisan action to end pharmacy gag clauses, so patients can work with pharmacists to lower their out-of-pocket costs. The Budget proposes to:

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

Reforming Medicare and Medicaid

Millions of Americans rely on Medicare and Medicaid for their health care. The Budget supports reforms to make these programs work better for the people they serve and reduce unnecessary spending. The FY 2020 Medicare budget aligns incentives within the Part D program to lower drug costs, continues to drive Medicare toward a value-based payment system, and combats the opioid crisis. The FY 2020 Medicaid budget provides additional flexibility to states, puts Medicaid on a path to fiscal stability by restructuring its financing and reducing waste, and refocuses on the low-income populations Medicaid was originally intended to serve: the elderly, people with disabilities, children, and pregnant women.

Paying for Value

The Administration is focused on ensuring federal health programs produce quality outcomes and results at the lowest possible cost for the American people. The Budget supports an expansion of value-based payments in Medicare. That expansion, along with implementation of a package of other reforms, will improve quality, promote competition, reduce the federal burden on providers and patients, and focus payments on value instead of volume or site of service. Two of these reforms are: 1) a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers; and, 2) a consolidated hospital quality program in Medicare to reduce duplicative requirements and create a focus on driving improvements in patients' health outcomes.

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

Combating the Opioid Crisis

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

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

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

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

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

Ending the HIV Epidemic: A Plan for America

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

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

Clients receiving medical care through the Ryan White HIV/AIDS Program (RWHAP) were virally suppressed at a record level of 85.9 percent in 2017. The Budget includes \$70 million in new funds for RWHAP within HRSA to increase direct health care and support services, further increasing viral suppression among patients in the target areas. The Budget includes

\$50 million in HRSA for expanded PrEP services, outreach, and care coordination in community health centers. Additionally, the Budget also prioritizes the reauthorization of RWHAP to ensure federal funds are allocated to address the changing landscape of HIV across the United States.

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

Together, these HHS investments will be the first step towards ending the HIV epidemic in America and saving hundreds of thousands of lives.

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

Prioritizing Biodefense and Preparedness

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

The Budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The Budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to

state and local governments. These investments protect our nation against health security threats such as anthrax, botulism, Ebola, and chemical, radiological, and nuclear agents.

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

Promoting Upward Mobility

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

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

Improving Outcomes in Child Welfare

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

Strengthening the Indian Health Service

The Budget provides \$5.9 billion for IHS, which is an additional \$392 million above the FY 2019 Continuing Resolution. The increase expands direct health care services across Indian Country, including hospitals and health clinics, Purchased/Referred Care, dental health, mental health and alcohol and substance abuse services. The Budget invests in new programs to improve patient care, quality, and oversight. It fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, ensuring tribes have the resources required to successfully manage

key programs. This investment reflects HHS's commitment to improve the health and well-being of American Indians and Alaska Natives.

FOSTER SOUND, SUSTAINED ADVANCES IN THE SCIENCES

Promoting Research and Prevention

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

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

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

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

Addressing Emerging Public Health Challenges

CDC is the nation's leading public health agency, and the Budget supports its work putting science into action. Approximately 700 women die each year in the United States as a result of pregnancy or delivery complications or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Findings from Maternal Mortality Review Committees indicate that more than half of these deaths are preventable. The Budget supports data analysis on maternal deaths and efforts to identify prevention opportunities.

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

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

The Budget strengthens the health security of our nation and prioritizes CDC activities to save lives and protect people from health threats. The Budget continues CDC's support to state and local government partners in implementing programs, establishing guidelines, and conducting research to improve the health, safety and well-being of the United States.

Innovations in the Food and Drug Administration

The Food and Drug Administration (FDA) plays a major role in protecting public health by assuring the safety of the nation's food supply and regulating medical products and tobacco. The responsibility to advance public health places FDA at the forefront of scientific

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

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

Almost one quarter of total federal outlays are made by HHS. The Department employs nearly 78,000 employees and administers more grant dollars than all other federal agencies combined. Efficiencies in HHS management have a tremendous impact on federal spending as a whole. The Budget demonstrates the Department's commitment to responsible stewardship of taxpayer dollars.

Advancing Fiscal Stewardship

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

HHS oversees Medicare and Medicaid, large federal health care programs serving millions of Americans. These activities must operate efficiently and effectively, both to rein in wasteful spending and to better serve beneficiaries. HHS is implementing actions such as enhanced provider screening, prior

authorization, and sophisticated predictive analytics technology, to reduce improper payments in Medicare and Medicaid without increasing burden on providers. HHS continues to work with law enforcement partners to target fraud and abuse in health care. The Budget includes a series of proposals to strengthen Medicare and Medicaid oversight, including increasing prior authorization and enhancing Part D plans' ability to address fraud, and strengthening the Department's ability to recoup overpayments made to states on behalf of ineligible Medicaid beneficiaries. Finally, the Budget increases investment in health care fraud and abuse activities overall.

Implementing ReImagine HHS

HHS eagerly took up the call in the Administration's Government-wide Reform Plan to more efficiently and effectively serve the American people. HHS developed a plan—"ReImagine HHS"—organized around core goals, such as accelerating clinical innovation, maximizing talent, and facilitating independence. HHS has already identified the actions necessary to meet these goals, and is now working to implement them.

ReImagine HHS is identifying ways to reduce federal spending through more efficient operations. For example, the Buy Smarter initiative streamlines the procurement process by using new and emerging technologies.

HHS also recognizes the importance of a workforce that is equipped to thrive in the 21st century. Through a ReImagine HHS initiative – Maximize Talent – the Department is working to enhance employee engagement and recognition for high performance, as well as modernize human resources information technology infrastructure. These actions can further ensure HHS remains one of the best places to work in the federal government.

HHS BUDGET BY OPERATING DIVISION /1

<i>dollars in millions</i>	2018	2019	2020
Food and Drug Administration /2,4			
Budget Authority	2,397	2,956	3,329
Outlays	2,057	2,766	2,837
Health Resources and Services Administration			
Budget Authority	11,703	11,995	11,004
Outlays	11,058	11,488	11,864
Indian Health Service /2			
Budget Authority	5,741	5,815	6,104
Outlays	5,003	6,358	5,970
Centers for Disease Control and Prevention /2			
Budget Authority	8,741	7,909	6,767
Outlays	7,976	7,595	7,877
National Institutes of Health /2,3,4			
Budget Authority	36,396	38,201	33,669
Outlays	32,716	35,454	36,652
Substance Abuse and Mental Health Services Administration			
Budget Authority	5,539	5,609	5,535
Outlays	3,833	4,912	5,684
Agency for Healthcare Research and Quality /4			
Program Level	432	451	0
Budget Authority	333	338	0
Outlays	324	230	299
Centers for Medicare & Medicaid Services /5			
Budget Authority	1,042,407	1,137,937	1,169,091
Outlays	999,392	1,098,072	1,156,333
Administration for Children and Families			
Budget Authority	58,618	58,299	52,121
Outlays	53,897	56,267	53,208
Administration for Community Living			
Budget Authority	2,115	2,148	1,997
Outlays	1,942	2,223	2,238
Departmental Management /6			
Budget Authority	493	506	340
Outlays	447	996	503

HHS BUDGET BY OPERATING DIVISION /1

<i>dollars in millions</i>	2018	2019	2020
Non-Recurring Expense Fund			
Budget Authority	-	-400	-400
Outlays	242	-93	-201
Office of Medicare Hearings and Appeals			
Budget Authority	182	182	186
Outlays	185	235	186
Office of the National Coordinator			
Budget Authority	60	60	43
Outlays	54	111	48
Office for Civil Rights			
Budget Authority	40	38	30
Outlays	35	26	43
Office of Inspector General			
Budget Authority	84	87	82
Outlays	84	123	83
Public Health and Social Services Emergency Fund			
Budget Authority	2,033	2,625	2,667
Outlays	1,970	2,826	2,861
Program Support Center (Retirement Pay, Medical Benefits, Misc. Trust Funds)			
Budget Authority	750	731	749
Outlays	561	1,819	741
Offsetting Collections			
Budget Authority	-963	-631	-629
Outlays	-963	-631	-629
Other Collections			
Budget Authority	-166	-163	-163
Outlays	-166	-163	-163
Total, Health and Human Services			
Budget Authority	1,176,503	1,274,242	1,292,523
Outlays	1,120,647	1,230,614	1,286,434
1/ The Budget Authority (BA) levels presented here are based on the Appendix and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.			
2/ FDA, IHS, ASTDR and SuperFund BA reflect the annualized level of the 2019 Continuing Resolution. IHS BA includes a \$15 million funding anomaly.			
3/ The 2020 Budget includes \$256 million to consolidate the Agency for Healthcare Research and Quality's activities within the National Institutes of Health.			
4/ FDA and NIH BA include the full allocations provided in 21st Century Cures Act.			
5/ 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.			
6/ Includes the Pregnancy Assistance Fund, the Health Insurance Reform Implementation Fund, and transfers from the Patient-Centered Outcomes Research Trust Fund; and payments to the State Response to the Opioid Abuse Crisis Account.			

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

<i>dollars in millions</i>	2018	2019	2020	2020 +/-2019
Discretionary Programs (Budget Authority):				
Food and Drug Administration /2,4,6	2,964	2,964	3,326	+362
<i>Program Level</i>	5,361	5,499	6,142	+643
Health Resources and Services Administration	6,730	6,853	5,853	-1,000
<i>Program Level</i>	11,416	11,714	10,733	-981
Indian Health Service /2	5,538	5,553	5,945	+392
<i>Program Level</i>	6,890	6,905	7,297	+392
Centers for Disease Control and Prevention /2, 7	6,899	6,553	5,277	-1,276
<i>Program Level</i>	12,642	12,107	11,954	-153
National Institutes of Health /2,3,4,5	36,151	38,010	33,477	-4,533
<i>Program Level</i>	37,224	39,306	34,368	-4,939
Substance Abuse and Mental Health Services Administration	5,507	5,597	5,535	-62
<i>Program Level</i>	5,654	5,744	5,679	-65
Agency for Healthcare Research and Quality /3	333	338	0	-338
<i>Program Level</i>	432	451	0	-451
Centers for Medicare & Medicaid Services	3,965	3,975	3,579	-395
<i>Program Level</i>	6,260	6,531	6,255	-277
Administration for Children and Families	22,997	23,210	18,327	-4,883
<i>Program Level</i>	22,997	23,210	18,327	-4,883
Administration for Community Living	2,136	2,169	2,033	-137
<i>Program Level</i>	2,219	2,253	2,088	-164
Office of the Secretary:				
General Departmental Management	470	481	340	-140
<i>Program Level</i>	566	585	425	-160
1/ Unless otherwise noted, the FY 2018 column reflects the 2018 Enacted levels (post UAC transfer and disaster supplemental).				
2/ FDA, IHS, ASTDR and Superfund (NIH) BA reflect the annualized level of the 2019 Continuing Resolution. IHS BA includes a \$15 million funding anomaly.				
3/ The 2020 Budget includes \$256 million to consolidate the Agency for Healthcare Research and Quality's activities within the NIH.				
4/ FDA and NIH BA include the full allocations provided in the 21st Century Cures Act.				

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

<i>dollars in millions</i>	2018	2019	2020	2020 +/-2019
Office of Medicare Hearings and Appeals	182	182	182	+0
<i>Program Level</i>	182	182	186	+4
Office of the National Coordinator	60	60	43	-17
<i>Program Level</i>	60	60	43	-17
Office for Civil Rights	39	39	30	-9
<i>Program Level</i>	48	52	53	+1
Office of Inspector General /6	82	87	80	-7
<i>Program Level</i>	367	381	403	+22
Public Health and Social Services Emergency Fund /7	2,557	2,631	2,667	+36
<i>Program Level</i>	2,557	2,631	2,667	+36
Discretionary HCFAC	745	765	792	+27
Accrual for Commissioned Corps Health Benefits	32	29	30	+1
Total, Discretionary Budget Authority	97,388	99,496	87,515	-11,981
<i>NEF Cancellation and Rescissions</i>	-240	-400	-400	-
<i>Less One-Time Rescissions</i>	-6,773	-7,665	-19,748	-12,083
Revised, Discretionary Budget Authority	90,375	91,431	67,367	-24,064
Discretionary Outlays	87,695	97,167	96,902	-265
5/ NIH BA reflects a \$5 million directed transfer to OIG.				
6/ FDA BA reflects a \$1.5 million directed transfer to OIG.				
7/ HHS administratively transferred the Strategic National Stockpile from CDC to ASPR in FY 2019. Funding in FY 2018 is comparably adjusted and includes a Secretarial transfer of \$6.1 million to CDC for transition costs. Funding in FY 2019 does not reflect an additional Secretarial transfer of \$6.1 million to CDC.				

COMPOSITION OF THE HHS BUDGET MANDATORY PROGRAMS

	2018	2019	2020	2020 +/-2019
<u>Mandatory Programs (Outlays):/1</u>				
Medicare	582,011	644,827	683,932	+39,105
Medicaid	389,157	418,681	418,151	-530
Temporary Assistance for Needy Families /2	17,081	17,133	15,205	-1,928
Foster Care and Adoption Assistance	8,581	7,876	8,435	+559
Children's Health Insurance Program /3	17,282	18,634	16,882	-1,752
Child Support Enforcement	4,137	4,235	4,356	+121
Child Care Entitlement	2,358	2,819	3,562	+743
Social Services Block Grant	1,587	1,619	487	-1,132
Other Mandatory Programs	11,721	18,254	39,151	+20,897
Offsetting Collections	-963	-631	-629	+2
Subtotal, Mandatory Outlays	1,032,952	1,133,447	1,189,532	+56,085
Total, HHS Outlays	1,120,647	1,230,614	1,286,434	+55,820
1/ Totals may not add due to rounding.				
2/ Includes outlays for TANF, and the TANF Contingency Fund. Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.				
3/ Includes outlays for the Child Enrollment Contingency Fund.				

Lowering the Cost of Prescription Drugs

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. We have access to the greatest medicines in the world, but access is meaningless without affordability.

To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First* Blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs, using four key strategies for reform: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

Recognizing that the status quo is indefensible, HHS has rapidly taken administrative steps where the Department has authority to turn the President’s vision into action. These actions include proposals to create competition for physician-administered drugs, improve competition and negotiation between Medicare’s prescription drug plans, increase price transparency for drugs advertised on television, end the payment of kickbacks by drug companies and demanded by pharmacy benefit managers that are artificially driving up prices, ensure beneficiaries are benefiting from

price concessions at the pharmacy counter, and address foreign free-riding so that Americans pay prices closer to what patients in other countries pay for the same drugs.

HHS will continue to use all of its administrative tools to achieve these goals, and recognizes Congress has the authority to implement more sweeping changes. The Administration looks forward to working with Congress on bipartisan solutions that lower costs, increase transparency, and protect patient access and safety.

The FY 2020 Budget legislative proposals complement the many successful administrative actions HHS has already taken to lower the cost of prescription drugs. These proposals:

- Protect seniors and taxpayers by modernizing Medicare Part D, and improving transparency and accuracy of payments under Medicare Part B;
- Ensure manufacturers pay their fair share of Medicaid rebates covering all price increases for a drug;
- Give the Health Resources and Services Administration (HRSA) the resources and

LOWERING THE COST OF PRESCRIPTION DRUGS



**OVER 2,000
GENERIC DRUGS**

approved or tentatively approved in 2017-18, including 128 in October 2018 — a new FDA record for one month

Proposed to **END** a system of **BACKDOOR REBATES** to middlemen and bring **transparent upfront discounts** to **patients** at the pharmacy counter

1st proposal to include drug prices in *direct-to-consumer advertising*



57%

fewer brand price increases in 2018, from May 11 to December 31, as there were in 2017, over the same time period



\$320M

in savings for seniors in 2018 from changes to Medicare payments for Part B drugs administered in 340B hospital clinics



2 BILLS

were signed by President Trump to ban pharmacy gag clauses so patients can always ask for the cheapest option

\$26 BILLION

in estimated savings from generic drugs approved during the Trump administration in 2017 and 2018

regulatory authority to better manage the 340B program; and

- Allow the Food and Drug Administration (FDA) to close loopholes in the drug approval and patent systems that allow manufacturers to engage in anti-competitive practices.

2020 LEGISLATIVE PROPOSALS

Increased Competition

Medicare

Reduce Average Sales Price Based Payments When the Primary Patent Expires to Increase Competition and Reduce Gaming

When a drug is about to go off patent, manufacturers often pay generic and biosimilar competitors to delay release of generic or biosimilar drugs, extending the time during which those drugs do not have competition. Likewise, when a biologic's 12-year market exclusivity period is set to expire, manufacturers may engage in other forms of patent disputes to block a competitor brand from coming to market. These "pay-for-delay" agreements and patent and exclusivity extending tactics slow the entry of generic, biosimilar, and biologic competition and keep drug prices high. Effective Calendar Year (CY) 2020, this proposal reduces payment for innovator drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action after the primary patent or market exclusivity period expires, whichever date is earliest. Once a competitor is commercially available, the Centers for Medicare & Medicaid Services (CMS) will pay for both innovator and competitor drugs at ASP plus 6 percent. These changes will create a financial disincentive to anti-competitive behavior. [Budget impact not available]

FDA

Reform Exclusivity for First Generics to Spur Greater Competition and Access

Currently, some generic drug applicants who file first limit competition by intentionally delaying seeking final approval in order to not trigger their 180-day exclusivity, thereby blocking subsequent generic competitors. Effective FY 2020, first-to-file generic applicants awarded a 180-day exclusivity period will not be able to unreasonably and indefinitely block

subsequent generics from entering the market beyond the exclusivity period. The proposal will trigger an initial generic drug applicant's 180-day exclusivity when a subsequent application is tentatively approved, subject to specific conditions. [\$960 million in Medicare savings over 10 years; \$200 million in Medicaid savings over 10 years]

Amend the 180-Day Forfeiture Provision Addressing Failure to Obtain Tentative Approval

Currently, first applicants with a deficient application for a generic drug before FDA can avoid forfeiting their 180-day exclusivity by claiming the failure is caused by a change in or a review of the requirements for approval imposed after the date on which the application is filed. Some first applicants have taken advantage of ambiguities of this provision, avoiding forfeiture and delaying generic competition. This legislative proposal closes this loophole by limiting it to instances where the change in the requirements for approval was the only reason the applicant failed to obtain tentative approval. As with the other proposal for ending gaming of the exclusivity period, this measure will mean more generics on the market, faster. [Budget impact not available]

Codify FDA's Approach to Determining New Chemical Entity Exclusivity

Some stakeholders have questioned the validity of FDA's current approach to determining what constitutes a new chemical entity. This proposal codifies the approach FDA has taken in interpreting the law, known as "active moiety" approach. Five-year new chemical entity exclusivity will apply only to drugs with significant changes to their chemical structure compared to current drugs. This proposal codifies a narrow definition to avoid awarding exclusivity to products that do not represent a true innovation. [Budget impact not available]

Provide FDA Enhanced Authority to Address Abuse of the Petition Process

Sham citizen petitions, which are requests to FDA with the intent to delay approval of new generic drugs, do not promote generic drug competition. This proposal provides FDA with greater flexibility to summarily deny these petitions, and eliminate the mandatory 150-day response timeframe for these petitions, which FDA believes is unnecessary because all generic drug applications have goal dates under law and language is no longer needed to prevent delay of approval. These changes would speed the approval of new generic

drugs and increase competition. [Budget impact not available]

Encourage Biosimilar Development

Biosimilars must meet the same monograph standards issued by the U.S. Pharmacopeia as other non-biologic products, which include standards for strength, quality, packaging and labeling. This requirement can impede biosimilar innovation and competition. This proposal amends the Public Health Service Act so that biological products do not have to meet separate standards designed specifically for drugs. This change will make it easier for biosimilars to enter the market and increase competition, which is essential to reducing costs for biologic products. [No budget impact]

Better Negotiation

Medicare

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

Under Part B, providers have limited ability to negotiate for cheaper Part B drug prices. Beginning in CY 2020, this proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D when savings can be gained from price competition. The Secretary would not use this authority when it limits a beneficiaries' access to the drug or increases beneficiary cost-sharing. Beneficiary cost-sharing for any drugs shifted from Part B to Part D may be counted toward the Medicare Advantage out-of-pocket limit for plans that have a combined Part D benefit. Moving certain Part B drugs to Part D, when appropriate, will allow HHS to leverage Part D plans' negotiating power to bring down prices and lower patient out-of-pocket costs. [Budget impact not available]

Give the Secretary Authority to Contract with Pharmaceutical Manufacturers Entering into New Coverage Gap Discount Program Agreements on a Quarterly Basis

The Coverage Gap Discount Program was created in 2010 to close the Medicare Part D "donut hole" and requires manufacturers of brand drugs to provide discounts to beneficiaries during the coverage gap phase of the Part D benefit. Manufacturers are required to have a Coverage Gap Discount Program agreement with CMS before their drugs can be covered under Medicare Part D. Because manufacturers of new

drugs are eager to get their drugs covered as soon as possible, they sometimes pay other manufacturers for the right to "piggy back" on their existing agreements, creating unnecessary costs to the system and administrative burden for CMS. This proposal allows the Secretary to initiate new contracts with pharmaceutical manufacturers on a quarterly, rather than an annual, basis. Increasing the frequency of the coverage gap discount program contracting process would ensure Medicare beneficiaries have continued access to a wide range of drugs, including newly approved drugs, without incurring additional costs for new manufacturers and the Medicare program. [Budget impact not available]

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

CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. When manufacturers choose not to report ASPs, Medicare sets the payment rate based only on the reported ASP data, and the rate does not truly reflect the average price. If no manufacturers report ASPs for a drug, CMS must resort to pricing drugs using alternative, potentially inflated, measures of price such as wholesale acquisition cost (WAC). Beginning in 2020, this proposal requires all Part B drug manufacturers to report ASP data and gives the Secretary the authority to penalize manufacturers who do not report required data. The penalties would be similar to those currently used in Medicaid, where manufacturers face civil monetary penalties of up to \$10,000 per day if data is not reported within 30 days of the end of the quarter. Requiring that all manufacturers of Part B drugs report ASP data improves the accuracy of CMS' drug payments and prevents CMS from relying on other, less accurate pricing mechanisms. [No budget impact]

Reduce Wholesale Acquisition Cost (WAC)-Based Payments

When ASP data are not available, Medicare pays for some single-source Part B drugs at 106 percent of WAC. Unlike an ASP, a drug's WAC does not incorporate rebates or other discounts. If discounts are available on these Part B drugs, Medicare is paying an inflated price compared to the ASP-based payment rate. Beginning in 2020, this proposal reduces the payment rate for single-source drugs, biologics, and biosimilars from 106 percent to 103 percent of WAC to reduce excessive payments. [Budget impact not available]

Medicaid

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

The Medicaid Drug Rebate Program allows state Medicaid agencies to receive manufacturer rebates, which offset some of their drug costs. Manufacturers must sign a rebate agreement with HHS to have their outpatient drugs covered by state Medicaid agencies. Ongoing misclassification of brand and generic drugs can result in lower rebates paid to the state and federal governments. 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. [\$347 million in savings over 10 years]

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

Even though prescription drug coverage is an optional Medicaid benefit that all states cover, states do not have the same flexible tools that commercial payers have to manage their prescription drug programs. As part of an Administration-wide effort to address the high cost of prescription drugs and provide states with more purchasing flexibility, this proposal includes a statutory demonstration authority allowing up to five states to test a closed formulary under which states negotiate prices directly with manufacturers, rather than participating in best price reporting or the Medicaid Drug Rebate Program. Participating states will include an appeals process so beneficiaries can access drugs outside the formulary based on medical necessity. [\$410 million in savings over 10 years]

Impose Greater Penalties for Manufacturer Reporting of False Information or False Product Data under the Medicaid Drug Rebate Program

Current civil monetary penalties for drug manufacturers that submit false or late reports to the Medicaid Drug Rebate program are too low to provide an effective deterrent. This proposal would increase the civil monetary penalty paid by drug manufacturers for providing false or late reporting of information to the Medicaid Drug Rebate Program. It would also apply the same penalty to drug companies that make false product data submissions under the Medicaid Drug Rebate Program, such as misclassifying a brand drug as a generic drug. These changes will help to hold

drug companies accountable for misleading or late disclosures. [Budget impact not available]

Exclude Brand Name and Authorized Generic Drug Prices from Medicaid's Federal Upper Limit

A state's Medicaid Federal Upper Limit (FUL) limits the federal match for pharmacy reimbursement to 175 percent of the weighted average of the Average Manufacturer Price of all therapeutically and pharmaceutically equivalent multiple-source drugs. When a state's FUL includes non-generic drug prices, it discourages generic prescribing. This proposal removes brand name and authorized generic drugs from the FUL calculation for drugs where there are generic options, reducing the maximum federal reimbursement. This change will encourage the use of generics by aligning the FUL with generic prices. [\$980 million in savings over 10 years]

Clarify Authorized Generic Drug Sales under the Medicaid Drug Rebate Program

Some drug manufacturers may be inappropriately reducing their rebates to the Medicaid program. They interpret current law and regulations as allowing the inclusion of heavily discounted authorized generic sales to secondary manufacturers in the primary manufacturer's average price. This proposal clarifies that the primary manufacturer's average price must exclude these sales. As a result, manufacturers will no longer be able to exploit a loophole that allows them to pay inappropriately low drug rebates to the Medicaid program. [\$150 million in savings over 10 years]

Incentives for Lower List Prices

Medicaid

Allow Rebates on Drugs that Exceed 100 Percent of the Average Manufacturer Price

When the Affordable Care Act (ACA) capped the Medicaid rebates from manufacturers at 100 percent of their Average Manufacturer Price, it enabled manufacturers to increase drug prices excessively without having to pay increased rebates. This proposal removes the ACA's cap on Medicaid rebates, allowing rebates to offset the cost of drugs when list prices exceed the rate of inflation. By eliminating the cap on Medicaid drug rebates that manufacturers pay for brand or generic drugs, this proposal protects Medicaid from the cost of excessive price spikes and incentivizes lower list prices. [Budget impact not available]

HRSA

Establish and Collect User Fees from 340B Drug Pricing Program Participating Covered Entities

Currently, HRSA lacks a reliable, continuous funding source for managing the 340B Drug Pricing Program. This proposal allows HRSA to collect a user fee set at 0.1 percent of total 340B drug purchases from participating covered entities, which would support improvements to the 340B public database, program audits and oversight, and the program's automated compliance management tool. [Budget impact not available]

Lowering Out-of-Pocket Costs

Medicare

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

Manufacturers have dramatically increased prices for many Part B drugs in recent years because nothing currently restricts them from doing so. Effective CY 2020, this proposal caps the growth of the ASP payment of Part B drugs at the Consumer Price Index for all Urban Consumers (CPI-U). Each quarter when CMS establishes the ASP plus 6 percent payment amounts, CMS would pay the lesser of the actual ASP plus 6 percent or the inflation-adjusted ASP plus 6 percent as measured by the CPI-U. The base for a drug's price increase will be the initial ASP, or the first quarter of CY 2018 for drugs that had an ASP prior to the date of enactment. This proposal will protect Medicare beneficiaries from substantial price increases for individual drugs and save taxpayer dollars. [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

A CY 2018 Medicare regulation reduced outpatient hospital payment for 340B drugs from ASP plus 6 percent to ASP minus 22.5 percent, a conservative calculation of the average discount 340B hospitals receive. This has already lowered out-of-pocket costs for beneficiaries who use these drugs and pay the 20 percent copayment. However, the law requires the savings be redistributed across Medicare payments to outpatient hospitals in a budget neutral manner.

Beginning in CY 2020, this proposal allows CMS to apply savings from these lower payments for drugs purchased under the 340B program in a non-budget neutral way. Hospitals providing at least 1 percent of patient care costs in uncompensated care will receive redistributed savings based on the percentage of all uncompensated care they provide compared with other outpatient hospitals. Hospitals not meeting that threshold will be ineligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Funds. These changes will save money not just for Medicare, but ensure the savings from the 340B program are passed on to patients as the program intended. [No budget impact]

Eliminate Pass-Through Payments for Drugs, Biologicals, and Biosimilars

The current system of pass-through payments rewards new drugs, even if they offer no additional value or clinical benefit, unnecessarily increasing outpatient spending, and allowing for manufacturer gaming.

The Medicare Outpatient Prospective Payment System (OPPS) currently pays for a newly approved drug, biologic, or biosimilar at ASP plus 6 percent for three years when the cost exceeds a certain threshold. These payments are known as "pass-through payments." Effective CY 2020, this proposal removes transitional pass-through payment for drugs, biologicals, and biosimilars from the OPPS. Eliminating pass-through payment for drugs, biologicals, and biosimilars will lower cost by making them eligible for the reduced 340B payment level, or immediate bundling under the OPPS, if applicable. Manufacturers will no longer have an incentive to make small changes to their products in order to qualify for higher pass-through payments, which adds costs to the system without true innovation. [\$4.3 billion in Medicare savings over 10 years]

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

Under current law, newly eligible low-income subsidy beneficiaries are randomly assigned to a qualifying Part D plan, which in turn is paid based on the standard Part D prospective payment regardless of a beneficiary's actual utilization of Part D services. 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

MEDICARE PART D STANDARD BENEFIT DESIGN

Current law and proposed law comparison

Current Law Part D Standard Benefit Design 2019

		Deductible (\$415)	Initial Coverage Period (\$3,820 in total drug costs)	Coverage Gap (Donut Hole) (\$5,100 in out-of-pocket costs)	Catastrophic Phase
Brand	Beneficiary Plan	100%	25%	25%	5%
	Manufacturer		75%	5%	15%
	Federal Government			70%	80%
Generic	Beneficiary Plan	100%	25%	37%	5%
	Manufacturer		75%		15%
	Federal Government			63%	80%

Proposed Law Part D Standard Benefit Design 2021

		Deductible (\$415)	Initial Coverage Period (\$3,820 in total drug costs)	Coverage Gap (Donut Hole) (\$5,100 in out-of-pocket costs)	Catastrophic Phase
Brand	Beneficiary Plan	100%	25%	25%	80%
	Manufacturer		75%	5%	20%
	Federal Government			70%	
Generic	Beneficiary Plan	100%	25%	25%	80%
	Manufacturer		75%		
	Federal Government			75%	20%

plan serves as the single point of contact for beneficiaries seeking reimbursement for retroactive claims. 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 the end of 2019, has shown the proposed approach to both save money and be less disruptive to beneficiaries. [\$300 million in savings over 10 years]

HRSA

Establish Requirements Regarding the Use of Savings and Expand Rulemaking Authority for the 340B Drug Pricing Program for Program Integrity

General regulatory authority over all aspects of the 340B Program would allow HRSA to create clear, enforceable standards for the 340B program. This proposal also requires all 340B covered entities to

report the savings achieved from the 340B program and their uses. [Budget impact not available]

Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management

When the Part D benefit began in 2006, it was designed to encourage a robust benefit and plan participation. But 13 years later, the drug market has changed. With new high-cost specialty drugs and unconstrained price increases on existing drugs, it is time to realign incentives and bring down costs for beneficiaries and the government. The Budget modernizes Part D to better protect beneficiaries from high drug prices, give plans more tools to manage spending, and address misaligned incentives of the Part D drug benefit structure. The three part proposal will:

- 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 component are below.

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

Under the current benefit structure, Part D plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate their progression through the coverage gap into the catastrophic phase, where Medicare covers 80 percent of costs. Required discounts paid by brand drug and biosimilar manufacturers in the coverage gap are included in the calculation of a beneficiary's "true out-of-pocket costs (TrOOP)," which are a combination of a beneficiary's actual out of pocket costs and these discounts. In contrast, generic drugs are not subject to a manufacturer discount that counts toward TrOOP. Once a beneficiary's out-of-pocket spending reaches the annually updated TrOOP threshold, a beneficiary moves out of the coverage gap and into the catastrophic phase of the benefit. The manufacturer discounts mean that patients using generic drugs are required to spend more out of their own pockets before reaching this threshold, compared with patients using brand drugs. 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 that encourages plans to promote costly brand drugs. [\$74.7 billion in savings over 10 years]

Eliminate Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Beneficiaries

Low-income subsidy (LIS) beneficiaries are three times more likely than non-LIS beneficiaries to have drug spending high enough to enter the catastrophic phase of the benefit. LIS beneficiaries use more prescriptions, and are less likely than overall Part D enrollees to select a generic drug when one is available. This proposal encourages the use of higher value products among LIS beneficiaries by reducing cost sharing to \$0 for generics, biosimilars, and preferred multiple source drugs. [\$930 million in savings over 10 years]

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

The Part D benefit creates a perverse incentive structure for plans, wherein drug price increases shift more drug spending into the catastrophic phase, where Medicare pays 80 percent of costs. Beneficiaries who reach the catastrophic phase continue to be responsible for five percent of their drug costs, which can be a substantial financial burden for those using high cost specialty drugs, such as those used to treat Hepatitis C. This proposal:

- Increases Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over 4 years from 15 percent to 80 percent;
- Decreases Medicare's reinsurance liability from 80 to 20 percent; and,
- Eliminates beneficiary coinsurance, creating a true out-of-pocket maximum in Part D for the first time in the program's history.

Together, these changes provide beneficiaries with more predictable annual drug expenses and incentivize plans to better manage spending throughout the entirety of the benefit. [\$14.0 billion in costs over 10 years]

Lowering the Cost of Prescription Drugs

FY 2020 Lowering the Cost of Prescription Drugs Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Increased Competition			
<i>Medicare</i>			
Reduce Average Sales Price-Based Payments when the Primary Patent Expires to Increase Competition and Reduce Gaming	*	*	*
<i>FDA</i>			
Reform Exclusivity for First Generics to Spur Greater Competition and Access	-75	-455	-1,160
<i>Medicare Impact (non-add)</i>	-60	-370	-960
<i>Medicaid Impact (non-add)</i>	-15	-85	-200
Amend the 180-Day Forfeiture Provision Addressing Failure to Obtain Tentative Approval	*	*	*
Codify FDA's Approach to Determining New Chemical Entity Exclusivity	*	*	*
Provide FDA Enhanced Authority to Address Abuse of the Petition Process	*	*	*
Encourage Biosimilar Development	*	*	*
Better Negotiation			
<i>Medicare</i>			
Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B	*	*	*
Give the Secretary Authority to Contract with Pharmaceutical Manufacturers Entering into New Coverage Gap Discount Program Agreements on a Quarterly Basis	*	*	*
Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates	-	-	-
Reduce Wholesale Acquisition Cost (WAC)-Based Payments	*	*	*
<i>Medicaid</i>			
Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates	-26	-143	-347
Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage	-5	-120	-410
Impose Greater Penalties for Manufacturer Reporting of False Information or False Product Data under the Medicaid Drug Rebate Program	*	*	*
Exclude Brand Name and Authorized Generic Drug Prices from Medicaid's Federal Upper Limit	-90	-480	-980
Clarify Authorized Generic Drug Sales under the Medicaid Drug Rebate Program	-15	-75	-150
Incentives for Lower List Prices			
<i>Medicaid</i>			
Allow Rebates on Drugs that Exceed 100 Percent of the Average Manufacturer Price	*	*	*
<i>HRSA</i>			
Establish and Collect User Fees from 340B Drug Pricing Program Participating Covered Entities	*	*	*

FY 2020 Lowering the Cost of Prescription Drugs Budget Proposals

<i>dollars in millions</i>			
	2020	2020 -2024	2020 -2029
Lowering Out of Pocket Costs			
<i>Medicare</i>			
Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs	*	*	*
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	-	-	-
Eliminate Pass-Through Payments for Drugs, Biologicals, and Biosimilars	-150	-1,500	-4,270
Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries	-20	-120	-300
<i>HRSA</i>			
Establish Requirements Regarding the Use of Savings and Expand Rulemaking Authority for the 340B Drug Pricing Program for Program Integrity	*	*	*
Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management			
Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap	-	-23,440	-74,730
Eliminate Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Beneficiaries	-	-350	-930
Establish a Beneficiary Out-of-Pocket Maximum in the Medicare Part D Catastrophic Phase	-	6,310	14,030
Subtotal, Medicare	-230	-19,470	-67,160
Subtotal, Medicaid	-151	-903	-2,087
Subtotal, HRSA	*	*	*
Subtotal, FDA	*	*	*
TOTAL, Lowering the Cost of Prescription Drugs FY 2020 Budget Proposals	-381	-20,373	-69,247

* Budget impact unavailable as of the publication date of the FY 2020 President's Budget.

Food and Drug Administration



	<i>dollars in millions</i>			2020 +/- 2019
	2018 /1	2019 /2	2020 /3	
FDA Programs				
Foods	1,070	1,070	1,122	+52
Human Drugs	1,634	1,713	1,980	+266
Biologics	364	379	432	+52
Animal Drugs and Feeds	200	220	240	+19
Medical Devices	513	523	632	+109
National Center for Toxicological Research	65	65	67	+2
Tobacco Products	627	627	762	+135
Headquarters and Office of the Commissioner	289	298	320	+22
White Oak Operations	51	51	59	+8
GSA Rental Payment	238	241	241	-0
Other Rent and Rent Related Activities	122	124	146	+22
Subtotal, Salaries and Expenses	5,172	5,311	5,999	+688
Export Certification Fund	5	5	9	+4
Color Certification Fund	10	10	11	+0
Rare Pediatric Priority Review Vouchers	8	8	8	+0
Buildings and Facilities	12	12	12	--
21st Century Cures Act	60	60	75	+15
Opioids - International Mail Facilities	94	94	--	-94
Over-the Counter Monograph	--	--	28	+28
Total, Program Level	5,361	5,499	6,142	+643
Current Law User Fees /4				
Prescription Drug	911	1,010	1,062	+52
Medical Device	193	205	220	+15
Generic Drug	494	502	512	+10
Biosimilars	40	39	40	+1
Animal Drug	18	30	31	+0
Animal Generic Drug	9	18	19	+0
Family Smoking Prevention and Tobacco Control Act	672	672	712	+40
Food Reinspection	6	6	7	+0
Food Recall	1	1	1	+0
Mammography Quality Standards Act	21	21	21	+1
Export Certification	5	5	5	--
Color Certification Fund	10	10	11	+0
Rare Pediatric Priority Review Vouchers	8	8	8	+0
Voluntary Qualified Importer Program	5	5	6	+0
Third Party Auditor Program	1	1	1	+0
Outsourcing Facility	1	2	2	+0
Subtotal, Current Law User Fees	2,396	2,535	2,655	+120
Proposed Law User Fees				

	<i>dollars in millions</i>			2020 +/- 2019
	2018 /1	2019 /2	2020 /3	
Export Certification	--	--	4	+4
Over-the Counter Monograph	--	--	28	+28
Innovative Food Products	--	--	28	+28
Increase to the Tobacco User Fee	--	--	100	+100
Subtotal, Proposed Law User Fees	--	--	161	+161
Less Total, User Fees	2,396	2,535	2,816	+281
Total Discretionary Budget Authority	2,964	2,964	3,326	+362
Full-Time Equivalents	17,018	17,607	18,062	+455

1/ Reflects FY 2018 Final, post required and permissive transfers and rescissions.

2/ Reflects the annualized level of the Continuing Resolution and directed transfers.

3/ All figures comparable to the FY 2020 Budget and assume implementation of a working capital fund.

4/ Does not reflect priority review voucher user fee for Medical Countermeasures as FDA continues to develop an estimated fee level.

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 efficiently advance innovations that make medicines more effective, safer, and affordable; and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. Furthermore, FDA 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 occurring public health threats.

The Food and Drug Administration (FDA) protects and advances public health through an array of activities from safeguarding the nation’s blood supply, to overseeing the safety of food, and advancing safe and effective medical products. The products FDA is responsible for regulating account for more than 20 percent of every consumer dollar spent on products in the United States.

The Fiscal Year (FY) 2020 Budget includes \$6.1 billion in total resources for FDA—an increase of \$643 million or 12 percent above FY 2019. The FY 2019 funding level for FDA in the Budget reflects the annualized level of the Continuing Resolution. The Budget increases user fees by \$281 million and budget authority by \$362 million. It invests in priority activities, including: modernizing food safety, strengthening foodborne illness response, helping fight the opioid crisis, promoting the development of innovative medical products, investing in blood pathogen reduction

technology, and supporting the preparedness infrastructure.

ADVANCING ACCESS TO SAFE AND EFFECTIVE MEDICAL PRODUCTS

FDA’s responsibilities to ensure safe and effective medical products are wide-ranging. FDA oversees the safety, quality, and effectiveness of an extensive scope of products, including: prescription and over-the-counter drugs; biologics, such as vaccines, blood products, and gene therapies; radiation-emitting products; and medical devices ranging from dental devices to surgical implants. FDA continuously ensures regulated products are marketed according to federal standards and that products are safe, especially as new clinical information becomes available. FDA incorporates cutting-edge regulatory science into its evaluations to support patient access to safe and effective medical products. This work is supported by

centers across FDA to establish effective and efficient review pathways.

FDA Accomplishments

In the past year, FDA had several notable innovations that will result in meaningful difference for patients. In November 2018, FDA approved the second cancer treatment based on a common biomarker across different types of tumors, rather than based on a specific type of tumor or location in the body. This approval marks an important milestone in the development of cancer drugs that are tissue agnostic. FDA also approved the first generic version of the EpiPen and EpiPen Jr. auto-injector for the emergency treatment of allergic reactions, including life-threatening ones such as anaphylaxis. FDA also launched a new device review pilot program to reduce review time by one-third for well understood, low-risk medical devices. FDA also approved seven biosimilars in 2018, marking a record for the number of biosimilar approvals in a single calendar year.

Leveraging Cutting-Edge Science to Improve Oversight

Areas of novel and emerging science such as gene therapy, targeted medicine, and digital health pose regulatory challenges, because traditional regulatory approaches are not well-suited for such products. To meet these challenges, FDA is adapting and modernizing its regulatory approach to enable technology development, while maintaining FDA's gold standard for product review and consumer protection. For example, FDA is promoting work that will enable the agency to use real-world data such as post-market safety and adverse event data in regulatory decision-making. In December 2018, FDA announced its Framework for the Real-World Evidence Program, a new, strategic approach aimed at leveraging information gathered from patients and the medical community to inform and shape FDA's decisions across its drug and biologic development efforts.

Innovations in Human Drug and Device Review

FDA continues to implement the 21st Century Cures Act, and applies an innovative and nimble regulatory approach, consistent with the goals of the Act. For example, FDA encourages state-of-the-art innovations such as adaptive trials, modeling, and simulations to evaluate a product's safety and effectiveness. FDA also deploys modeling and simulation tools to predict clinical outcomes, inform trial design, support evidence of effectiveness, and evaluate adverse event mechanisms. The drug and biologic centers are

updating guidance to assist sponsors in incorporating modeling and simulation and applying these tools, for instance, to optimize product dosing based on individual physiology and genetics.

In FY 2020, the Budget requests a total of \$3.8 billion for medical product safety investments, which is \$428 million above FY 2019. This total includes \$1.8 billion in budget authority and \$1.9 billion in user fees. The Budget advances FDA's highest priority activities to ensure safe and effective medical products for the American public. The Budget includes \$220 million to continue proposing several initiatives promoting public health and spur growth in the domestic economy.

Supporting the Administration's Drug Pricing Initiative with Increased Competition

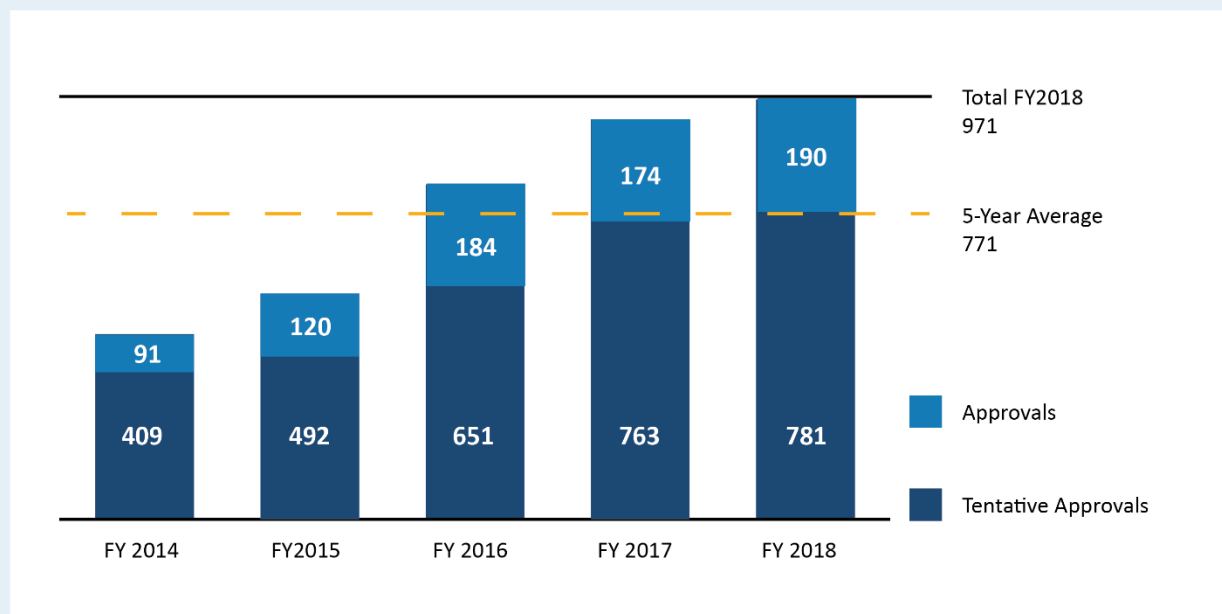
In support of the Administration's drug pricing initiative, FDA has taken significant steps to promote competition that can help lower costs and broaden patient access. FDA has focused on ensuring that regulatory requirements are efficient, predictable, and science-based, which can ultimately help reduce the time, uncertainty, and cost of generic and biosimilar product development. In FY 2018, FDA approved a record number of generic approvals in a fiscal year.

Moving forward, FDA will build on these successes. In 2019, FDA will encourage generic entry for drugs that face inadequate competition by laying out new, efficient guidelines for the use of a novel pathway that provides incentives for developing generic versions of drugs that currently face little or no competition. FDA is also taking additional new actions to advance the Biosimilar Action Plan and promote competition in the biologics space, including limiting the ability of branded drug companies from preventing biosimilar sponsors access to product samples needed for testing to support their product applications.

The Budget will include five FDA legislative proposals to support the Administration's drug pricing initiative, including a legislative proposal to eliminate a loophole manufacturers are exploiting to reduce generic competition on the market. Currently, a first applicant for a generic drug forfeits their 180-day exclusivity if they fail to obtain tentative approval for their application within a specific timeframe. A first applicant can avoid forfeiture under this provision if the failure to obtain tentative approval is caused by a change in or a review of the requirements for approval

APPROVAL OF GENERICS

FDA Sets a Record for the Greatest Number of Generics Approved in a Single Fiscal Year



imposed after the application filing date. Currently, first applicants with deficient applications are taking advantage of this provision by avoiding forfeiture even though they have deficiencies in their application unrelated to any change in or review of the requirements for approval. The legislative proposal clarifies the exception to avoid exploitation, so the exception to forfeiture will only apply if the change in or review of the requirements for approval was the only cause of the applicant's failure to obtain tentative approval. This change will result in increased generic competition and choice for consumers. FDA can proceed with final approval of competing generic drugs that otherwise would generally have had to wait until the first applicant with the deficient application had been approved and the 180-day exclusivity period had run out before being approved by FDA.

Additional details on the remaining FDA legislative proposals can be found in the "Lowering the Cost of Prescription Drugs" chapter.

Fighting the Opioids Epidemic

The Budget provides an additional \$55 million to support FDA's opioids activities. FDA's overall approach to the opioids epidemic focuses on four priorities:

- Decrease exposure to prescription opioids to reduce the rate of new addiction;
- Support the treatment of those with opioid use disorder;
- Foster development of novel pain treatment therapies; and
- Increase enforcement activities to crack down on illegal sales of opioids.

For this last priority, FDA is focused on illicit drugs sold online and typically shipped through the mail. Funding will be dedicated to hiring additional key staff, from Consumer Safety Officers who examine these mail facilities to scientists that provide laboratory support. This investment will support an increase of the inspection of packages at international mail facilities. These FDA activities help prevent illegal products from flowing across our borders, including products ordered online.

In 2018, FDA launched major operations with other federal partners, including Customs and Border Protection and the Drug Enforcement Administration

to target shipments and accurately estimate the number of illegal opioid mail shipments.

FIGHTING ILLICIT DRUG SHIPMENTS

Various loose blister packs and unmarked, unlabeled capsules at the John F Kennedy Airport International Mail Facility



Transform Medical Device Safety, Cybersecurity, Review, and Innovation

FDA has been improving policies and processes to address scientific advances and enhance the safety of medical devices. These improvements are critical to protect patients and foster innovation. FDA's fragmented information technology systems are not well-suited to support these activities. The Budget proposes \$55 million for an initiative to build an integrated knowledge management system and portal for medical devices using modern, agile information technology systems. These systems will have secure cloud-based data storage that will enable safety issues to be monitored along the total life cycle of the device, from bench testing to premarket clinical trials to postmarket adverse events and real-world evidence. This capability to better leverage pre-existing and new data in near real time is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity. Overall, it will make device reviews, postmarket surveillance, and cybersecurity efforts significantly more efficient and informative. These efforts could shorten review cycles, quickly identify and address safety signals and cyber vulnerabilities, and spur the development of innovative, safer, more effective devices.

Integrated Blood Pathogen Reduction

The Budget includes \$20 million to pilot a robust, simple technology that could eliminate contaminating viruses and other microorganisms from whole blood and still allow its subsequent separation into various blood components. The current level of safety of the blood supply was achieved through a combination of deferral of at-risk individuals and laboratory testing. Existing and emerging infectious diseases present a continued risk to blood safety, as they are spreading faster and are more quickly emerging. Continued vigilance against emerging threats is critical, including the introduction of new technologies to keep the blood supply safe. This investment could ensure availability of the blood supply even in the event of an emerging pathogen.

Supporting Quality Compounded Drugs

FDA continues to find significant problems at many outsourcing facilities it inspects, including conditions that could lead to product contamination and patient harm. The sector is new and would greatly benefit from more frequent and in-depth engagement by the FDA to support their efforts to improve compounding quality. The Budget invests in strengthening the establishment of the outsourcing facility sector to provide quality compounded drugs. The Budget provides \$76 million, an increase of \$25 million above FY 2019, for compounding activities such as to regulate this sector and inform facility, process, and system design; establish a list of bulk drug substances; and increase engagement with industry to promote compliance and identify ongoing gaps at facilities. With this funding increase, outsourcing facilities are better positioned to meet health care providers' and patients' needs for quality compounded drugs.

Over-the-Counter Drug Monograph Reform

The Budget also includes a legislative proposal to modernize the over-the-counter drug monograph system. The current monograph system has not kept up in product innovation, leaving a framework that does not well serve consumers or industry. FDA still has not been able to complete many monographs begun decades ago. Nor has it been able to make timely monograph modifications to account for evolving science and emerging safety issues, or to accommodate product innovation or marketing changes. Approximately one third of the monographs are not yet final.

The Budget envisions a framework that converts the current burdensome process to a streamlined administrative order process that: removes barriers to innovation, implements a new mechanism for quickly responding to urgent safety issues, and reduces the backlog by finalizing unfinished monographs. To support this effort, FDA will create a user fee program for over-the-counter monograph drugs and collect an estimated \$28 million in user fee resources in FY 2020.

Office of Laboratory Science and Safety

In FY 2020, FDA will continue to carry out high-priority medical product safety activities, including strengthening FDA's standard for regulatory decision making. The Budget includes \$17 million for the Office of Laboratory Science and Safety, an increase of \$1 million from FY 2019. This funding will support improved IT solutions for laboratory science, security, and environmental and occupational safety and health program management. It will also improve FDA-wide training programs and implement quality management systems to ensure oversight for the science, security, and environmental management components of FDA's mission.

MODERNIZING THE FOOD SAFETY SYSTEM

Since 2011, FDA has carried out its responsibilities under the FDA Food Safety Modernization Act (FSMA) and set new standards for a prevention-based food safety system. Entering the next decade, FDA will continue to ensure compliance with these standards, operating within a new food safety system.

The Budget includes \$1.4 billion for food safety across FDA programs, an increase of \$67 million above FY 2019. This total includes \$1.4 billion in budget authority—an increase of \$38 million—and \$44 million in user fees, flat with FY 2019. This work will be supported by centers across FDA that ensure that our approach to food safety is preventive, not reactive, and based on risk strategies.

Signal Detection of Foodborne Illness

The Budget includes an increase of \$16 million to improve signal detection of foodborne illness and strengthen FDA's response to human and animal food contamination. FDA urgently needs additional resources to increase capacity for evaluating and responding to foodborne outbreaks for both human and animal food. In FY 2018, FDA's Coordinated Outbreak Response and Evaluation network evaluated

a record 122 potential human food safety outbreak incidents. That is a 20 percent increase from FY 2017, which saw 101 evaluations, and almost a 70 percent increase from FY 2016 and 2015. Of those signal evaluations, in FY 2015, 18 evolved into large scale outbreak responses. FDA will add new staff and resources to enhance signal detection, response to outbreaks, and post-response evaluations. FDA will also add staff to oversee its recall process and make the recall process timelier.

Implementing the Food Safety Modernization Act

The Budget also includes an increase of \$16 million to advance implementation of FSMA. FDA will support state cooperative agreements to increase preventive controls inspections and human food produce safety inspections. These additional resources are essential to successful implementation of FSMA and are key to protecting public health by ensuring that manufacturing and processing facilities comply with the new FSMA requirements. Most critically, FDA does not have the existing resources to conduct additional preventive controls inspections, which are complex and lengthy.

Food and Feed Ingredient Review

FDA supports industry as it develops and implements new technologies in food, cosmetics, and veterinary products, including biotechnology products. The Budget invests \$36 million above FY 2019 to provide FDA additional capacity to review human food and animal feed ingredients. This total includes establishing a new user fee program that would collect \$28 million in its first year. This initiative will ensure that FDA keeps pace with how changes in the marketplace affect the human and animal food supply.

Food Safety Activities

With its food safety resources, FDA will continue to support other priority food and feed safety activities, such as implementing mandatory standards for imported food, rapidly detecting and responding to major foodborne illness outbreaks, and providing consumers with information about healthy choices using the most up-to-date science. FDA will continue support for food safety research, cosmetics safety, partnerships with academic institutes, and international capacity building.

FDA INFRASTRUCTURE AND FACILITIES

FDA infrastructure and facilities, including 56 laboratories strategically located across the continental United States and Puerto Rico, provide the necessary capabilities to meet the agency's regulatory responsibilities, strategic priorities, and program initiatives. FDA relies on optimally functional facilities to foster scientific innovation, improve health care, expand access to medical products, and advance public health. The Budget funds high-priority infrastructure that directly supports FDA's mission-critical work to ensure food and medical product safety. The Budget invests a total of \$458 million, \$30 million above FY 2019, in FDA infrastructure, which will support increased facility needs for rent, utilities, and maintenance, as well as continued rent costs at current laboratories and facilities.

The Budget also provides \$12 million for repairs and improvements to FDA's owned site infrastructure, offices, and laboratories across the country. The current backlog of maintenance and repairs is \$192 million.

ADVANCING MEDICAL COUNTERMEASURES

FDA works with partners at all levels of government—local, state, national and international—to support medical-countermeasure-related public health preparedness and response efforts. This includes working closely with federal partners through the Public Health Emergency Medical Countermeasures Enterprise to build and sustain the medical countermeasures programs necessary to respond effectively to chemical, biological, radiological, and nuclear (CBRN) threats and emerging public health threats, such as pandemic influenza, as well as with the Department of Defense to support the development of medical products needed to protect American military personnel. In FY 2018, FDA approved 28 medical countermeasures, including the first drug with an indication for treatment of smallpox.

The Budget includes \$128 million for medical countermeasure activities, of which \$31.5 million is for the Medical Countermeasure Initiative, an increase of \$7 million above FY 2019. This investment will increase FDA capacity to facilitate the development and availability of medical countermeasures to respond to CBRN and emerging infectious disease threats by furthering the establishment of clear, scientifically

supported regulatory pathways for medical countermeasures, filling critical scientific gaps, and advancing platform and manufacturing technologies for medical countermeasures.

REDUCING THE USE AND HARMS OF TOBACCO

The 2009 Family Smoking Prevention and Tobacco Control Act provides FDA authority to regulate the manufacturing, distribution, and marketing of tobacco products. Through the Center for Tobacco Products, FDA executes its regulatory and public health responsibilities to reduce initiation, decrease the harms, and encourage cessation of tobacco product use. Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year.

From 2017 to 2018, there was a 78 percent increase in e-cigarette use among high school students and a 48 percent increase among middle school students. In response to this epidemic of e-cigarette use among youth, FDA is acting across the full range of the agency's regulatory authorities, including increased enforcement of age- and identification-verification requirements. FDA is re-examining aspects of FDA's comprehensive plan on tobacco and nicotine regulation in order to strengthen the Youth Tobacco Prevention Plan.

The Budget includes a total of \$812 million in user fees to support the FDA tobacco program. The Budget includes a legislative proposal to increase the user fee collected in support of the tobacco program by \$100 million and adds electronic nicotine delivery system manufacturers and importers as entities subject to the user fees. The proposal supports FDA's goal to prevent a new generation of children from becoming addicted to nicotine through e-cigarettes.

USER FEES

FDA user fee programs help the agency to fulfill its mission of protecting the public health and accelerating innovation in the industry. User fees are an important resource that supplement, not replace, appropriated dollars. FDA has benefited from fees since the enactment of the Prescription Drug User Fee Act in 1993. Industry fees support FDA capacity to carry out its food and medical product safety responsibilities. The Budget increases overall currently authorized user fee programs by \$220 million, when including the fee

total for tobacco. It adds new manufacturers and importers to the list of entities subject to that user fee. The Budget proposes new fee programs for over-the-counter monograph and innovative food activities.

In 2018, Congress enacted the Animal Drug and Animal Generic Drug User Fee Amendments, allowing FDA to

continue collecting medical product user fees through 2023. These two user fee programs enhance the FDA's ability to maintain a predictable and timely animal drug review process, foster innovation in drug development, and expedite access to new therapies for food-producing and companion animals.

Health Resources and Services Administration



	dollars in millions			2020
	2018/1	2019	2020	+/- 2019
Primary Health Care				
Health Centers	5,332	5,506	5,506	--
<i>Discretionary Budget Authority [non-add]</i>	1,507	1,506	1,506	--
<i>Current Law Mandatory [non-add]</i>	3,825	4,000	--	-4,000
<i>Proposed Law Mandatory [non-add]</i>	--	--	4,000	+4,000
Health Centers Tort Claims	115	120	120	--
Free Clinics Medical Malpractice	1	1	1	--
Subtotal, Primary Care	5,448	5,627	5,627	--
Health Workforce				
National Health Service Corps	415	430	415	-15
<i>Discretionary Budget Authority [non-add]</i>	105	120	105	-15
<i>Current Law Mandatory [non-add]</i>	310	310	--	-310
<i>Proposed Law Mandatory [non-add]</i>	--	--	310	+310
Training for Diversity	88	88	--	-88
Training in Primary Care Medicine	49	49	--	-49
Oral Health Training	41	41	--	-41
Teaching Health Centers Graduate Medical Education	127	127	127	--
<i>Discretionary Budget Authority [non-add]</i>	--	--	--	--
<i>Current Law Mandatory [non-add]</i>	127	127	--	-127
<i>Proposed Law Mandatory [non-add]</i>	--	--	127	+127
Area Health Education Centers	38	39	--	-39
Health Care Workforce Assessment	6	6	5	-1
Public Health and Preventive Medicine Programs	17	17	--	-17
Nursing Workforce Development	249	234	83	-151
Children's Hospital Graduate Medical Education	314	325	--	-325
National Practitioner Data Bank User Fees	19	19	19	--
Other Workforce Programs	151	177	111	-66
Subtotal, Health Workforce	1,514	1,552	760	-792
Maternal and Child Health				
Maternal and Child Health Block Grant	650	678	661	-17
Sickle Cell Demonstration Program	4	4	-	-4
Autism and Other Developmental Disorders	49	51	-	-51
Heritable Disorders	16	16	-	-16
Healthy Start	110	123	123	--
Universal Newborn Hearing Screening	18	18	-	-18
Emergency Medical Services for Children	22	22	-	-22
Pediatric Mental Health Care Access Grants	10	10	--	-10
Screening and Treatment for Maternal Depression	5	5	--	-5
Family-to-Family Health Information Centers	6	6	6	--
<i>Discretionary Budget Authority [non-add]</i>	--	--	--	--

	<i>dollars in millions</i>			
	2018/1	2019	2020	2020 +/- 2019
<i>Current Law Mandatory [non-add]</i>	6	6	--	-6
<i>Proposed Law Mandatory [non-add]</i>	--	--	6	+6
Home Visiting [Mandatory]	400	400	400	--
Subtotal, Maternal and Child Health	1,291	1,333	1,189	-144
Ryan White HIV/AIDS Program				
Emergency Relief - Part A	656	656	656	--
Comprehensive Care - Part B	1,309	1,315	1,315	--
<i>AIDS Drug Assistance Program [non-add]</i>	894	900	900	--
Early Intervention - Part C	201	201	201	--
Children, Youth, Women, and Families - Part D	75	75	75	--
AIDS Education and Training Centers - Part F	34	34	34	--
Dental Services - Part F	13	13	13	--
Special Projects of National Significance (SPNS)	25	25	25	--
Ending HIV Epidemic Initiative	--	--	70	+70
Subtotal, Ryan White HIV/AIDS	2,313	2,319	2,389	+70
Healthcare Systems				
Organ Transplantation	25	26	28	+2
Cord Blood Stem Cell Bank	15	16	12	-4
C.W. Bill Young Cell Transplantation Program	24	25	25	--
Poison Control Centers	21	23	23	--
340B Drug Pricing Program	10	10	29	+19
<i>Discretionary Budget Authority [non-add]</i>	10	10	10	--
<i>User Fees [non-add]</i>	--	--	19	+19
Hansen's Disease Programs	16	16	14	-2
Subtotal, Healthcare Systems	111	115	130	+15
Rural Health				
Rural Outreach Grants	71	78	41	-37
Rural Hospital Flexibility Grants	49	54	-	-54
Telehealth	23	25	10	-15
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	10	11	11	--
Rural Communities Opioids Response Program	100	120	120	--
Rural Residency Program	15	10	--	-10
Subtotal, Rural Health	290	318	189	-129
Other Activities				
Family Planning	286	286	286	--
Program Management	155	155	152	-3
Vaccine Injury Compensation Program Direct Operations	9	9	11	+2
Subtotal, Other Activities	450	450	449	-1

	dollars in millions			2020
	2018/1	2019	2020	+/- 2019
Total, Discretionary Budget Authority	6,730	6,853	5,853	-1,000
Mandatory Funding	4,668	4,843	4,843	--
User Fees	19	19	38	+19
Total, Program Level	11,416	11,714	10,733	-981
Full-Time Equivalents	2,108	2,130	2,099	-31

1/ Reflects FY 2018 required and permissive transfers. Funding level does not include supplemental hurricane appropriations (\$60 million).

The mission of the Health Resources and Services Administration (HRSA) is to improve health and achieve health equity 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) 90-plus programs and more than 3,000 grantees across the United States. HRSA works across diverse populations—across the lifespan—to ensure people in the United States can access a broad range of essential health care and public health services. HRSA also supports training for health professionals, helps assure sufficient providers in areas that need them most, and improves health care delivery. In addition, HRSA oversees organ, bone marrow, and cord blood donation; compensates individuals harmed by vaccination; and maintains databases used to protect against health care malpractice, waste, fraud and abuse.

The Fiscal Year (FY) 2020 Budget requests \$10.7 billion for HRSA. This total includes \$5.9 billion in discretionary budget authority and \$4.8 billion in mandatory funding. The Budget prioritizes:

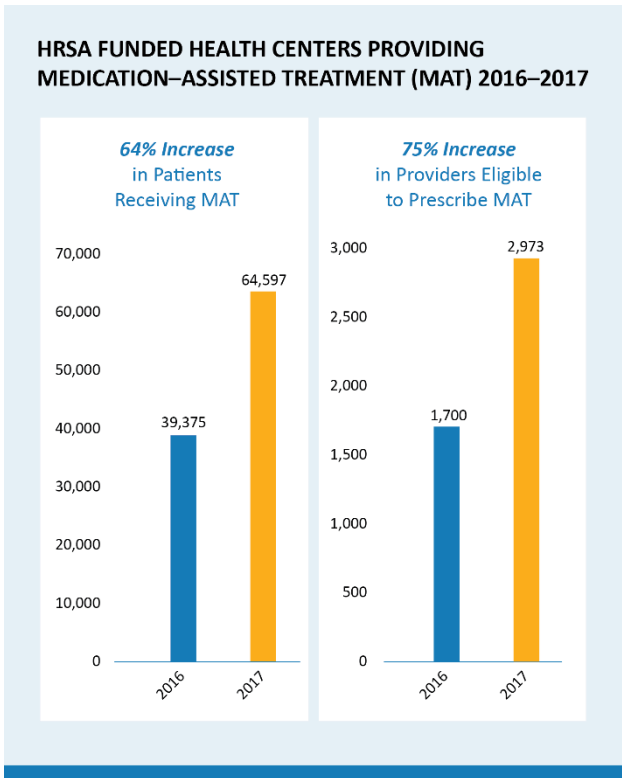
- Direct health care services through key programs such as Health Centers and the Ryan White HIV/AIDS program,
- Workforce enhancement by increasing the number of health care professionals working in communities facing shortages,
- Combatting the opioids epidemic and reducing maternal mortality, and
- Contributing to the Department-wide initiative to end the HIV epidemic in America by expanding access to pre-exposure prophylaxis (PrEP) and HIV care and treatment.

ENSURING ACCESS TO DIRECT HEALTH CARE SERVICES

The FY 2020 Budget prioritizes direct health care services, including through Health Centers and the Ryan White HIV/AIDS Program. These safety-net providers deliver critical health care services to low-income and vulnerable populations across the United States.

Health Centers

For more than 50 years, Community Health Centers have delivered affordable, accessible, high-quality, and cost-effective primary health care services to patients. The FY 2020 Budget provides \$5.6 billion for Health



Centers, which includes \$4 billion in mandatory resources in each of FYs 2020 and 2021.

Health centers use a holistic approach to patient care. They treat the entire person by integrating mental health, oral health, substance use disorder and primary medical care services. Approximately 1,400 health centers operate nearly 12,000 service delivery sites nationwide, serving more than 27 million people.

Primary care settings are increasingly a gateway to integrated care for individuals with substance use disorder and primary care needs. Patients with opioid or alcohol use disorders were significantly more likely to receive treatment and to abstain from alcohol and drugs when they received a collaborative care intervention at their primary care clinic.

In FY 2020, the Health Center Program will continue to support access to substance use disorder services, including medication-assisted treatment and pain management services. In 2017 alone, nearly 65,000 health center patients received medication-assisted treatment services, and the number of health center clinicians providing medication-assisted treatment increased by 75 percent between 2016 and 2017. Additionally, 90 percent of HRSA-funded health centers across the nation provide mental health services.

In FY 2020, the Health Center Program will support the Ending HIV Epidemic: A Plan for America Initiative coordinated by HHS. The Health Center Program will dedicate \$50 million to expand PrEP and HIV/AIDS services, outreach, and care coordination.

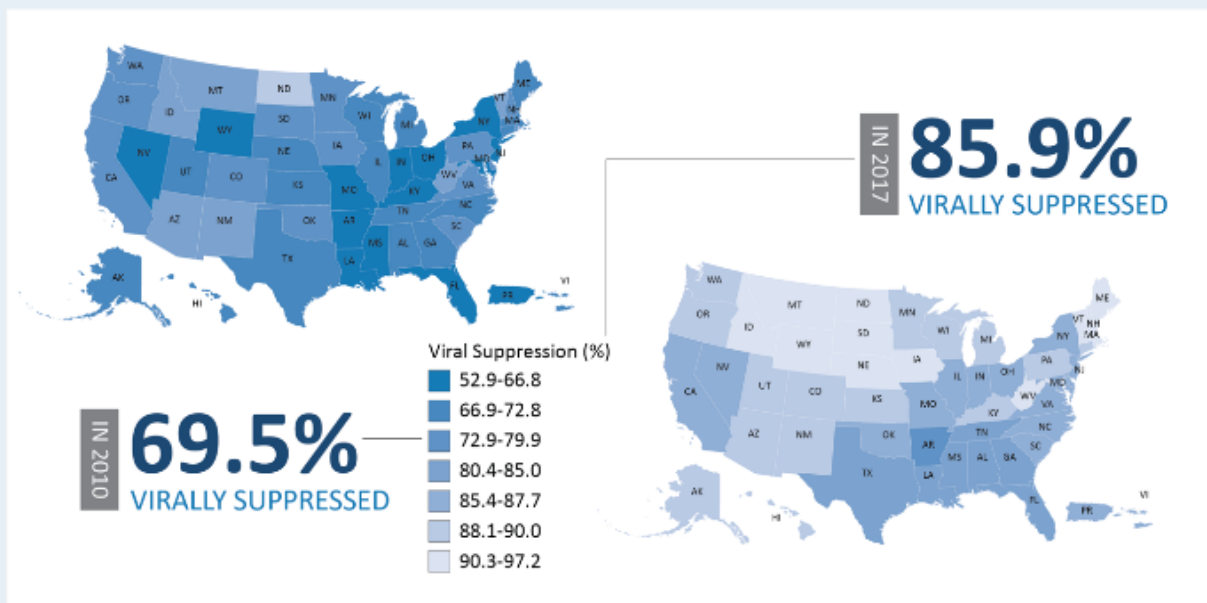
Ryan White HIV/AIDS Program

HRSA's Ryan White HIV/AIDS Program is an integral part of the Administration's initiative to end the HIV epidemic in America. The program funds grants to cities, counties, states, and local community-based organizations to provide comprehensive HIV primary medical care, essential support services, and medications for low-income people living with HIV. It serves approximately 50 percent of people living with diagnosed HIV infection in the United States.

As the largest domestic federal program providing HIV/AIDS care, the Ryan White HIV/AIDS Program increases access to health services for underserved populations, improves retention in care and survival, reduces use of more costly inpatient care, and reduces HIV transmission.

The FY 2020 Budget requests \$2.4 billion, which is \$70 million above FY 2019, for the Ryan White HIV/AIDS Program. To support the Ending HIV Epidemic Initiative, the Budget also proposes to reauthorize the Ryan White HIV/AIDS Program to

VIRAL SUPPRESSION AMONG RYAN WHITE CLIENTS, BY STATE, 2010 AND 2017—UNITED STATES AND TWO TERRITORIES



ensure 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 requested funding level provides \$900 million for the AIDS Drug Assistance Program, maintains other Ryan White programs at the FY 2019 level, and adds \$70 million for the initiative to end the HIV epidemic in America to reduce new HIV infections by 75 percent within 5 years, and by 90 percent within 10 years. As part of this Department-wide initiative, the Ryan White HIV/AIDS Program will increase funds for Part A and B jurisdictions within high-need areas identified by the Centers for Disease Control and Prevention to deliver additional care and treatment for people living with HIV.

Title X Family Planning

For more than 40 years, title X family planning clinics have ensured access to a broad range of family planning and related health services for millions of low-income or uninsured individuals. The FY 2020 Budget provides \$286 million, the same level as FY 2019, to support family planning and related services for nearly 4 million persons. Approximately 90 percent of those served have family incomes at or below 200 percent of the federal poverty level.

OPTIMIZING THE NATION'S HEALTH WORKFORCE

The FY 2020 Budget provides \$760 million in mandatory and discretionary resources for HRSA health workforce programs. The Budget prioritizes funding for health workforce programs requiring service commitments in underserved areas, training health care professionals to deliver integrated behavioral health services, and the National Center for Health Workforce Analysis.

National Health Service Corps

The National Health Service Corps provides scholarships and loan repayment to health care professionals in return for service commitments in communities with a shortage of health professionals. Approximately 50,000 primary care medical, dental, and mental and behavioral health professionals have

served in the National Health Service Corps since it began in 1972.

The FY 2020 Budget requests \$415 million for the National Health Service Corps, \$105 million in discretionary budget authority and \$310 million in mandatory resources for FY 2020 and 2021. In FY 2018, an estimated 11.5 million patients received care from more than 10,900 National Health Service Corps clinicians. Another 1,725 future primary care professionals are either in school or residency preparing for future service with the Corps programs. In addition to primary care, mental health and dental care, National Health Service Corps clinicians provide opioid and other substance use treatment to their patients. One in three National Health Service Corps clinicians is a behavioral health provider.

NURSE Corps Scholarship and Loan Repayment Program

The NURSE Corps Program awards scholarships and loan repayment to nurses, nursing students, and nurse faculty. By supporting nurses, healthier communities are built across the country, especially in areas of greatest need. The Budget provides \$83 million to support over 1,400 NURSE Corps clinicians providing care in rural and underserved communities. The Budget proposes to expand tax-exempt status to the Nurse Corps Scholarship Program and the Nurse Corps Loan Repayment Program similar to that provided to the National Health Service Corps to enhance recruitment of students and clinicians who have committed to serve in critical shortage facilities in underserved communities. In FY 2020, NURSE Corps will also support improved access to opioid treatment and prevention services.

Teaching Health Center Graduate Medical Education

The Teaching Health Center Graduate Medical Education Program increases the number of primary care physician and dental residents across the nation and supports training in community-based ambulatory care settings. The Budget requests \$127 million in mandatory funding for both FY 2020 and FY 2021 to support 750 resident slots.

KEEPING FAMILIES AND COMMUNITIES HEALTHY

Reducing Maternal Mortality

Maternal mortality rates in the United States have more than doubled over the past few decades. Each year, about 700 women die of pregnancy-related causes in the United States. The most common causes of maternal death are hemorrhage, severe high blood pressure, and venous thromboembolism.

Notwithstanding advances in medicine and medical technologies, pregnancy-related morbidity in the United States continues to affect 50,000 women. Yet, according to the CDC Foundation's report from Nine Maternal Mortality Review Committees, 60 percent of these deaths are preventable.

HRSA is a leader in addressing maternal mortality and morbidity through health promotion, risk prevention, and training of health care professionals to identify and treat early warning signs. In FY 2020, HRSA-supported maternal and child health programs will provide services to nearly 54 million mothers and children in the United States, including two-thirds of all pregnant women and half of all infants and children.

The FY 2020 Budget requests \$661 million for the Maternal and Child Health Block Grant to support federal and state partnerships to address gaps in services to mothers, children, and their families in all 50 states, the District of Columbia, and the territories. In FY 2017, nearly 56 million mothers and children nationwide benefitted from a Block Grant-supported service, including 86 percent of pregnant women, 99 percent of infants, and 55 percent of children (including children with special health care needs).

Within the requested funding level, \$23 million will support grants for State Maternal Health Innovation and data capacity, which focuses on implementing evidence-based interventions, assessing their effectiveness, and reducing disparities in maternity services and outcomes.

An additional \$3 million will continue the expanded implementation of the Alliance for Innovation in Maternal Health Initiative maternal safety bundles to all 50 U.S. states, the District of Columbia, the territories, and tribal entities. Safety bundles are straightforward sets of evidence-based practices proven to improve patient outcomes when performed in a health care setting. Expanded implementation of safety bundles in birthing facilities across the United

ALLIANCE FOR INNOVATION IN MATERNAL HEALTH INITIATIVE

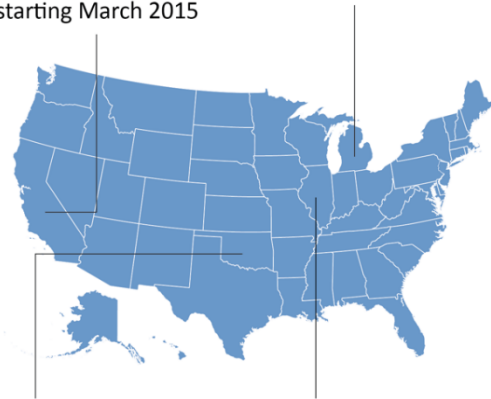
Nearly 2 Million Annual Births, 23 States and Growing, Highlights Include...

California

Reduced severe maternal hemorrhage by 20% over 12 months starting March 2015

Michigan

Decreased maternal hemorrhage by 18% since November 2015



Oklahoma

Reduced severe maternal morbidity by 20.5% since April 2015

Illinois

Reduced morbidity due to hypertension by 19.9% since April 2015

States will address the leading causes of maternal death, such as hemorrhage and hypertension, and enhance the delivery of safe, high-quality, comprehensive maternity care services.

The Budget provides \$123 million for the Healthy Start Program to support community-based strategies to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk areas. In FY 2020, the program will address maternal mortality by continuing to place clinical service providers at Healthy Start sites to provide direct access to well woman care and maternity care services. This will reduce barriers in access to care and better address health disparities among high-risk and underserved women.

Rural Health

The FY 2020 Budget requests \$189 million for the Federal Office of Rural Health Policy for grants to enhance health care delivery in rural communities, conduct research on rural health care issues, and provide technical assistance, such as training and

dissemination of best practices to rural communities and stakeholders. The Budget targets critical rural health activities and services such as Telehealth, Rural Health Policy Development, and Black Lung Clinics, and the Rural Communities Opioids Response Program (RCORP).

The FY 2020 Budget requests \$120 million for RCORP, which supports treatment and prevention of substance use disorder, including opioid abuse, in the highest-risk rural communities. The Budget will target some of the RCORP funding to specific initiatives, such as maternal and child health and telehealth activities focused on reducing opioid abuse. In FY 2018, HRSA awarded 95 RCORP planning grants to strengthen infrastructure and capacity within rural communities to provide needed prevention, treatment, and recovery services to rural residents.

OTHER HRSA PROGRAMS

340B Drug Pricing Program

The 340B Drug Pricing Program requires drug manufacturers, as a condition of participating in Medicaid, to provide discounts on outpatient prescription drugs to certain safety net health care providers. The Budget proposes to authorize a new user fee for the 340B Drug Pricing Program, and provides \$29 million for the administration and oversight of the 340B Program, of which \$10 million is discretionary budget authority and \$19 million is funded by the new user fee on covered entities to improve the program's operations and oversight.

The FY 2020 Budget proposes to improve 340B program integrity, and to ensure that the benefits of the program are used to help low-income and uninsured patients. The FY 2020 Budget proposes general regulatory authority for the 340B Drug Pricing Program to establish enforceable standards for program participation and to require all covered entities to report on the use of program savings. These reforms would strengthen program integrity and oversight.

Organ Transplantation

The Budget requests \$28 million for the Organ Transplantation Program, an increase of \$2 million above FY 2019. The Organ Transplantation Program extends and enhances the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment. In 2018, there were more than 145 million people registered to be organ donors—an all-time high. In FY 2020, HRSA will be working to increase financial support of certain living donors and provide educational awareness about living organ donation.

Program Management

The Budget requests \$152 million, which is \$3 million below FY 2019, to support program management activities such as oversight of grant and contracts, program integrity, information technology investments, and other operations costs.

Indian Health Service



	<i>dollars in millions</i>			
	2018 /1	2019 /2	2020 /3	2020 +/- 2019
Services Programs				
Clinical Services	3,606	3,616	3,997	+382
<i>Hospitals and Health Clinics (non-add)</i>	2,055	2,055	2,363	+309
<i>Quality Improvement and Certification/4 (non-add)</i>	58	58	68	+10
<i>Ending HIV Epidemic/Hepatitis C Initiative (non-add)</i>	--	--	25	+25
<i>National Community Health Aide Program (non-add)</i>	--	--	20	+20
<i>Electronic Health Record System</i>	--	--	25	+25
<i>Purchased/Referred Care (non-add)</i>	963	964	968	+5
<i>Indian Health Care Improvement Fund (non-add)</i>	72	72	72	--
Preventive Health	167	171	118	-53
<i>Public Health Nursing (non-add)</i>	84	86	92	+6
<i>Health Education (non-add)</i>	19	20	--	-20
<i>Community Health Representatives (non-add)</i>	62	63	24	-39
Other Services	179	179	171	-8
<i>Tribal Management Grant Program (non-add)</i>	2	2	--	-2
<i>Direct Operations (non-add)</i>	72	72	74	+2
Subtotal, Services Programs	3,952	3,966	4,287	+321
Contract Support Costs				
Contract Support Costs	763	718	855	+137
Subtotal, Contract Support Costs	763	718	855	+137
Facilities Programs				
Health Care Facilities Construction	243	243	166	-78
Sanitation Facilities Construction	192	192	193	+1
Facilities and Environmental Health Support	241	242	251	+9
Maintenance and Improvement	168	168	169	+1
Medical Equipment	24	24	24	--
Subtotal, Facilities Programs	868	869	803	-66
Total Discretionary Budget Authority	5,582	5,553	5,945	+392
Funds from Other Sources				
Health Insurance Collections	1,194	1,194	1,194	--
Rental of Staff Quarters	9	9	9	--
Diabetes Grants	150	150	150	--
Subtotal, Other Sources	1,352	1,352	1,352	--
Total Program Level	6,935	6,905	7,297	+392
Full-Time Equivalents	15,285	15,285	15,399	+114

1/ Reflects the FY 2018 Final level including actual Contract Support Costs and a \$25 million reprogramming notified to Congress on August 28, 2018.

- 2/ Reflects the annualized level of the continuing resolution and directed or permissive transfers. Includes an anomaly of \$15.3 million for staffing of newly-constructed health care facilities.
- 3/ The Budget requests a total of \$97.5 million for staffing of newly-constructed health care facilities and \$68.8 million for current services, which is allocated across several funding lines.
- 4/ Includes \$58 million for accreditation emergencies in order to meet CMS Conditions of Participation.

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) 2020 Budget requests \$5.9 billion for the Indian Health Service (IHS), an increase of \$392 million or 7 percent above FY 2019. The Budget strengthens the Administration’s commitment to improve the health and well-being of American Indians and Alaska Natives through strategic investments across Indian Country.

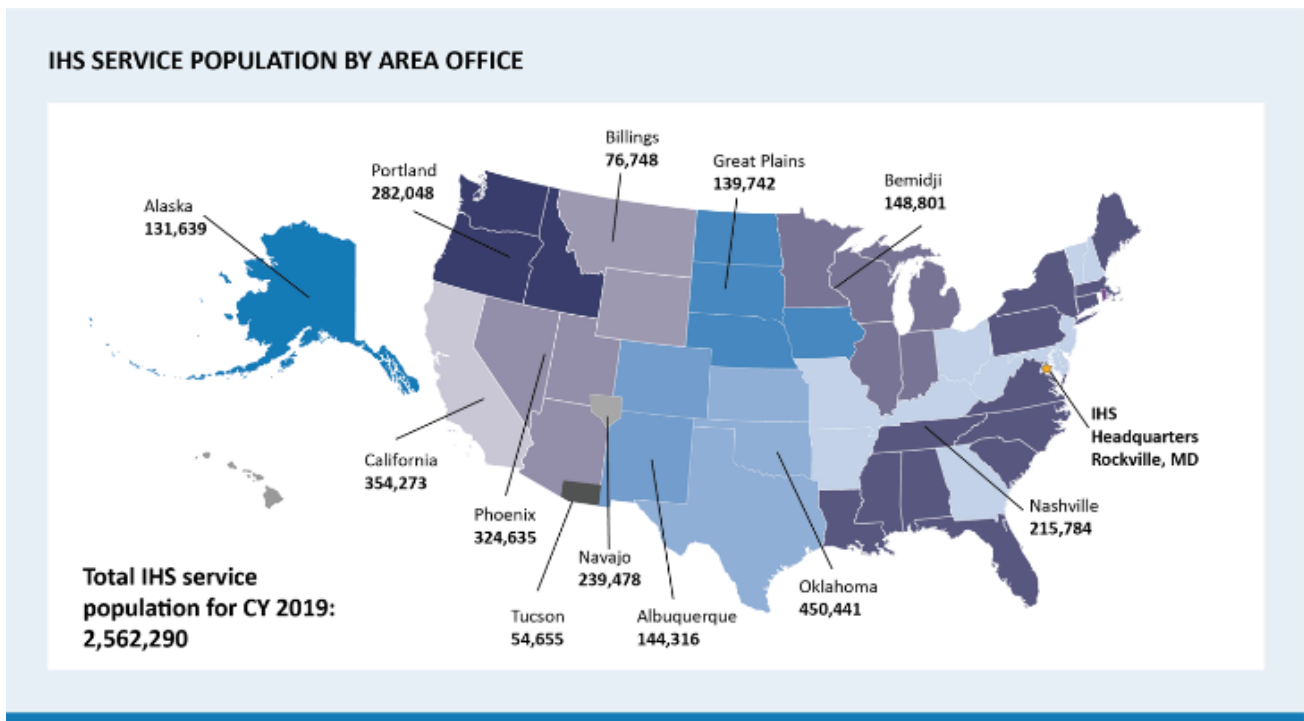
The FY 2020 Budget increases investments in programs making the greatest impact in Indian Country. These programs provide direct health care services through hospitals and health clinics and address dental health, mental health, and alcohol and substance abuse. The Budget fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, which supports tribes that administer their own health programs and facilities.

The Budget invests in new programs to improve patient care, including: quality and oversight, recruitment and

retention of health care professionals, Hepatitis C prevention and treatment, the National Community Health Aide Program, and the Electronic Health Record System transition. The Budget also provides \$69 million for current services for pay and medical inflation costs, so that purchasing power is not diminished. These funding increases support IHS’s goal to ensure that comprehensive, culturally acceptable public health services are available and accessible to American Indian and Alaska Native people.

FULFILLING THE UNIQUE ROLE OF THE INDIAN HEALTH SERVICE BY EXPANDING ACCESS TO CARE

The federal government has a unique government-to-government relationship with 573 tribes. More than sixty percent of the IHS budget funds services that are administered directly by tribes. IHS consults and partners with tribes to maximize participation in administering the programs that impact their



communities. IHS and tribes provide a comprehensive health service delivery system to nearly 2.6 million American Indians and Alaska Natives.

In line with tribal recommendations, the Budget expands health care services delivered through a federal and tribal network of 45 hospitals, 335 health centers, 83 health stations, and 134 Alaska village clinics across the nation. IHS also provides contracts and grants to 41 nonprofit urban Indian organizations providing health care services at 59 locations throughout the United States. The FY 2020 Budget provides \$4 billion for Clinical Services, an increase of \$382 million above FY 2019. This increase will support direct health care services across the IHS system, including inpatient, outpatient, ambulatory care, dental care, and medical support services such as laboratory, pharmacy, nutrition, behavioral health services, and physical therapy.

Purchased/Referred Care

IHS contracts with hospitals and health care providers through the Purchased/Referred Care program for the services it cannot directly provide within its network. The Budget provides \$968 million for this program, an increase of \$5 million above FY 2019, to support medical care for catastrophic injuries, specialized care, and other critical care services. IHS supports a growing number of medical services in several areas across the country, and this increase continues that expansion.

Addressing Behavioral Health Disparities

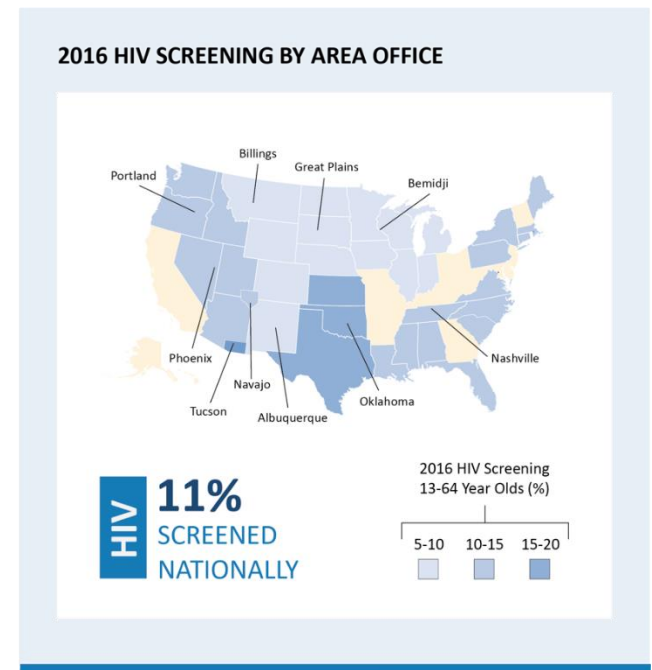
Substance use disorders, mental health disorders, suicide, violence, and behavior-related chronic diseases disproportionately impact the health of American Indian/Alaska Native individuals, families, and communities. IHS programs prioritize integrated behavioral health and primary care while respecting the balance, wellness, and resilience of American Indian and Alaska Native people. To combat these disparities, the Budget requests a total of \$356 million for Mental Health, Alcohol and Substance Abuse programs, an increase of \$27 million above FY 2019.

Eliminating Hepatitis C in Indian Country and Ending the HIV Epidemic: A Plan for America

The Budget provides \$25 million for establishing the Eliminating Hepatitis C and HIV/AIDS in Indian Country

Initiative to provide treatment and case management services to prevent Hepatitis C infection and enhance HIV testing and linkages to care in support of the Administration's Ending HIV Epidemic Initiative.

The new Initiative will also aim to diagnose all individuals with HIV as early as possible after infection, treat the infection rapidly and effectively to achieve sustained viral suppression, protect individuals at risk of HIV using proven prevention approaches, and respond rapidly to growing HIV clusters to prevent new HIV infections. The Initiative will work to reduce new infections in the United States by 75 percent in the next five years and by 90 percent in the next 10 years. American Indians and Alaska Natives are ranked fourth in the nation for the rate of new infections of HIV when compared with all other races and ethnicities.¹



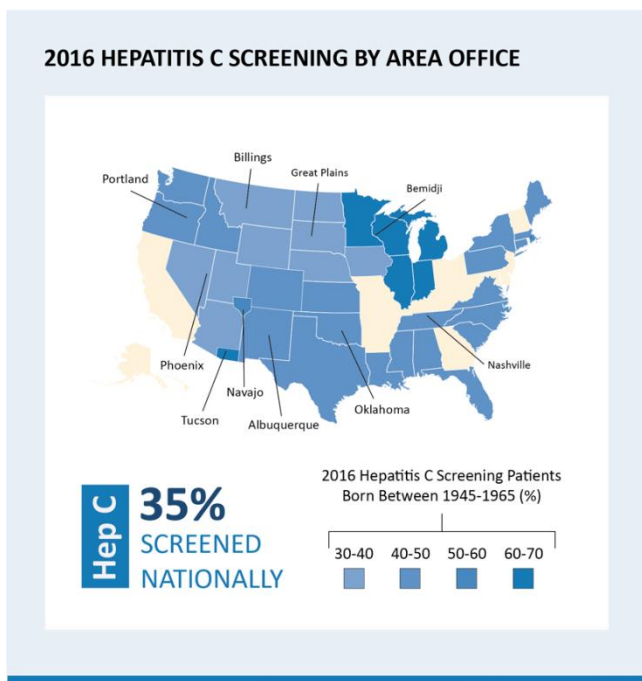
American Indian and Alaska Native people are also disproportionately affected by Hepatitis C infection. National data reveal that American Indian and Alaska Native people experience more than double the

¹ U.S. Centers for Disease Control and Prevention. (2018, April 3). IV Among American Indians and Alaska Natives in the United States. Accessed February 26, 2019, from

<https://www.cdc.gov/hiv/group/raciaethnic/aian/index.html>

national rate of Hepatitis C-related mortality and have the highest rate of acute Hepatitis C.²

The Initiative focuses on both Hepatitis C and HIV/AIDS to maximize public health benefits and make the most of taxpayer dollars. Hepatitis C prevention and treatment services help reduce active transmission of HIV/AIDS, a frequent co-infection. The Health Resources and Services Administration estimates about 25 percent of people living with HIV also have Hepatitis C, and people who are co-infected are more likely to have life-threatening complications from Hepatitis C.



Quality Improvement and Certification

The Budget prioritizes quality health care services at \$68 million, an increase of \$10 million above FY 2019, to implement nationwide quality and recruitment programs, and assist facilities to meet and maintain CMS quality health care standards. This total includes \$8 million for a new Recruitment and Retention Initiative to implement a variety of strategies, including housing subsidies, compensation supplements, and additional IHS Loan Repayment and Scholarship awards to improve recruitment and retention of qualified health care professionals. The Budget also includes \$2 million for a new Quality and Oversight Initiative to implement nationwide evidence-based quality assurance tools and practices to improve quality care.

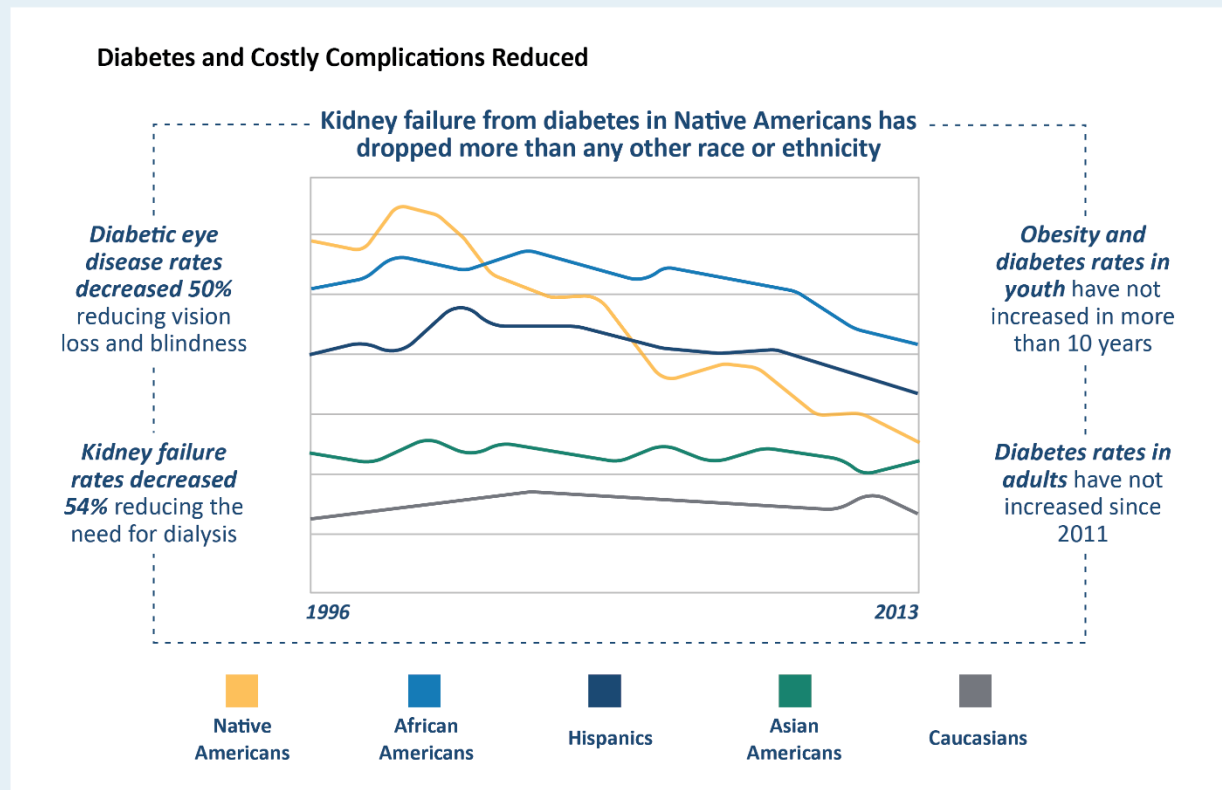
Preventive Health Services

The Budget includes \$118 million for Preventive Health Services to invest in evidence-based and outcome-driven programs that improve the health of American Indians and Alaska Natives. The Budget reforms in-home clinical health care services through nationwide expansion of the evidence-based Community Health Aide Program and starts phase out of the Community Health Representatives Program. The new National Community Health Aide Program will build a network of health aides to partner with health care providers and provide health care, health promotion, and disease prevention services. Aides will help expand access to health services in areas that are challenging to serve due to proximity to health care facilities and provider vacancies.

The Budget funds Public Health Nursing at \$92 million, an increase of \$6 million, and immunization programs to deliver direct health care services and expand access to care for rural and isolated communities.

² U.S. Centers for Disease Control and Prevention, Division of Viral Hepatitis. Viral Hepatitis Surveillance—United States, 2016. Accessed February 27, 2019.

SPECIAL DIABETES PROGRAM FOR INDIANS : CHANGING THE COURSE OF DIABETES



Special Diabetes Program for Indians

In 1997, Congress established the Special Diabetes Program for Indians in response to the diabetes epidemic among American Indians and Alaska Natives. The Budget provides \$150 million in mandatory funding each year in FY 2020 and FY 2021 for this results-driven grant program that has changed the course of diabetes across Indian Country. The program serves an estimated 780,000 people each year.

The Special Diabetes Program has reduced diabetes and costly complications among American Indian and Alaska Natives, who are substantially more likely than the general population to be diagnosed with diabetes. For example, diabetic eye disease rates have decreased by 50 percent, reducing vision loss and blindness. Kidney failure rates have decreased by 54 percent, reducing the need for dialysis. Additionally, youth obesity and diabetes rates have not increased in more than ten years, and diabetes rates in adults have not increased since 2011.

Staffing Increases

The Budget provides \$98 million to fully fund staffing and operating costs for four newly-constructed health care facilities, including Cherokee Nation Regional Health Center, Oklahoma; Yakutat Tlingit Health Center, Alaska; Northern California Youth Regional Treatment Center, California; and Ysleta Del Sur Health Center, Texas. These investments will expand health care services and address critical needs in these communities. Three of the facilities, Cherokee Nation Regional Health Center, Yakutat Tlingit Health Center, and Ysleta Del Sur Health Center, are part of the Joint Venture Construction program where tribes provide funding for the construction of a new or replacement facility, and IHS works with Congress to fund staffing and operating costs.

Health Information Technology

Health Information Technology provides the framework for comprehensive management of health information and its secure exchange between consumers, providers, government quality entities, and insurers. Health Information Technology also offers tools to improve quality, safety, and efficiency of the

health care delivery system. In FY 2020, the Budget invests \$25 million to begin transition to a new and modernized Electronic Health Record system. This funding will lay the groundwork to improve the quality of care, reduce the cost of care, promote interoperability, simplify IT service management, increase the security of patient data, enhance cybersecurity, and update infrastructure across rural locations to enable a successful Electronic Health Record transformation.

Health Insurance Reimbursements

The Indian Health Care Improvement Act authorizes IHS to collect Medicaid, Medicare, Veterans Health Administration, and private health insurance reimbursements for services provided by IHS to eligible beneficiaries. The Budget request for IHS estimates \$1.2 billion in health insurance reimbursements, which have been used to maintain accreditation standards through hiring additional medical staff, purchasing and updating equipment, and making necessary building improvements.

FACILITIES AND CONSTRUCTION

IHS supports a comprehensive health care facilities program, including the construction and maintenance of health care facilities, and the purchase and maintenance of medical equipment in those facilities. IHS and tribally-run facilities total 17 million square feet in 37 states across the country. The Budget provides \$803 million for facilities programs, prioritizing direct health care services.

Health Care Facilities Construction

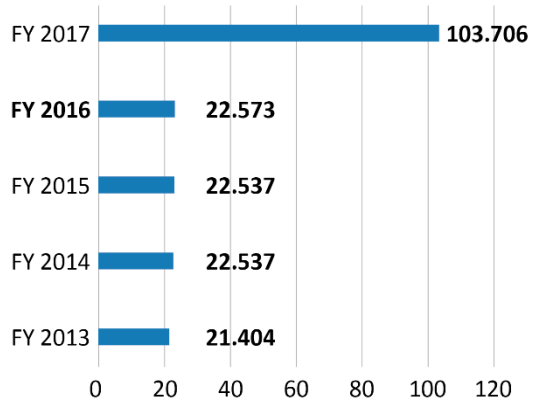
The Budget provides \$166 million for health care facilities construction to complete the construction of Bodaway Gap Health Center in Arizona and the Albuquerque West Facility in New Mexico. The 1993 Health Facilities Construction Project Priority List, developed by IHS in consultation with tribes in 1992, governs new and replacement facilities construction. The 2010 reauthorization of the Indian Health Care Improvement Act incorporated the priority list into the statute. In addition to federally-funded facilities construction, IHS administers the Joint Venture Construction program, which authorizes IHS to fund and staff facilities constructed by tribes.

Sanitation Facilities Construction

The Indian Health Care Improvement Act requires IHS to identify sanitation facility needs for existing

**MEDICAL EQUIPMENT INVESTMENTS
(DOLLARS IN MILLIONS)**

Due to Department-Wide investments through the Non-Recurring Expenses Fund, as displayed below, the current IHS medical equipment backlog has been significantly reduced from \$103 million in FY 2013 to \$33 million in FY 2018.



Includes appropriated funding and funding provided through the Non-Recurring Expenses Fund.

American Indian and Alaska Native homes by documenting deficiencies and proposing projects to address their needs. These projects provide new and existing homes with first time services such as water wells, onsite wastewater systems, or connecting homes to community water and wastewater facilities. As a result of this program, infant mortality rates and mortality rates for gastroenteritis and other environmentally-related diseases have dropped approximately 80 percent since 1973. The Budget requests \$193 million for these activities to continue progress of this successful activity.

Other Facilities Programs

The Budget includes \$444 million for maintenance and improvement, medical equipment, and the Facilities and Environmental Health Support program, \$11 million above FY 2019. These programs fund IHS's ability to maintain, repair, and improve existing IHS and tribal health care facilities, purchase medical equipment, and support an extensive array of real property, community and institutional environmental health, and injury prevention programs.

FURTHERING INDIAN SELF-DETERMINATION

IHS recognizes that tribal leaders and members are in the best position to understand the health care needs and priorities of their communities. The number of Tribal Self-Governance Program success stories grows each year, and IHS offers information, technical assistance, and policy coordination to enable this success. Today, tribes directly administer over 60 percent of the IHS budget through Indian Self-

Determination and Education Assistance Act contracts and compacts.

Contract Support Costs

Contract support costs cover the reasonable costs incurred by tribes for activities necessary for administering Federal programs. The Budget fully funds Contract Support Costs at an estimated \$855 million and continues the use of an indefinite appropriation, allowing IHS to guarantee full funding of this program.



Centers for Disease Control and Prevention

	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Programs				
Immunization and Respiratory Diseases	797	798	730	-68
<i>Prevention and Public Health Fund (non-add)</i>	324	321	153	-168
Vaccines for Children	4,389	4,176	4,761	+586
HIV/AIDS, Viral Hepatitis, STI and TB Prevention	1,116	1,125	1,318	+193
Emerging and Zoonotic Infectious Diseases	604	612	509	-103
<i>Prevention and Public Health Fund (non-add)</i>	52	52	137	+85
Chronic Disease and Health Promotion	1,160	1,188	951	-237
<i>Prevention and Public Health Fund (non-add)</i>	248	255	604	+349
Birth Defects, Developmental Disabilities, Disabilities and Health	140	156	112	-44
Environmental Health	205	209	157	-52
<i>Prevention and Public Health Fund (non-add)</i>	17	17	--	-17
Injury Prevention and Control	648	649	629	-20
Public Health and Scientific Services	497	504	468	-36
<i>PHS Evaluation Funds (non-add)</i>	--	--	423	+423
Occupational Safety and Health	334	336	190	-146
Global Health	495	496	457	-39
Public Health Preparedness and Response /1	846	855	825	-30
Buildings and Facilities /2	510	30	30	--
CDC-Wide Activities and Program Support	274	324	155	-169
<i>Prevention and Public Health Fund (non-add)</i>	160	160	--	-160
Agency for Toxic Substances and Disease Registry (ATSDR) /3	75	75	62	-13
User Fees	2	2	2	--
Total Program Level	12,642	12,107	11,954	-153
Less Funds from Other Sources				
Vaccines for Children	4,389	4,176	4,761	+586
Energy Employee Occupational Illness Compensation Program	50	55	55	--
World Trade Center Health Program	470	517	541	+25
Childhood Obesity Research Demonstration Project	30	--	--	--
PHS Evaluation Funds	--	--	423	+423
Prevention and Public Health Fund	801	805	894	+89
User Fees	2	2	2	--
Total Discretionary Budget Authority	6,899	6,553	5,277	-1,276
Full-Time Equivalents	11,583	11,693	11,715	22

1/ The FY 2019 Enacted funding for the Strategic National Stockpile was administratively transferred from CDC to ASPR, effective October 1, 2018. The FY 2018 level is comparably adjusted.

2/ The FY 2018 Enacted bill provided \$480 million in one-time funding to support the construction of a high-containment lab.

3/ FY 2019 is comparably adjusted for the FY 2020 Budget and reflects the annualized continuing resolution level for ATSDR.

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

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

The Centers for Disease Control and Prevention (CDC) is the nation's leading public health agency, dedicated to saving lives and protecting the health of Americans. CDC keeps America secure by preventing and controlling disease outbreaks, protecting against foodborne illnesses, helping people avoid leading causes of death such as heart disease, cancer, stroke, and diabetes, and working globally to reduce threats to the nation's health.

CDC accomplishes its public health mission through three main strategies: putting science into action; developing the public health workforce; and fighting diseases before they reach our nation's borders.

CDC saves lives by responding to emergencies, providing expertise, and detecting disease outbreaks wherever they arise. CDC's scientists collect and analyze data to determine how health threats affect specific populations. This work protects people from public health threats every day. By connecting state and local health departments across the United States, CDC can discover patterns of disease and respond effectively. CDC strengthens local and state public health departments and promotes health programs that are proven to work. Approximately 78 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.

The Fiscal Year (FY) 2020 Budget for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) requests \$12.0 billion. This total includes \$5.3 billion in budget authority, \$894 million from the Prevention and Public Health Fund, and \$423 million in Public Health Service (PHS) Evaluation Funds.

The Budget prioritizes funding where CDC can have the greatest impact, including: fighting opioid abuse, misuse, and overdose; working towards ending the HIV epidemic in America; strengthening global health security; and focusing efforts to prevent and control infectious diseases. The Budget prioritizes flexible

funding, allowing CDC to efficiently adapt and support mission-critical programs driven by cutting-edge science and public health expertise, and current events.

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

CDC protects the nation and helps Americans lead healthier and longer lives through programs that prevent and control HIV, viral hepatitis, sexually transmitted infections and tuberculosis. CDC identifies and disseminates proven, cost-effective interventions to achieve the greatest impact. These programs support state, tribal, local, and territorial health departments as they respond to disease outbreaks, and CDC's laboratories make vital discoveries and develop cutting-edge technology to prevent the spread of infection. The FY 2020 Budget includes a total of \$1.3 billion for these activities, which is \$193 million above FY 2019.

Ending the HIV Epidemic: A Plan for America

The Budget includes \$929 million for CDC's domestic HIV/AIDS surveillance and prevention efforts, which is \$140 million above FY 2019. The FY 2020 Budget provides \$140 million for CDC to begin a new multi-year strategic initiative to end the HIV epidemic in America. Medical and technological advancement provides the United States the unprecedented opportunity to control the HIV epidemic. These investments will lay the foundation to reduce new HIV diagnoses by 75 percent over the next five years and 90 percent over the next ten years.

This Initiative will be coordinated across HHS, with efforts from CDC, the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH). CDC will leverage its HIV prevention infrastructure to plan and implement a targeted strategy in collaboration with other HHS Operating Divisions. CDC's efforts will be focused on reducing new HIV infections by working closely with State and local health departments on

intensive testing and referral to care and other efforts. This strategy will develop and deploy innovative data management solutions, and implement strategic testing linked to immediate treatment. The Initiative will also utilize the clinical care system to expand the use of pre-exposure prophylaxis (PrEP) by people at high risk, and develop approaches to better detect and respond to clusters of HIV.

Half of all new HIV diagnoses are concentrated in a relatively limited geographic area. By using existing data to target scientifically proven approaches, the United States can prevent new infections and control the HIV epidemic. Through these activities in FY 2020, CDC will begin to ‘bend the curve’ of the HIV epidemic and take the first steps toward HIV epidemic control.

Infectious Diseases

CDC estimates that nearly 2.4 million Americans—1 percent of the adult population—were living with hepatitis C from 2013 through 2016, with rising infections due to the opioid crisis and related injection drug use. Yet, while new infections are rising at an alarming rate, hundreds of thousands of Americans have also been cured now that new, more effective, therapies are available. We can win the fight against viral hepatitis. The FY 2020 Budget includes \$39 million to invest in partnerships with state and local health departments, universities, medical centers, and

community-based organizations to prevent and control viral hepatitis.

CDC data indicates the United States is experiencing a steep and sustained increase in sexually transmitted infections. The FY 2020 Budget includes \$157 million to support CDC’s continued national leadership, research, and policy development to prevent sexually transmitted infections nationwide. Funding will support health departments, health care providers, and non-government organizations to expand prevention training programs and develop new technologies and surveillance methods. CDC is working with HHS in calendar year 2019 to develop an STD Action Plan that will focus on how the agencies’ combined efforts can turn the tide on the rising rates of STDs in the United States.

CDC is the lead agency for eliminating tuberculosis (TB) in the United States, and is a global leader in the science of TB elimination. HHS is the only United States Government agency with a mandate to carry out programmatically relevant domestic TB research. The Budget includes \$135 million which reflects the realignment of \$7 million for global tuberculosis activities to CDC’s Center for Global Health. CDC’s TB program works to eliminate tuberculosis in the United States through increased testing and treatment among people who are at high risk for TB, aggressive case

HHS PROPOSES A BOLD NEW INITIATIVE TO END HIV WITH FOCUSED EFFORTS IN STATES AND CITIES WHERE 50% OF NEW HIV CASES ARE CONCENTRATED



finding and treatment for active tuberculosis disease, and research on drug regimens and diagnostic tools. CDC's clinical and programmatic research form the evidence base for U.S. TB elimination guidelines, which in turn, inform global strategies and recommendations. CDC has contributed to the reduction of TB infections through investigating every reported domestic case of TB, identifying contacts and providing treatment to prevent future cases, and ensuring medical care, laboratory testing and other services support the complete cure of infected TB patients to halt further transmission. Progress to reduce the number of new TB infections has slowed. The Budget will allow CDC to continue to make progress towards eliminating TB in America.

Due to the opioid epidemic, the United States is experiencing increases in certain infectious diseases as well as an increased number of disease outbreaks. The FY 2020 Budget provides \$58 million to increase CDC's Infectious Diseases and the Opioid Epidemic activities, \$53 million above FY 2019. This program addresses the infectious disease consequences of the opioid epidemic and supports prevention and surveillance interventions in high-risk areas to reduce the spread of infectious disease.

IMMUNIZATION AND RESPIRATORY DISEASES

CDC prevents disease, disability, and death of children, adolescents, and adults through immunization and control of respiratory and related diseases. CDC promotes immunization and infection control practices, which are critical in defending against public health threats. CDC supports epidemiology and laboratory capacity, and leads preparedness planning for pandemic influenza. CDC also improves access to immunization through the discretionary-funded immunization program and the mandatory-funded Vaccines for Children program.

The FY 2020 Budget includes \$5.5 billion for these activities, of which \$730 million is for discretionary immunization programs.

Combating Acute Flaccid Myelitis

Acute Flaccid Myelitis (AFM) is a rare but serious condition that affects the nervous system, particularly in children. CDC works closely with national experts, health care providers, and state and local health departments to thoroughly investigate AFM. The Budget includes \$10 million to expand efforts to

monitor AFM nationwide, and, where possible, to update diagnosis and treatment guidelines.

Addressing the Threat of Influenza

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands of people die from flu every year. CDC provides scientific expertise, resources, and leadership to support diagnosis, prevention, and control of influenza domestically and address the threat posed by seasonal and pandemic influenza.

The Budget includes \$198 million to support these activities, which is \$10 million above FY 2019. In FY 2020, CDC will support high-priority seasonal influenza activities, including efforts to help modernize the seasonal influenza vaccine and remove obstacles that prevent people from getting vaccinated.

Vaccines for Children

Through the Vaccines for Children Program, CDC provides immunizations at no cost to children who might not otherwise have access to recommended childhood vaccines. Approximately 50 percent of young children and one-third of adolescents in the United States are eligible for this program. CDC estimates vaccinations prevented 25 million hospitalizations and 855,000 deaths among children born in the last 20 years, which resulted in net savings of \$1.7 trillion in total societal costs. The Budget includes \$4.8 billion in mandatory funding to support the Vaccines for Children program in FY 2020.

EMERGING AND ZOOLOGICAL INFECTIOUS DISEASES

CDC works throughout the United States and around the world to prevent illness, disability, and death caused by a wide range of infectious diseases. These programs protect Americans from rare but deadly diseases like anthrax and Ebola, and also more common threats like foodborne disease and health care-associated infections. CDC provides infectious disease expertise to help identify and prevent illness and contain outbreaks that sometimes span many states. The Budget includes \$509 million to support CDC's National Center for Emerging and Zoonotic Infectious Diseases.

Vector-Borne Diseases

Vectors are mosquitoes, ticks, and fleas that spread pathogens. A person who gets bitten by mosquitoes, ticks, fleas or other such arthropods and gets sick has a vector-borne disease. Between 2004 and 2016, the number of reported cases of disease from mosquito, tick, and flea bites more than tripled in the United States. The number of Americans at risk of vector-borne diseases continues to increase as global travel and urbanization contribute to vector-borne disease outbreaks in new regions and countries. The Budget includes \$51 million for vector-borne disease activities. CDC will continue support for public health programs that address emerging diseases from mosquitoes and ticks, advance innovation and discovery, and support states, particularly those that are at the greatest risk of outbreaks.

Antibiotic Resistance

Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die from these infections. The Budget includes \$137 million for CDC to prevent, detect, and respond to resistant infections. CDC will invest in states and communities across the United States, expand laboratory capacity for antibiotic resistant testing, and support innovation to determine successful practices in combatting antibiotic resistance and share these practices to inform how the nation responds to some of the most serious antibiotic-resistant threats.

PUBLIC HEALTH SCIENTIFIC SERVICES

The factors affecting our health are wide-ranging—from new and changing health threats, natural disasters, bioterrorism, access to health care, and the growing burden of noncommunicable diseases. These issues require strategic thinking, new ideas, flexibility, and readiness to connect across disciplines. CDC leads, promotes, and facilitates science standards and policies

to reduce the burden of diseases in the United States and globally. The Budget includes \$468 million for these activities.

The National Center for Health Statistics is the nation's principal health statistics agency, and provides statistical information to guide actions and policies to improve the health of the American people. The Budget includes \$155 million for health statistics.

INJURY PREVENTION AND CONTROL

In the United States, injury is the leading cause of death for children and adults between the ages of 1 and 45. Unintentional injuries and intentional violence affect all Americans, regardless of age, race, or economic status. The FY 2020 Budget includes \$629 million for injury prevention and control activities. CDC collaborates with national organizations, state health agencies, and other key groups to develop, implement, and promote effective injury and violence prevention and control practices. CDC tracks injuries and deaths to identify trends, develops prevention strategies, and supports states to implement effective prevention programs.

Effective prevention strategies incorporate the unique factors of a community. To better understand localized factors, CDC will continue support for the National Violent Death Reporting System (NVDRS) in all 50 states, the District of Columbia, and Puerto Rico. The FY 2020 Budget includes \$24 million for NVDRS. NVDRS is a state-based surveillance system that links data from law enforcement, coroners and medical examiners, vital statistics, and crime laboratories to identify violence trends at national and regional levels. This allows states to access all important data elements from one central database, and informs the development and implementation of tailored interventions.

Fighting the Opioids Epidemic

From 2013 to 2017, drug overdose death rates increased in 35 of 50 states and Washington, D.C., and significant increases in death rates involving synthetic opioids occurred in 15 of 20 states, likely driven by illicitly manufactured fentanyl. From 2016 to 2017, overdose deaths involving all opioids and synthetic opioids increased, but deaths involving prescription opioids and heroin remained stable but still high. The opioid overdose epidemic continues to evolve because of the continuing increase in deaths involving synthetic opioids. Provisional data from 2018 indicate potential improvements in some drug overdose indicators; however, analysis of final data from 2018 is necessary for confirmation. Over 399,000 people have died from overdoses involving prescription or illicit opioids in the United States from 1999 to 2017.

The FY 2020 Budget continues to prioritize opioid activities at CDC, with a total funding level of \$476 million. CDC is committed to fighting the opioid overdose epidemic and supporting states and communities as they collect data, respond to overdoses, and provide care to those in their communities. CDC's efforts support the Department's five-point strategy to combat the opioid crisis. Accurate and timely data on the opioid epidemic is essential to implement the most effective interventions for each community. CDC improves data quality and tracks trends to better understand and quickly respond to the epidemic. CDC collects and analyzes data on opioid-related overdoses to identify high-risk areas and evaluate prevention efforts. CDC supports states with funding, resources, and information to: aid data collection; prevent opioid use disorder, overdose, and death; and helps improve access to safer and more effective pain treatment.

The FY 2020 Budget supports state efforts to combat prescription and illicit opioid abuse and overdose. CDC will enhance state capacity for opioid overdose surveillance through support to all 50 states. This program supports activities to build capacity at the state-level for overdose monitoring, tracking problematic prescribing patterns, and identifying changes in illicit supply. These activities will improve states' abilities to monitor the epidemic by improving the timeliness and quality of surveillance data for both fatal and nonfatal opioid overdose as well as to leverage timely data to target effective responses. The Budget will improve multi-state opioid surveillance and response, enhance prescription drug monitoring

PREVENTING OPIOID OVERDOSES AND RELATED HARMS



programs, and improve prescribing practices, and increase awareness and knowledge among consumers about the risks of prescription opioids.

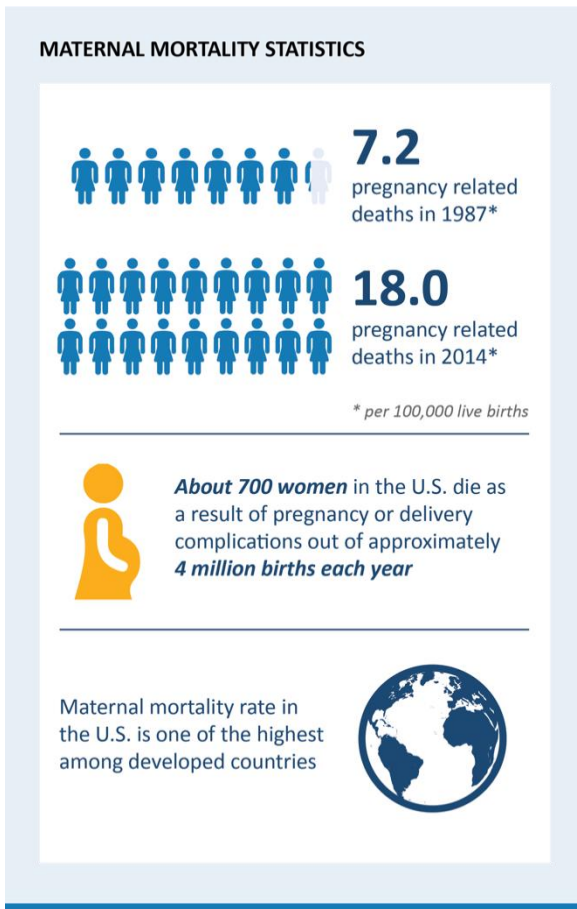
BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Birth defects affect 1 in 33 babies and are a leading cause of infant mortality in the United States. The FY 2020 Budget includes \$112 million to prevent birth defects and developmental disabilities. CDC identifies causes of birth defects, finds opportunities to prevent them, and improves the health of those living with birth defects. CDC utilizes three essential strategies to prevent birth defects: surveillance and disease tracking; research to identify causes; and prevention research and programs. These efforts rapidly translate scientific findings into appropriate public health interventions.

Emerging Threats to Mothers and Babies

The FY 2020 Budget includes \$10 million for the Emerging Threats to Mothers and Babies program. This program supports state, tribal, territorial, and local health departments in their efforts to capture emerging scientific information from surveillance systems and turn this data into relevant clinical guidance for obstetricians, gynecologists and pediatricians. This program will support the dissemination of information to the clinical community caring for mothers and their infants who are exposed

to emerging or known threats and continue to build clinical and public health partnerships to address emerging threats in the communities as they occur. These activities will support effective interventions to prevent future birth defects.



Neonatal Abstinence Syndrome

Neonatal abstinence syndrome is a growing problem in the United States. Neonatal abstinence syndrome occurs when newborn babies experience withdrawal after being exposed to drugs in the womb. The FY 2020 Budget provides \$2 million to support CDC’s continued work to advance our understanding of neonatal abstinence syndrome and translate these findings to improve the care of mothers and babies.

CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Six in ten Americans live with at least one chronic disease, like heart disease, cancer, stroke, or diabetes. Chronic diseases are responsible for 7 in 10 deaths each year, are the leading causes of death and disability in America, and are a leading driver of health care costs.

The FY 2020 Budget includes \$951 million for chronic disease prevention and health promotion activities. CDC works to reduce the risk factors for chronic diseases. CDC funds states, tribes, cities, and territories to study how chronic diseases affect different populations in the United States, research effective interventions, and share information to help Americans understand risk factors for chronic diseases and how to prevent them.

The FY 2020 Budget proposes the America’s Health Block Grant as a reform to state-based chronic disease programs. This \$500 million block grant program will provide states the flexibility to support interventions that best address public health challenges specific to their state.

The Budget includes \$337 million for cancer prevention and control, to continue to support cross-cutting activities for multiple types of cancer.

Maternal Mortality Review Committees

The Budget includes \$12 million to support Maternal Mortality Review Committees to reduce maternal mortality. This funding will support state health departments strengthen data collection to understand the key factors leading to increasing maternal mortality. CDC will use this data to develop evidence-based approaches to reduce maternal deaths in the United States.

ENVIRONMENTAL HEALTH

Environmental hazards may be found in American’s everyday environment, from air, water, or food. CDC’s activities work to prevent illness, disability, and death from contacts between people and the environment.

The FY 2020 Budget includes \$157 million to support CDC’s environmental health activities. CDC will monitor health outcomes following environmental exposures, prepare for and respond to public health emergencies, including chemical, biological, radiological, and nuclear incidents, and support environmental health programs and interventions to protect and promote health.

OCCUPATIONAL SAFETY AND HEALTH

CDC’s National Institute for Occupational Safety and Health is the lead research agency focused on worker safety and health to protect the nation’s 161 million

workers. The FY 2020 Budget provides \$190 million for occupational safety and health activities. CDC works cooperatively with employers and employees to adapt research findings into effective solutions that prevent injuries and illness. In addition to the discretionary resources provided for these activities, the Budget provides \$55 million for the Energy Employee Occupational Injury Compensation Act program.

World Trade Center Health Program

The Budget includes \$541 million in mandatory Federal share funding for the World Trade Center Health Program to provide medical monitoring and treatment to specific groups of individuals affected by the September 11, 2001 terrorist attacks on the United States. Those served by the program include responders at the World Trade Center and related sites in New York City, Pentagon, and Shanksville, PA, and survivors who were in the New York City disaster area. The program was established by the James Zadroga 9/11 Health and Compensation Act of 2010 and, in 2015, was reauthorized until 2090.

PUBLIC HEALTH PREPAREDNESS AND RESPONSE

CDC strengthens national preparedness for public health emergencies including natural, biological, chemical, radiological, and nuclear incidents. The Budget provides \$825 million for these activities. State and local public health departments are key in preparing for, responding to, and recovering from public health emergencies. The Budget provides \$675 million for the Public Health Emergency Preparedness cooperative agreements. CDC will continue to fund 62 awardees, including all 50 states, eight United States territories and freely-associated states, and four localities. The program provides critical resources for state, local, and territorial public health departments to build and strengthen their abilities to effectively respond to public health threats ranging from infectious diseases to natural disasters to radiological events. In FY 2020, CDC will continue to allocate funding to states and localities according to need and potential risk. CDC tracks recipient programmatic performance to inform future grant awards and ensure effective use of federal funds. State and local health departments use this funding to improve capabilities across the country so that communities can effectively manage public health emergencies.

GLOBAL HEALTH

The most efficient and cost-effective way to protect Americans from health threats that begin overseas is to stop them before they spread to our shores. Because disease can travel from a rural village to any international or domestic major city in as little as 36 hours, disease threats anywhere in the world are a threat to America. CDC detects and controls disease outbreaks at their source, saving lives and reducing health care costs.

CDC has world experts in epidemiology, surveillance, informatics, laboratory systems, and other essential disciplines who work to prevent and respond to a variety of health threats across the globe. To support these activities, the Budget includes \$457 million for CDC's global health efforts.

Global Health Security

The FY 2020 Budget includes \$100 million for global health security. CDC's global health security activities enhance global capacity to prevent, detect, and rapidly respond to infectious disease threats. Investing in global health security protects Americans from emerging and re-emerging disease threats and prevents against future epidemics.

DISEASE OUTBREAKS CAN CAUSE ECONOMIC DISRUPTION

Decreasing demand for U.S. exports

Putting U.S. export-related jobs at risk

Global health security helps safeguard America's health and economic stability

The infographic consists of three horizontal sections. The top section features a map of the United States with a downward-pointing arrow and the text 'Decreasing demand for U.S. exports' next to a cargo ship. The middle section shows a forklift moving boxes with the text 'Putting U.S. export-related jobs at risk'. The bottom section contains a globe icon and the text 'Global health security helps safeguard America's health and economic stability'.

To accelerate progress toward a world safe and secure from infectious disease threats, the Budget continues to support CDC as the global leader in building disease

detection and response capabilities in other countries. This funding supports partnering with countries to achieve measurable improvements to their own capacity to respond to disease threats, activities preventing outbreaks, detecting threats early to save lives, and responding rapidly and effectively once outbreaks occur. CDC will leverage regional platforms that increase flexibility and efficiencies in addressing public health opportunities and challenges as they evolve and emerge globally.

This Budget also includes \$7 million realigned from the HIV/AIDS, Viral Hepatitis, Sexually-Transmitted Infections, and Tuberculosis Prevention account to better align the operation of the Tuberculosis program. CDC will continue on-going global tuberculosis efforts in 25 high burden countries to find, cure, and prevent tuberculosis and help sustain partner countries' efforts to do the same.

INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND

The United States must be ready to respond to a pandemic, natural disaster, or chemical or radiological release at any moment. The FY 2020 Budget provides \$50 million for the Infectious Diseases Rapid Response Reserve Fund for CDC that could be used to rapidly and effectively respond to emerging infectious disease outbreaks that threaten the health of Americans.

BUILDINGS AND FACILITIES

CDC's facilities support the dedicated personnel who work to protect Americans from health threats every day. Safe, secure, and fully operational buildings and facilities enable CDC to prevent new disease threats and address evolving public health needs.

The FY 2020 Budget includes \$30 million to support repairs for and improvements to CDC's buildings and facilities. These investments enable the replacement, maintenance, and improvement of existing facilities essential for CDC's core mission.

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 which protects communities from harmful health effects of exposure to natural and man-made hazardous substances. ATSDR reduces morbidity and mortality related to exposure to natural and man-made toxic substances by responding to environmental health emergencies, investigating environmental health threats, and building capabilities of and providing actionable guidance to state and local health partners.

The FY 2020 Budget includes \$62 million for ATSDR, with a priority on activities related to asthma, children's health, safe drinking water, and innovative laboratory methods.

National Institutes of Health



	<i>dollars in millions</i>			2020
	2018 /1	2019 /2	2020	+/- 2019
Institutes/Centers				
National Cancer Institute	5,944	6,144	5,247	-897
National Heart, Lung, and Blood Institute	3,374	3,488	3,003	-486
National Institute of Dental and Craniofacial Research	447	462	397	-64
National Institute of Diabetes & Digestive & Kidney Diseases	2,113	2,180	1,896	-283
National Institute of Neurological Disorders and Stroke	2,145	2,274	2,026	-248
National Institute of Allergy and Infectious Diseases	5,268	5,523	4,754	-769
National Institute of General Medical Sciences	2,781	2,873	2,473	-400
Eunice K. Shriver Natl. Institute of Child Health & Human Development	1,457	1,506	1,297	-210
National Eye Institute	770	797	686	-111
Natl Institute of Environmental Health Sciences: Labor/HHS Appropriation	749	775	667	-108
National Institute of Environmental Health Sciences: Interior Appropriation	77	77	67	-11
National Institute on Aging	2,572	3,083	2,654	-429
National Institute of Arthritis & Musculoskeletal & Skin Diseases	585	605	521	-84
National Institute on Deafness and Communication Disorders	459	474	408	-66
National Institute of Mental Health	1,754	1,870	1,630	-240
National Institute on Drug Abuse	1,374	1,420	1,296	-123
National Institute on Alcohol Abuse and Alcoholism	508	526	452	-73
National Institute of Nursing Research	158	163	140	-23
National Human Genome Research Institute	557	576	495	-80
National Institute of Biomedical Imaging and Bioengineering	377	389	336	-53
National Institute on Minority Health and Health Disparities	304	315	271	-44
National Center for Complementary and Integrative Health	142	146	126	-20
National Center for Advancing Translational Sciences	761	806	694	-112
Fogarty International Center	76	78	67	-11
National Library of Medicine	428	442	380	-62
Office of the Director	1,804	1,917	1,769	-148
21 st Century Cures Innovation Accounts	110	196	157	-39
Buildings and Facilities	129	200	200	--
National Institute for Research on Safety and Quality /3	--	--	256	+256
Total, Program Level	37,224	39,306	34,368	-4,938
Less Funds from Other Sources				
PHS Evaluation Funds	-923	-1,147	-741	-406
Current Law Mandatory Funding – Type 1 Diabetes	-150	-150	--	+150
Proposed Law Mandatory Funding – Type 1 Diabetes	--	--	-150	-150
Total, Discretionary Budget Authority	36,151	38,010	33,477	-4,533

	<i>dollars in millions</i>			2020
	2018 /1	2019 /2	2020	+/- 2019
Appropriations				
Labor/HHS Appropriation	36,074	37,933	33,410	-4,523
Interior Appropriation	77	77	67	-10
Full-Time Equivalents /4	17,532	18,101	18,339	+238

1/ Reflects the FY 2018 Final level including funding authorized by the 21st Century Cures Act and directed or permissive transfers. Funding level does not include supplemental hurricane appropriations (\$50 million).

2/ FY 2019 reflects the annualized continuing resolution level for the NIEHS Interior Appropriation and the \$5 million directed transfer to the HHS Office of the Inspector General.

3/ The FY 2020 Budget consolidates the highest priority activities of the Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality (NIRSQ). AHRQ’s Enacted appropriation in FY 2018 and FY 2019 was \$334 million and \$338 million respectively. In addition, AHRQ received mandatory transfers from the Patient-Centered Outcomes Research Trust Fund (PCORTF) in FY 2018 and FY 2019 for total Program Levels of \$433 million and \$451 million, respectively. The PCORTF sunsets in FY 2019.

4/ Full-time equivalent levels include NIRSQ in FY 2020.

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

In pursuit of its mission, the National Institutes of Health (NIH) conducts and supports biomedical research that fosters fundamental creative discoveries, innovative research strategies, and their applications to improve human health.

As the nation’s premier biomedical research agency, NIH plays a critical role in advancing basic and clinical biomedical research. NIH develops, maintains, and renews scientific, human, and physical resources to ensure the nation’s capability to prevent disease and disability. The biomedical research enterprise depends not only upon NIH’s support of cutting-edge science and technology, but also its wise investment of public resources to fund research in support of its mission to enhance the lives of all Americans.

NIH is a vital contributor to the U.S. economy. NIH-funded research drives economic growth in the pharmaceutical, biotechnology, and medical device industries.

The Fiscal Year (FY) 2020 Budget provides \$34.4 billion for NIH. This total includes \$492 million in resources available through the 21st Century Cures Act and \$150 million in mandatory resources. To streamline federal research, the Budget also includes \$256 million for the new National Institute for Research on Safety

and Quality (NIRSQ) to continue key research activities currently administered by the Agency for Healthcare Research and Quality (AHRQ).

RESEARCH PRIORITIES IN FY 2020

Confronting the Opioid Crisis

More than two million Americans have an opioid use disorder³, and millions more use opioids inappropriately by taking opioid medications longer or in higher doses than prescribed. The Budget includes \$1.3 billion for opioids and pain research across NIH as part of the government-wide effort to combat the opioid epidemic. This total includes \$500 million to continue the Helping to End Addiction Long-term (HEAL) Initiative and nearly \$800 million to support ongoing research. Within NIH, NIRSQ will accelerate evidence on preventing and treating opioid abuse in primary care, especially older adults. NIH continues to develop long-lasting preventative and therapeutic solutions to the opioid crisis that can be implemented across the country, particularly in the areas hardest hit by the epidemic.

Helping to End Addiction Long-Term

To bring evidence-based solutions to the opioid crisis, and to provide safe and effective options for the more than 25 million Americans who suffer from daily

³ <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>

chronic pain, NIH launched the HEAL Initiative in April 2018. Through HEAL, NIH is building on basic science discoveries to accelerate the development of novel medications and devices to treat all aspects of the opioid addiction cycle, including chronic use, withdrawal symptoms, craving, relapse, and overdose. In addition, HEAL funds studies on integrating prevention and treatment approaches into practice, including the HEALing Communities study, which will inform our understanding of how the implementation of promising and evidence-based strategies and treatments can decrease opioid use disorder and overdose deaths.

Long-lasting solutions to the opioid crisis require additional pharmacological and non-pharmacological options for pain management. As part of HEAL, NIH will continue working with experts from the biopharmaceutical industry and Federal partners to develop a data sharing collaborative, new biomarkers for pain, and a clinical trials network for testing new pain therapies.

Neonatal Abstinence Syndrome

To improve developmental outcomes for infants with Neonatal Abstinence Syndrome/Neonatal Opioid Withdrawal syndrome, NIH will determine the best approaches to identify and treat newborns exposed to opioids by expanding the Advancing Clinical Trials in Neonatal Opioid Withdrawal syndrome (ACT NOW) pilot studies. Results will inform clinical trials to identify evidence-based clinical practices, including assessment of drug-free treatment approaches and currently used medications.

Acute to Chronic Pain Signatures

The high prevalence of chronic pain in the United States, and the reliance on opioids for its management, has created an urgent need for safer, more effective pain control. Launched in 2018, the Acute to Chronic Pain Signatures program collects neuroimaging, sensory testing, and psychosocial data from patients with acute pain associated with a surgical procedure or acute musculoskeletal trauma. Through this study, NIH seeks to predict which patients will develop long-lasting chronic pain, and guide precision acute pain management approaches to prevent lasting pain.

Creating a National Research Resource to Advance Precision Medicine

Precision medicine represents a frontier of human health and disease, and considers individual differences

in lifestyle, environment, and biology to prevent and treat diseases using strategies tailored to the individual. Initiated in 2016, the NIH *All of Us* Research Program, a key element of the Precision Medicine Initiative, is an historic effort to collect data from over one million people living in the United States to accelerate research and improve health. Unlike research studies focused on a specific diseases or populations, *All of Us* serves as a national research resource to support thousands of studies, spanning various health conditions.

National enrollment for *All of Us* launched in May 2018 and by mid-December 2018, more than 90,000 people completed all steps in the initial protocol. More than 75 percent of these participants are from communities

NATIONAL CANCER INSTITUTE - CHILDREN'S ONCOLOGY GROUP MATCH TRIAL

Cancer Research Includes 4 Broad Categories



Basic Research

seeks to understand the fundamental aspects of nature. It provides the foundation for advances against cancer.



Clinical Research

tests drugs, medical devices, or other interventions in human volunteers to improve all aspects of patient care.



Population-Based Research

explores the causes of cancer, cancer trends, and factors that affect the delivery and outcomes of cancer care in specific populations.



Translational Research

moves basic research findings into the clinic and clinical research findings into everyday care. In turn, results from clinical and population-based studies can guide basic research.

historically underrepresented in biomedical research, and more than 50 percent are from racial and ethnic minority groups. To encourage enrollment of diverse populations, NIH created a network of community engagement partners to promote outreach and build trust.

Genomic data from participants is a critical component of the program’s research platform. In September 2018, NIH issued three Genome Center awards to support this effort. *All of Us* is planning a pilot program on the responsible return of genetic information to participants, including education and genetic counseling, as part of the program’s commitment to give participants access to their own data.

Changing the Course of Childhood Cancer

The science of understanding pediatric cancer is especially challenging, and too many children and adolescents die from their disease. Many others endure lifelong adverse effects from their cancers or their treatment. Progress to treat some childhood cancers has been encouraging. However, for other cancers, advances in treatment have been limited.

NIH’s current efforts to address pediatric cancer are notable and cross-cutting. For instance, the Children’s Oncology Group, which is part of National Cancer Institute’s (NCI’s) National Clinical Trials Network, develops and coordinates pediatric cancer clinical trials that are available at more than 200 member institutions, including cancer centers throughout the United States and Canada. Additionally, the Pediatric MATCH precision medicine trial is a nationwide trial to explore whether targeted therapies can be effective for children and adolescents with solid tumors with specific gene mutations.

In FY 2020, NIH will invest \$50 million to launch an initiative to accelerate and expand drug discovery and clinical trials, understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer. This initiative will support research to develop new, more effective, and safer treatments for childhood cancers, and complement ongoing research within the NCI. Through this initiative, NCI will aggregate data from pediatric cancer cases and coordinate with others that maintain data sets to create a comprehensive, shared resource to support childhood cancer in all its forms. This knowledge, spanning from basic biology to clinical outcomes,

**NCI-CHILDREN’S ONCOLOGY GROUP
PEDIATRIC MATCH TRIAL**

Pediatric MATCH is for patients ages 1 to 21 who have both:

Solid tumors, including lymphomas and brain tumors, or histiocytoses	Tumors that no longer respond to standard treatment or that have come back after treatment
----------------------------------------------------------------------	--------------------------------------------------------------------------------------------

The precision medicine clinical trial, funded by NCI and conducted by Children’s Oncology Group, matches children and adolescents with treatment based on genetic changes in their tumors.

ABOUT 200-300 PEDIATRIC PATIENTS ARE EXPECTED TO BE SCREENED EACH YEAR

TUMOR TISSUE WILL UNDERGO TESTING FOR CHANGES IN MORE THAN 160 GENES

If a patient’s tumor has a genetic change that matches one targeted by a drug used in the trial, the patient may be eligible to join the treatment arm targeting that genetic change.

THE TRIAL IS OFFERED IN THE U.S. AT ABOUT **—200—** CHILDREN’S ONCOLOGY GROUP SITES

provides a path to change the course of cancer in all children.

IDEA States Pediatric Clinical Trial Network

Infants and children living in rural and medically underserved states are less likely to be enrolled in clinical trials than children living in other states across

the nation. To address this gap, NIH created the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network.

The goal of the IDeA program is to broaden geographic distribution of NIH funding, and as part of that program, the goals of the IDeA States Pediatric Clinical Trials Network include providing medically underserved and rural populations with access to cutting-edge clinical trials and applying findings from other relevant pediatric cohort studies to children in IDeA State locations. The IDeA States Pediatric Clinical Trials Network builds national pediatric research capacity by providing professional development opportunities for researchers as well as supporting investment in infrastructure.

In FY 2020, NIH will invest \$15 million in the IDeA States Pediatric Clinical Trials Network to support studies such as a multi-site clinical trial, which will evaluate the dosing, safety, and efficacy of drugs that are commonly prescribed to children. The IDeA States Pediatric Clinical Trials Network is also partnering with ACT NOW pilot studies to develop best practices for treatment of Neonatal Opioid Withdrawal syndrome and advancing clinical trial protocols for a study that aims to decrease pediatric obesity rates in rural areas through the use of mobile health technology.

Supporting the Next Generation of Researchers

In August 2017, NIH launched the Next Generation Researchers Initiative. This initiative, which responds to the 21st Century Cures Act, addresses challenges faced by researchers trying to embark upon and sustain independent research careers. With dedicated funding of \$100 million, NIH will continue to prioritize meritorious applications that request funding for early stage investigators seeking their first award and for investigators currently supported by NIH who are at risk of losing all research support. NIH Institutes and Centers will consider factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce, including enhanced workforce diversity when making awards.

In response to an advisory committee recommendation and a recent report from the National Academy of Sciences, NIH is creating a new pathway for applications from early-stage investigators that does not require preliminary data and continues to provide a separate review of applications. NIH is also lengthening the window for early-stage eligibility to 11

years with additional flexibility due to significant life events.

Ending the HIV Epidemic: A Plan for America

HHS is proposing a once-in-a-generation opportunity to eliminate new HIV infections in our nation. Ending the HIV Epidemic: A Plan for America will work to reduce new infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 250,000 HIV infections in that span. NIH-funded research has supported development of the science and tools that make the ambitious goals of this initiative possible.

The FY 2020 Budget provides \$6 million for NIH-sponsored Centers for AIDS Research to inform HHS partners on best practices, based on state-of-the-art biomedical research findings, and by collecting data on the effectiveness of approaches used in this initiative.

Working Toward a Universal Influenza Vaccine

NIH-supported research advances our understanding of how influenza (flu) strains emerge, evolve, infect, and cause disease. This research informs the design of new and improved therapies, diagnostics, and vaccines, including a universal influenza vaccine. Circulating and emerging influenza viruses present a public health threat and place substantial health and economic burdens on the United States and the world. Annual influenza vaccination is the most effective way to reduce influenza morbidity and mortality. However, traditional vaccine development relies heavily on predicting which strains will be in circulation each year. This approach is suboptimal for dealing with constantly evolving and newly emerging virus strains.

NIH invests both in ways to make seasonal flu vaccines longer lasting and more effective to protect the population, and supports efforts in rational design of a universal influenza vaccine, to protect against multiple influenza strains—including those that may pose a pandemic threat.

In FY 2018, NIH released a strategic plan to guide future basic, translational, and clinical research investments in areas essential to creating a safe and effective universal influenza vaccine. Along this path, NIH funds basic research to understand the transmission, natural history, and disease process of influenza. NIH supports research that characterizes how immunity occurs and how to tailor vaccination

responses to achieve immunity and extend protection duration.

Through cutting-edge vaccine technology, NIH modernizes vaccine development approaches to design a broadly protective flu vaccine for all ages. Several universal flu vaccine strategies are currently in testing in NIH-supported clinical trials. The Budget supports continued efforts to accelerate research progress toward developing a universal influenza vaccine, which would promote the protection of millions of people from infection and significantly mitigate the public health threat posed by influenza viruses.

Buildings and Facilities

Conducting cutting-edge biomedical research requires infrastructure and facilities that are conducive to leading-edge research and research support. The Budget includes \$200 million to support NIH facilities projects, reduce the Backlog of Repair and Maintenance, and increase flexibility for Institutes and Centers to fund repair and improvement projects.

New Technologies to Revolutionize the Practice of Medicine

Rapid, early, and accurate identification of disease improves the chances of treatment success and is ultimately key to saving lives. NIH supports a diverse portfolio of research focused on developing cutting-edge diagnostic technologies, and NIH-funded technological advances that are pushing the boundaries of disease treatment and prevention. Examples include a miniature device that simultaneously detects and distinguishes between various tick-borne diseases, and another that captures mutated genetic material and proteins shed by brain tumors into the bloodstream for developing personalized treatments. Both devices use just a single drop of blood.

NIH invests in mobile health technology research that makes lifesaving health care more accessible. One application designed by NIH researchers includes a reusable glucose meter system built into a smartphone case, providing people with diabetes a mobile option for monitoring their glucose levels.

Leveraging Big Data and Artificial Intelligence

NIH has initiated a variety of programs to advance scientific discovery and cures by leveraging the incredible growth in the volume, speed of delivery, and complexity of large biomedical datasets. In June 2018,

NIH released the Strategic Plan for Data Science. The plan articulates NIH's vision for making big data sustainable, interoperable, accessible and usable for the broader community by 1) optimizing data infrastructure, 2) modernizing data resources, 3) advancing data management, analytics, and tools, 4) promoting workforce development, and 5) enhancing policy stewardship and sustainability. NIH is now mapping out implementation activities, which will intensify over the next year, and include creating a new position—the NIH Chief Data Strategist—to collaborate closely with key stakeholders and lead implementation of the Plan.

NIH is focused on the promise of artificial intelligence and machine learning for catalyzing advances in basic and clinical research. NIH recognizes that there are many areas of biomedical research where novel computing, machine intelligence, and deep learning techniques have the potential to advance human health. NIH is committed to pushing those frontiers and is convening a new working group to further harness artificial intelligence and machine learning to advance biomedical research.

MAXIMIZING THE IMPACT OF NIH RESEARCH

Healthcare Research and Quality

To streamline HHS research activities, the Budget consolidates select activities of the Agency for Healthcare Research and Quality (AHRQ) into NIH as the National Institute for Research on Safety and Quality (NIRSQ). This new Institute within NIH will serve as a center of excellence for improving the quality and safety of health care. Within NIH, the Budget includes \$256 million for NIRSQ. The Budget continues to emphasize NIRSQ's integral role in support of the Secretary's priority to move health care organizations from "volume" to "value" by focusing on improving outcomes, reducing cost and expanding choices for consumers. NIRSQ will achieve this by supporting health services research, addressing pressing health care issues through data and technology, and harnessing the power of predictive analytics to improve diagnostics.

Health Services Research and Data

Within NIRSQ, the Budget includes \$58 million for Health Services Research, Data and Dissemination. Within the total, \$43 million supports investigator-initiated research grants, which is a source for extramural researchers, to identify and pursue the

most innovative projects. This will allow NIRSQ to produce successful yet unexpected discoveries in the nation's most pressing health care issues such as the opioid epidemic and value-based research.

The Budget supports the Healthcare Cost and Utilization Project, which is the nation's most comprehensive source of hospital care data. This program helps federal, state, and local policymakers, and others make more informed decisions about health care delivery and based on the cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, state, and local levels.

Patient Safety

The Budget provides \$65 million for the NIRSQ patient safety portfolio. Patient Safety activities will support lifesaving research and dissemination projects that prevent, mitigate, and decrease the number of patient safety risks and hazards. NIRSQ research in this area will provide the evidence base that CMS and other HHS agencies use to improve patient safety on a national

scale. It will support the efforts of hospitals, long term care facilities, and others to improve care.

The Budget maintains key activities such as the national Combating Antibiotic-Resistant Bacteria enterprise and Patient Safety Learning Labs. These learning labs apply system engineering approaches to address both diagnostic and treatment errors in health care.

Medical Expenditure Panel Survey

The Medical Expenditure Panel Survey (MEPS) is a unique set of large-scale surveys of families and individuals, their medical providers, and employers across the United States. The Budget includes \$72 million for MEPS activities in FY 2020, including improving its national estimates by expanding the capacity of individual states and groups of states through an expansion of MEPS. The survey expansion will increase the sample size by 1,000 households, a total of 2,300 persons, and redistribute the sample to states. As the only national comprehensive annual data on the use of medical care in the United States, the survey provides an important data source for research efforts aimed at improving health services.

Overview by Mechanism

Mechanism	dollars in millions			2020
	2018 /1	2019 /2	2020	+/- 2019
Research Project Grants (dollars)	21,206	22,579	19,545	-3,035
[# of Non-Competing Grants]	[25,858]	[27,492]	[28,760]	[+1,268]
[# of New/Competing Grants]	[11,461]	[11,675]	[7,894]	[-3,781]
[# of Small Business Grants]	[2,035]	[2,222]	[1,911]	[-311]
[Total # of Grants]	[39,354]	[41,389]	[38,565]	[-2,824]
Research Centers	2,583	2,688	2,218	-470
Other Research	2,446	2,490	2,210	-280
Research Training	856	889	802	-87
Research and Development Contracts	3,073	3,133	2,795	-337
Intramural Research	3,996	4,130	3,634	-496
Research Management and Support	1,816	1,898	1,739	-159
Office of the Director (OD) /3	1,024	1,204	1,144	-60
NIH Common Fund (non-add)	601	619	533	-86
Office of Research Infrastructure Programs (non-add)	289	289	249	-40
OD Appropriation (non-add)	1,914	2,119	1,926	-187
Buildings and Facilities /4	147	218	214	-4
NIEHS Interior Appropriation (Superfund)	77	77	67	-10
Total, Program Level	37,224	39,306	34,368	-4,938
Less Funds from Other Sources				
PHS Evaluation Funds (NIGMS) /5	-923	-1,147	-741	+406
Current Law Mandatory Funding – Type 1 Diabetes (NIDDK) /6	-150	-150	--	+150
Proposed Law Mandatory Funding – Type 1 Diabetes (NIDDK) /6	--	--	-150	-150
Total, Discretionary Budget Authority	36,151	38,010	33,477	-4,533
Appropriations				
Labor/HHS Appropriation	36,074	37,933	33,410	-4,523
Interior Appropriation	77	77	67	-10
Full-time Equivalents /7	17,532	18,101	18,339	+238

1/ Reflects the FY 2018 Final level including funding authorized by the 21st Century Cures Act and directed and permissive transfers.

2/ Reflects the FY 2019 Enacted level including funding authorized by the 21st Century Cures Act for Labor/HHS appropriated funding, the FY 2019 continuing resolution level for NIEHS Superfund, and the \$5 million directed transfer to the HHS Office of Inspector General.

3/ Number of grants and dollars for the Common Fund and Office of Research Infrastructure Programs components of OD are distributed by mechanism and the dollars are noted here as a non-add. OD appropriations are noted as a non-add because the remaining funds are accounted for under OD-Other.

4/ Includes Buildings and Facilities appropriation and funds for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.

5/ Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above. Therefore, the amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.

6/ Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above. Therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/ HHS Budget Authority.

7/ Full-time equivalent levels include NIRSQ in FY 2020.

Substance Abuse and Mental Health Services Administration



	dollars in millions			2020 +/-
	2018	2019	2020	2019
Mental Health				
Community Mental Health Services Block Grant	723	723	723	--
<i>PHS Evaluation Funds (non-add)</i>	21	21	21	--
Programs of Regional and National Significance	439	460	430	-30
<i>Prevention and Public Health Fund (non-add)</i>	12	12	--	-12
Certified Community Behavioral Health Clinics	100	150	150	--
Children's Mental Health Services	125	125	125	--
Projects for Assistance in Transition from Homelessness	65	65	65	--
Protection and Advocacy for Individuals with Mental Illness	36	36	14	-22
Subtotal, Mental Health	1,487	1,558	1,506	-52
Substance Abuse Prevention				
Programs of Regional and National Significance	248	205	144	-61
Drug Free Communities	--	--	100	+100
Subtotal, Substance Abuse Prevention	248	205	244	+39
Substance Abuse Treatment				
Substance Abuse Prevention and Treatment Block Grant	1,858	1,858	1,858	--
<i>PHS Evaluation Funds (non-add)</i>	79	79	79	--
Formula Grants to States to Address Opioids	1,500	1,500	1,500	--
Programs of Regional and National Significance	399	461	430	-31
<i>PHS Evaluation Funds (non-add)</i>	2	2	--	-2
Subtotal, Substance Abuse Treatment	3,757	3,819	3,788	-31
Health Surveillance and Program Support				
Program Support	79	79	73	-6
Health Surveillance	47	47	34	-13
<i>PHS Evaluation Funds (non-add)</i>	30	30	31	+1
Public Awareness and Support	13	13	12	-1
Drug Abuse Warning Network	10	10	10	--
<i>PHS Evaluation Funds (non-add)</i>	--	--	10	+10
Performance and Quality Information Systems	10	10	10	--
Data Request and Publications, User Fees	2	2	2	--
Behavioral Health Workforce Data and Development, PHS Eval	1	1	1	--
Subtotal, Health Surveillance and Program Support	162	162	141	-21
SAMHSA Budget Totals				
TOTAL, Program Level	5,654	5,744	5,679	-65
Less Funds from Other Sources:				
<i>Prevention and Public Health Fund</i>	-12	-12	--	+12
<i>PHS Evaluation Funds</i>	-134	-134	-143	-9
<i>Data Request and Publications User Fees</i>	-2	-2	-2	--
TOTAL, Discretionary Budget Authority	5,507	5,597	5,535	-62
Full-Time Equivalents	561	611	606	-5

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

The Fiscal Year (FY) 2020 President's Budget provides \$5.5 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds programs, policies, information, data, contracts and grants, and leads the U.S. to act, on the knowledge that:

- Behavioral Health is essential to health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

HHS has five priority areas to meet the behavioral health care needs of individuals, communities, and service providers:

- Combating the opioid crisis through the expansion of prevention, treatment, and recovery support services;
- Addressing serious mental illness and serious emotional disturbances;
- Advancing prevention, treatment, and recovery support services for substance use;
- Improving data collection, analysis, dissemination, and program and policy evaluation; and
- Strengthening health practitioner training and education.

SUBSTANCE ABUSE

An estimated 20 million Americans needed treatment for a serious substance abuse problem in 2017. Substance abuse complicates existing health issues, causes suffering well outside of the health care system, and increases health care costs. Deaths from drug overdose have risen over the past two decades, and are the leading cause of death from injury in the United States. From 2000 to 2017, nearly 700,000 people died from drug overdoses. The Budget provides \$3.9 billion for substance abuse prevention and treatment activities.

Continuing the Fight against the Opioid Crisis

The opioid epidemic remains a public health emergency, as first declared by the Secretary in October of 2017. Opioids contribute to two-thirds of the 192 deaths every day from drug overdose. HHS requests \$4.8 billion for programs across the Department that address the opioid crisis and serious

mental illness; \$1.9 billion of that is specifically for SAMHSA programs that address opioid misuse, abuse, and overdose. This funding will continue all existing opioid-related programs at the FY 2019 funding level including:

- \$1.5 billion for the State Opioid Response program;
- \$89 million to expand the availability of medication-assisted treatment, the most effective evidence-based treatment for opioid use disorder;
- \$70 million for drug courts; and
- \$48 million for training and equipping first responders on the use of opioid-overdose reversing drugs.

In addition to the ongoing efforts associated with fighting the opioids crisis, the Budget also funds a new \$4 million program authorized by the SUPPORT for Patients and Communities Act (SUPPORT Act) signed into law in October of 2018. This program provides grants to accredited medical schools and teaching hospitals to develop curricula that satisfies the requirements to prescribe medication-assisted treatment.

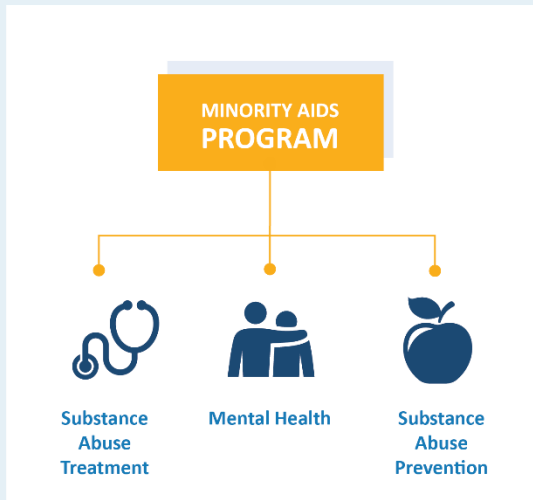
The Budget includes additional support services to help those in recovery succeed, including pregnant women and families struggling with addiction, and for states to enhance opioid abuse prevention strategies. SAMHSA will continue to direct \$9 million for oversight, to ensure safe and effective operation of opioid treatment programs.

Substance Abuse Prevention and Treatment Block Grant

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

FIGHTING HIV/AIDS AMONG VULNERABLE POPULATIONS

The Minority AIDS program enhances and expands the provision of effective, culturally competent, HIV/AIDS-related mental health and substance use disorder treatment services among vulnerable populations. This is achieved through grants to community-level domestic public and private non-profit entities, tribes, and tribal organizations.



Preventing Substance Abuse

Addressing substance abuse behaviors before they reach a crisis is more effective and less expensive than breaking the cycle of addiction. The Budget includes \$244 million for substance abuse prevention efforts. This total includes demonstration programs to fight underage drinking and expand tribal behavioral health services, and to support state grants for the Strategic Prevention Framework. This amount also 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 on behalf of the Office of National Drug Control Policy.

The Budget maintains \$5 million for federal drug-free workplace regulatory efforts and for states, tribes, and communities to receive technical assistance and training on best practices to prevent substance abuse.

Fighting HIV/AIDS

The Minority AIDS program enhances and expands the provision of effective, culturally, competent, HIV/AIDS-related mental health and substance use prevention and treatment services among vulnerable populations in an effort to reduce domestic HIV transmission and support those with HIV/AIDS. The program provides grants to community-level entities, tribes, and tribal organizations.

MENTAL HEALTH

In 2017, approximately 19 percent of American adults met the medical standard for a mental, behavioral, or emotional disorder that substantially interfered with major life activities. Of these 47 million people, approximately 11 million people—or 4.5 percent of all American adults—had a serious mental illness.⁴

The Budget provides \$1.5 billion for mental health activities to meet the needs of those with the most serious mental health issues.

Continuing the Fight against Serious Mental Illness

The Budget includes \$1 billion targeted specifically to programs that assist those with serious mental illness. This includes an increase of \$10 million for a total of \$15 million for the Assertive Community Treatment for Individuals with Serious Mental Illness program to help communities establish, maintain, or expand efforts to engage patients with serious mental illness through emergency and inpatient settings. The program reduces hospitalization of those with serious mental illness at the same cost and with higher patient satisfaction by coordinating care among a team of health care providers.

The Budget includes an increase of \$10 million for a total of \$14 million for Criminal and Juvenile Justice Programs. This program provides comprehensive treatment and recovery supports for people with co-occurring mental illness and addiction who are in the criminal justice system, including offenders re-entering the community. In a recent evaluation, participants reported mental health issues declined by 20 percent in the first six months of the program, alcohol and other drug use declined by 60 percent and employment rates increased from 36 percent to

⁴ <https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report>.

45 percent. In addition, nearly 74 percent of participants reported physical health improvements.

The Budget provides \$14 million for Protection and Advocacy for Individuals with Mental Illness for legal-based advocacy services to protect the rights of individuals with mental illness who are at risk for abuse, neglect, and rights violations while residing in public or private care or treatment facilities.

Community Mental Health Services Block Grant

The Budget provides \$723 million for the Community Mental Health Services Block Grant. This block grant is a flexible funding source that states use to address the needs of adults living with serious mental illness and children experiencing serious emotional disturbances. States will continue to spend at least 10 percent of the funds on early interventions for those experiencing a first episode of psychosis. States target local needs with this funding, prioritizing activities that insurance does not cover, such as payment infrastructure, physician training, and anti-fraud efforts.

Children’s Mental Health Services

The Budget maintains the Children’s Mental Health Services program at \$125 million. This program helps states, tribes, and communities deliver evidence-based services and supports for children and youth with serious emotional disturbances. Grantees use these competitive grant awards to ensure effective collaboration between the juvenile justice, child welfare, and education systems. New findings by the National Institute of Mental Health⁵ show that earlier intervention may prevent or lessen the further development of serious emotional disturbances and ultimately serious mental illness. The Budget proposes that up to 10 percent of the funds be available for a new demonstration targeting those at risk of developing serious mental illness.

Certified Community Behavioral Health Clinics

The Certified Community Behavioral Health Clinic (CCBHC) grant program provides funding for high quality behavioral health services at the local level. CCBHCs provide a comprehensive, coordinated range of behavioral health services certified to meet six key aspects of improved care. These include: Staffing, Organization Authority, Care Coordination, Scope of Services, Quality and other Reports, and Availability and Accessibility of Services.

CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINICS

The Certified Community Behavioral Health Clinic (CCBHC) grant program provides funding for high quality behavioral service at the local level. CCBHCs provide a comprehensive, coordinated range of behavioral health services certified to meet 6 key aspects of improved care.



Staffing



Organization Authority



Care Coordination



Scope of Services



Quality and Other Reports



Availability & Accessibility of Services

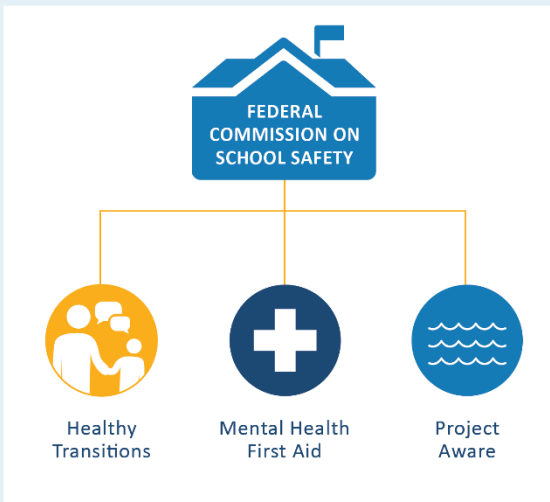
Mental Health Needs of Students

In response to the tragedy in Parkland, Florida, the President established a Federal Commission on School Safety. This commission heard testimony from members of the public, as well as key stakeholders, about the importance of developing a positive school climate and addressing the mental health needs of the nation’s students. The Budget includes an increase of \$15 million, for a total of \$107 million, to expand access to school-based programs, including school safety programs such as Project AWARE, Healthy Transitions, and Mental Health First Aid. This increase in funding will target rural communities through telehealth models, behavioral health aides, and linkages to services. The program will also develop trainings within schools for school personnel to better recognize the signs and symptoms of mental illness in students.

⁵ <https://www.nimh.nih.gov/health/topics/schizophrenia/raise/>.

ADDRESSING THE WORK OF THE FEDERAL SCHOOL SAFETY COMMISSION

Expanding access to school-based and school safety programs including:



Preventing Suicide

Suicide is a leading cause of death in the United States. Over 47,000 people in the United States died from suicide in 2017. This exceeds the rate of death from automobile accidents. The Budget provides \$74 million for Suicide Prevention programs in SAMHSA. These programs include competitive grants to reduce suicide deaths and technical assistance to disseminate best practices to stakeholder and medical communities.

Grantees increase awareness of suicide warning signs and knowledge of how to help those in need.

Other efforts implement the most effective evidence-based approaches to addressing suicide. This includes, for example, improving emergency room referral processes and clinical care practice standards, as well as assisting states in developing and implementing suicide prevention strategies.

Primary and Behavioral Healthcare Integration

The Budget does not include funding for the Primary and Behavioral Healthcare Integration program. States are free to use funds from the mental health and substance abuse block grants to support the integration of primary and behavioral health care systems.

HEALTH SURVEILLANCE AND PROGRAM SUPPORT

The Budget includes \$141 million to monitor and provide program oversight to SAMHSA programs and to support nationwide Health Surveillance efforts. This funding will prioritize activities for which there is a unique federal role, such as the National Survey on Drug Use and Health. Within this funding, the Budget maintains \$10 million for the Drug Abuse Warning Network (DAWN). DAWN is a national public health surveillance system that uses emergency room monitoring of mental and substance abuse crises to track non-fatal overdose rates for opioids and other trends in non-fatal substance abuse emergency department visits.

Centers for Medicare & Medicaid Services: Overview



	dollars in millions			2020 +/-
	2018	2019	2020	2019
Current Law /1 /2				
Total Net Outlays, Current Law	999,437	1,104,397	1,171,660	+67,263
Proposed Law /1 /3				
Total Proposed Law	--	-6,301	-13,098	-6,797
Total Net Outlays, Proposed Law /4	999,437	1,098,096	1,158,562	+60,466

1/ Current law Medicare outlays net of offsetting receipts.

2/ Reflects other CMS health insurance programs.

3/ Reflects hospital payments that are proposed to be administered by CMS but financed outside of the Part A Trust Fund.

4/ 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 2018-2020.

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

The Centers for Medicare & Medicaid Services (CMS) funds Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), the Center for Medicare and Medicaid Innovation (CMMI), other health insurance programs, program integrity efforts, and operating costs. The Fiscal Year (FY) 2020 Budget estimate is \$1.2 trillion in mandatory and discretionary outlays for CMS, a net increase of \$60.5 billion above FY 2019. In total, the Budget proposes targeted savings of

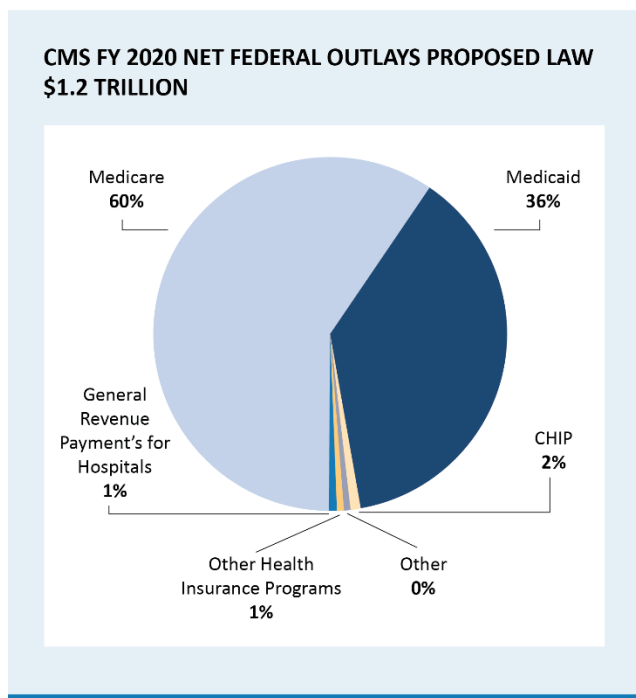
\$954.1 billion in CMS mandatory programs over the next decade.

BUDGET REQUEST

The FY 2020 Budget request for CMS promotes all four of the Secretary’s priorities to improve the health and well-being of the American people by (1) reducing prescription drug costs, (2) transforming the health care system to one that pays for quality and outcomes, (3) combating the opioid crisis, and (4) reforming America’s health insurance system. As the Nation’s largest administrator of health benefit programs, CMS is uniquely positioned to accelerate new initiatives that advance these priorities. In pursuing them, CMS is dedicated to putting patients first by empowering individuals with quality and cost information, and supporting Medicaid flexibilities that allow states to align their programs to their unique populations and improve health outcomes for Americans on Medicaid.

REDUCING PRESCRIPTION DRUG COSTS

The bipartisan effort began in 2018 when President Trump and Secretary Azar unveiled *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. The Blueprint is a package of comprehensive, cross-cutting drug pricing reforms built on four pillars: improved competition, better negotiation, incentives for lower



list prices, and lowering patient out-of-pocket costs. In FY 2018 and 2019, HHS made progress toward all of these goals. For example, CMS brought new negotiating tools from private insurance to both Medicare Part D and Medicare Advantage. CMMI also announced a potential proposal, the International Pricing Index Model, to leverage market forces in lowering the price of the most costly physician-administered drugs in Medicare Part B, which, due to a lack of negotiation, cost almost twice as much as they do in economically similar countries. CMS also proposed to require that drugs' list prices be disclosed in direct-to-consumer advertising, to help ensure consumers are aware of a drug's price before they talk to their doctor and facilitate increased price transparency.

The FY 2020 Budget legislative proposals complement administrative actions CMS has already taken to achieve the Blueprint's goals.

The Budget proposes a number of legislative changes to Medicare, including proposals to modernize the Medicare Part D prescription drug benefit, improve transparency and accuracy of payments for drugs under Medicare Part B, and better align the incentives of providers and health plans with those of beneficiaries and taxpayers.

The Budget also includes Medicaid proposals to lower prescription drug costs for states and taxpayers by ensuring manufacturers pay their fair share of Medicaid rebate covering all price increases for a drug, providing flexibility for states to develop innovative drug coverage and financing approaches, ensuring state Medicaid programs appropriately reimburse pharmacies for generic drugs, and ensuring drug companies pay appropriate rebates under the Medicaid Drug Rebate Program.

PROMOTING VALUE-BASED CARE

Delivery and payment reforms will transform our health system from one that pays for services and procedures to one that pays for quality and outcomes. The Budget increases transparency around price and quality by clarifying the Medicare coverage process through additional guidance and publicly releasing survey findings for all accredited facilities. The Budget creates a consolidated hospital quality program, reducing regulatory burden and aligning incentives

similar to previous reform of the physician quality payment program.

The Budget includes innovative new CMMI models for both the Medicare and Medicaid Programs. In Medicare, models will encourage the adoption of high-value innovative technologies and discourage the use of low-value services. CMS will test interventions to improve maternal mortality and morbidity under Medicaid. By eliminating arbitrary thresholds to encourage participation in Advanced Alternative Payment Models, the Budget removes barriers that impede provider access to innovative payment programs.

COMBATING THE OPIOID CRISIS

The Budget includes several proposals to address Medicare and Medicaid beneficiaries impacted by the opioids crisis, while also implementing HHS's five-point strategy to combat the opioid epidemic by (1) improving access to prevention, treatment, and recovery support services; (2) collecting opioid epidemic data; (3) updating guidance for pain management; (4) targeting of overdose-reversing drugs; and (5) increasing support for research on pain and addiction. Proposals include allowing collaboration between CMS and the Drug Enforcement Administration (DEA) to revoke a provider's DEA Certification of Registration, after CMS revokes a provider's Medicare enrollment based on a pattern of abusive behavior, such as over-prescribing. The Budget also proposes to make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder.

In October 2018, the President signed the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*, the most comprehensive legislation to address a single drug crisis in history. This bold, bipartisan legislation addresses the opioid crisis by expanding access to substance abuse treatment, cracking down on shipments of illicit drugs, and providing more grant funding for prevention, treatment, and recovery.

Several FY 2019 Budget proposals to improve access to opioid use disorder treatment for Medicare and Medicaid beneficiaries were passed into law in the SUPPORT Act, including: a demonstration to expand

CMS EFFORTS TO COMBAT THE OPIOID EPIDEMIC

Over the past year, CMS has taken aggressive action to address the opioid epidemic's impact on Medicare and Medicaid beneficiaries, including:

- Improving provider education and outreach efforts, including the introduction of new tools and data sources to publicize ways to reduce overprescribing and support efforts that address the crisis.
- Working with states to support and improve opioid use prevention and treatment efforts, including medication-assisted and alternative treatments, through Section 1115 demonstration waivers, technical assistance, institution for Mental Disease facility exclusion waivers, and quality metrics.
- Publishing the CMS Opioids Roadmap outlining key prevention activities, opioid use disorder treatment, and data-driven policies and activities.
- Issuing new policies through Medicare rulemaking to advance several key opioid objectives, including: 1) requesting comment on a physician bundled payment for substance use disorder treatment; 2) finalizing a proposal to pay separately at average sales price plus 6 percent for non-opioid pain medications used for post-surgical pain management in ambulatory surgery centers; 3) removing pain-related questions from quality assessments that could incentivize opioid prescribing.
- Announcing the Integrated Care for Kids and Maternal Opioid Misuse models, focusing on delivering care to children and mothers with opioid use disorders.

access to comprehensive substance use disorder treatment for Medicare beneficiaries; requiring plan participation in a program to prevent prescription drug abuse in Part D; and a temporary requirement for states to cover Medication-Assisted Treatment under Medicaid. CMS is implementing these key changes, along with many other actions to improve treatment and access to care for Medicare and Medicaid beneficiaries included under the Act. The FY 2020 Budget builds on these initiatives.

HEALTH REFORM

The Budget includes a number of proposals to improve federal health programs so they work better for the people they serve. These reforms leverage competition within the private sector, allow patients to make choices that work for them, and give states the freedom to innovate.

In October 2018, HHS issued updated guidance for State Relief and Empowerment Waivers (Section 1332 Waivers), which loosened excessive restrictions that limited state flexibility and consumer choice in the individual market. This new guidance allows states to

promote more affordable health insurance coverage options, while maintaining statutory requirements. The Budget proposes a number of legislative proposals, aligned with the core values of the Administration, to increase competition, put patients at the center of their own health care decisions, allow states to innovate, and deliver care in an affordable and sustainable way. These proposals include reforming medical liability to promote high-quality, evidence-based care and strengthening protections against governmental discrimination for individual and institutional health care entities that refuse to perform, pay for, or cover abortions.

The Budget also advances health care reforms that empower states and consumers to reform health care, expand options, and put the states in the driver's seat. The Budget supports market-based innovation and comprehensive Medicaid reform.

Empowering States and Consumers to Reform Health Care

The Fiscal Year (FY) 2020 Budget proposes bold, crosscutting reforms to our nation's safety net and federal health programs, so that they actually work for the people they serve. They aim to empower states to take charge of the health care system and create solutions that will be best suited for their citizens. These proposals also empower consumers to purchase coverage that best suits their health care needs. The goal of these proposals is more than a better-run health care system; it is more affordable, better-quality health care for all Americans.

These proposals align with the Administration's core values. First, they rely, to the extent possible, on competition within the private sector because that is a key way to drive down costs while improving quality. Second, these changes put patients at the center, free to make choices that work for them. Third, these reforms defer to states to innovate, rather than assuming the federal government knows best. Finally, these reforms aim to deliver care in an affordable, fiscally sustainable way, while maintaining a safety net for those in need.

These ideas are a departure from the way American health care has worked for too long. For the past half century, the federal government has been the dominant factor in both the financing and delivery of our health care.

Obamacare created a thicket of subsidies, regulations, and taxes designed to help those without employer insurance secure coverage on the individual market. It was supposed to not only expand this kind of private coverage, but also bring down costs. It has come up short on both of these objectives.

Using flexibilities under current law, this Administration has taken key steps to deregulate the health care system and introduce new options that expand choices and encourage competition. These steps include the expansion of access to short-term insurance policies and the ability to allow small businesses and sole proprietors to band together and form association health plans.

CMS also released four State Relief and Empowerment Waiver (also referred to as Section 1332 Waiver) concepts for states' use to promote more affordable, flexible health insurance coverage options. These concepts aim to spur innovative, state-initiated ideas to improve their health care markets. They are as follows:

- **Account-Based Subsidies:** a state directs public subsidies into a defined-contribution, consumer-directed account that an individual uses to pay for premiums or other health care expenses.
- **State-Specific Premium Assistance:** states design subsidy structures to meet the unique needs of their populations.
- **Adjusted Plan Options:** states provide financial assistance for different types of health insurance plans, increasing consumer choice.
- **Risk Stabilization Strategies:** states have flexibility to implement reinsurance programs or high-risk pools.

PREMIUMS ON EXCHANGES DROP FOR 2019

Average premiums have dropped for the first time since the implementation of the federally facilitated Exchanges in 2014, suggesting that the numerous actions taken by the Administration to stabilize the market are working. These actions include: implementing the market stabilization rule early in the Administration, granting states flexibility to set their essential health benefit benchmark, and using waiver authority to approve reinsurance programs in seven states.

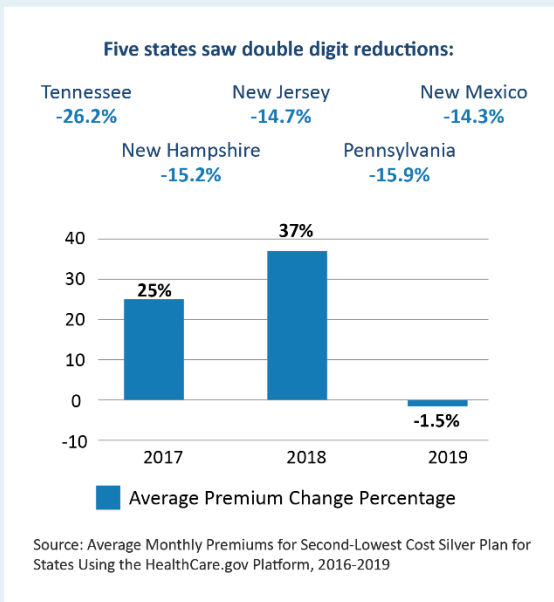
All told, the number of counties with only one insurer has dropped from 56 percent in 2018 to 39 percent in 2019, and only five states will have one insurer, cutting the 2018 number in half. Additionally, HHS has worked to provide consumers the choices they want in the market for affordable health coverage, including expanding access to short-term, limited duration insurance plans that may be up to 50-80 percent less expensive than other individual market plans.

This Budget includes legislative changes that build on what the Administration has already achieved to strengthen the federal government’s major benefits programs by placing them on more sustainable financial footing. These proposals empower states and consumers to reform health care. States are more capable of tailoring health care programs to their unique markets, increasing options for patients and providers, and building financial stability and personal responsibility.

The Budget continues to support the Exchanges while the Administration works with Congress on broader health care reforms.

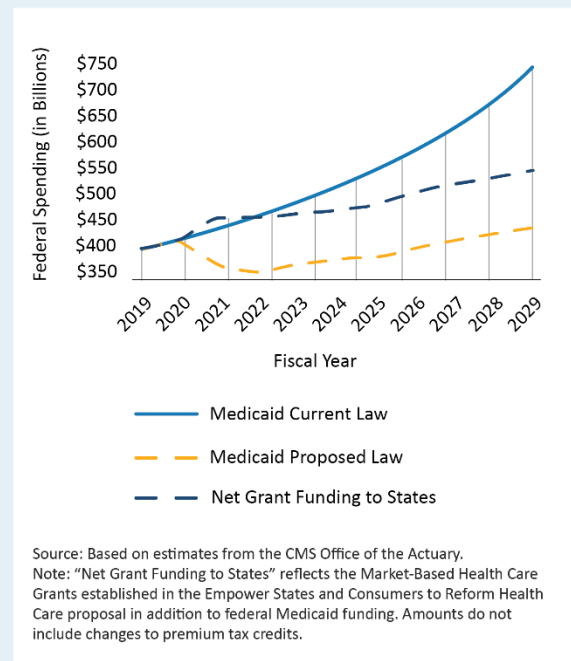
PREMIUMS ON EXCHANGES DROP FOR 2019

Average premiums for the second lowest cost silver plans for 2019 dropped 1.5 percent.



THE BUDGET SUPPORTS STATE REFORM, WHILE CURBING MEDICAID GROWTH

Recognizing that states are better positioned to address the unique needs of their populations, the Budget returns substantial control over health care from Washington, DC back to the states. The Budget replaces federal dollars currently spent on Obamacare’s Medicaid expansion and premium tax credits with \$1.2 trillion in Market-Based Health Care Grants for states over 10 years. Reforms to Medicaid will reduce overall Medicaid spending over the next ten years, putting the program on a more sustainable path.



2020 LEGISLATIVE PROPOSALS

Reforming the Health Care System

Empowering States and Consumers to Reform Health Care

The Administration is committed to empowering states and consumers to reform health care. The Budget supports a two-part approach to move away from Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-

Heller-Johnson bill that include Market Based Health Care Grants. In Medicaid, this includes allowing states a choice between a per-capita cap or a block grant, and repealing Obamacare’s Medicaid expansion, to modernize Medicaid financing and refocus the program on those it was originally intended to serve. The second part of the Budget proposal includes additional reforms to address unsustainable health care spending trends and builds upon the Graham-Cassidy-Heller-Johnson bill to make the system more efficient. This includes proposals to align the growth rates for the Market-Based Health Care Grant Program and Medicaid per capita cap and block grant with the Consumer Price Index for All Urban Consumers (CPI-U).

The Budget acknowledges the importance of ensuring protections for individuals with pre-existing conditions

and states would be required to include such plans in their applications for these grants. Specifically, states will be required to allocate at least 10 percent of their grant funding to ensure protections for high-cost individuals, including those with pre-existing conditions. [\$267.0 billion in savings to HHS and \$658.6 billion in government-wide net deficit reduction over 10 years].

Reform Graduate Medical Education Payments

Effective FY 2020, this proposal consolidates federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2020 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U 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. These changes modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable. [\$47.9 billion in savings over 10 years]

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 \$26.9 billion, and the federal government overall \$31.5 billion, over 10 years. A

significant portion of these savings is attributable to the estimated reduction in unnecessary services and curbing the practice of defensive medicine. These medical liability reforms will benefit all Americans by cutting unnecessary health care spending.

In addition to reducing health care costs, by providing a safe harbor based on clinical guidelines, physicians can focus on delivering effective patient care and evidence based medicine rather than on unsubstantiated lawsuits. If an inherently risky medical procedure does not 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 3 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.

[\$31.5 billion in government-wide net deficit reduction over 10 years]

Improving the Availability and Affordability of Private Health Insurance

Introduce New Minimum Required Contribution for Premium Tax Credits

This proposal introduces a new minimum required contribution percent for subsidized enrollees in health plans on the Exchanges. While the credits would continue to be calculated in the same way, an individual's premium tax credit would be reduced so that the individual is required to contribute a minimum

percentage of their income on any health plan, increasing personal responsibility. [\$345 million in savings to Treasury in 2020 and 2021 prior to eliminating the tax credits; no HHS budget impact]

Provide Appropriation to Pay Cost-Sharing Reductions

This proposal provides a mandatory appropriation for Cost-Sharing Reduction payments through CY 2020. While these payments would end after 2020, the Administration requests funding while the requirement remains. [\$479 million in costs in FY 2020 related to exempting this funding from sequestration]

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. This proposal places more responsibility on individuals that fall behind on premiums thereby reducing the amount of time

payments remain outstanding. [\$78 million in savings to Treasury over 10 years; no HHS budget impact]

Other Health Care Reforms

Strengthen Protection against Governmental Discrimination for Health Care Entities that Refuse to Perform, Pay for, or Cover Abortion

This proposal would strengthen, clarify, and further codify the prohibition against government entities discriminating against individual and institutional health care entities that refuse to perform, refer for, participate in, pay for, or provide (or sponsor) coverage of abortion services, or facilitate or make arrangement for such activities, ensure that HHS has appropriate enforcement tools to address potential violations of that prohibition, and enable health care entities that are the victims of such discrimination to pursue civil actions for appropriate relief. [No budget impact]

Empowering States and Consumers to Reform Health Care



FY 2020 Empowering States and Consumers to Reform Health Care Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Empowering States and Consumers to Reform Health Care			
Subtotal, Non-Medicaid HHS Impact	2,190	475,830	1,118,565
<i>Market-Based Health Care Grant Program (non-add)</i>	-	508,240	1,212,125
<i>Other HHS Impact (non-add)</i>	2,190	-32,410	-93,560
<i>Medicaid Impact (non-add)</i>	1,280	-429,058	-1,385,515
Subtotal, HHS Impact (non-add)	3,470	46,772	-266,950
Subtotal, Non-HHS Impact (non-add)	959	-153,251	-391,624
Total, Government-wide Impact (non-add)	4,429	-106,479	-658,574
Reform Graduate Medical Education Payments			
General Fund Impact (HHS Impact)	15,290	87,380	185,280
<i>Medicare Impact (non-add)</i>	-14,480	-89,640	-211,840
<i>Medicaid Impact (non-add)</i>	-1,600	-9,000	-21,300
<i>HRSA Impact (non-add) /1</i>	-	-	-
Total, HHS-wide Impact (non-add)	-790	-11,260	-47,860
Reform Medical Liability			
Cost-Sharing Reductions Impact (HHS Impact)	-1	-1	-1
<i>Medicare Impact (non-add)</i>	-69	-5,250	-26,895
<i>Medicaid Impact (non-add) /2</i>	-46	-46	-46
<i>Non-HHS Impact (non-add)</i>	-25	-1,540	-4,569
Total, Government-wide Impact (non-add) /2/3	-141	-6,836	-31,511
Improving the Availability and Affordability of Private Health Insurance			
<i>Introduce Minimum Required Contribution for Premium Tax Credits (Treasury Impact)</i>	-230	-345	-345
Provide Appropriation to Pay Cost-Sharing Reductions (HHS Impact)	479	479	479
<i>Reduce the Grace Period for Exchange Premiums (non-add) (Treasury Impact)</i>	-85	-78	-78
Other Health Care Reform			
<i>Improve and Expand Access to Health Savings Accounts (non-add) (Treasury Impact)</i>	0	11,588	28,530
Prohibit Governmental Discrimination against Health Care Providers that Refuse to Cover Abortion (HHS Impact)	-	-	-
Total Outlays, Empowering States and Consumers to Reform Health Care Budget Proposals (HHS non-Medicaid Impact)	17,958	563,688	1,304,323

1/ Children's Hospital Graduate Medical Education is shown as \$0 for FY 2020 and future years because this program is currently funded under a discretionary appropriation; in the FY 2020 Budget, HHS is no longer requesting funding for this program-specific appropriation. However, this proposal assumes that Children's teaching hospitals will continue to receive approximately the same amount of Graduate Medical Education funding from the General Fund as they do under current law in FY 2019 (\$325 million).

2/ Savings reduced to account for the interaction with the proposal to Empower States and Consumers to Reform Health Care.

3/ Includes savings to programs overseen by the Department of the Treasury, the Department of Veterans Affairs, and the Office of Personnel Management.

Medicare



	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Current Law Outlays and Offsetting Receipts				
Benefits Spending (gross) /1	697,707	767,152	842,104	+74,952
Less: Premiums Paid Directly to Part D Plans /2	-10,484	-10,159	-12,884	-2,725
Subtotal, Benefits Net of Direct Part D Premiums Payments	687,223	756,993	829,220	+72,227
Related-Benefit Expenses /3	14,683	15,087	15,383	+296
Administration /4	9,614	9,952	8,912	-1,040
Total Outlays, Current Law	711,520	782,032	853,515	+71,483
Premiums and Offsetting Collections	-122,650	-130,885	-139,654	-8,769
Current Law Outlays, Net of Offsetting Receipts	588,870	651,147	713,860	+62,714
Proposed Law				
Medicare Proposals, Net of Offsetting Receipts	0	0	-23,257	-23,257
Medicare Trust Fund Administration /5	0	0	36	+36
Subtotal, Medicare Proposed Law	0	0	-23,221	-23,221
Total Net Outlays, Proposed Law	588,870	651,147	690,640	+39,493
Mandatory Total Net Outlays, Proposed Policy /6	582,011	644,827	683,932	+39,105
<p>1/ Represents all spending on Medicare benefits by either the federal government or through other beneficiary premiums. Includes Medicare Health Information Technology Incentives.</p> <p>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.</p> <p>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.</p> <p>4/ Includes CMS Program Management, the Health Care Fraud and Abuse Control Program (HCFAC), Quality Improvement Organizations, and other administration.</p> <p>5/ A portion of this supports the State Health Insurance Assistance Programs through the Administration for Community Living (ACL). Please see the ACL chapter for more information.</p> <p>6/ Removes total Medicare discretionary amount: FY 2018 -\$6,859 million; FY 2019 -\$6,320 million; and FY 2020 -\$6,708 million.</p>				

Medicare provides health benefits to individuals who are aged 65 or older, disabled, or have end-stage renal disease. In Fiscal Year (FY) 2020, the Office of the Actuary has estimated that gross current law spending on Medicare benefits will total \$842.1 billion and the program will provide health benefits to 62.7 million beneficiaries.

THE FOUR PARTS OF MEDICARE

Part A

Medicare Part A pays for health care services in inpatient hospitals and skilled nursing facilities, home health care related to a hospital stay, and hospice care. A 2.9 percent payroll tax, paid by both employees and employers, is the primary financing mechanism for Part

A. Part A gross fee-for service spending will total an estimated \$216.9 billion in Calendar Year (CY) 2020.

Individuals who have worked for 10 years (40 quarters) and paid Medicare taxes during that time generally receive Part A benefits without paying a premium, but most services require beneficiary coinsurance. In CY 2019, beneficiaries pay a \$1,364 deductible for a hospital stay of 1–60 days, and a \$170.50 daily coinsurance for days 21–100 in a skilled nursing facility.

Part B

Medicare Part B pays for physician, outpatient hospital, end-stage renal disease, laboratory, durable medical equipment, home health care unrelated to a hospital

stay, and other medical services. Part B coverage is voluntary and 91 percent of all Medicare beneficiaries are enrolled in Part B through both fee-for-service and Medicare Advantage. Beneficiary premiums finance approximately 25 percent of Part B costs with the remaining 75 percent covered by general revenues from the U.S. Treasury. Part B gross fee-for-service spending will total \$220.3 billion in CY 2020.

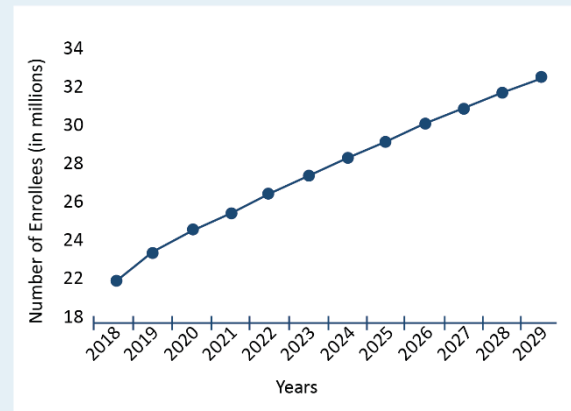
The standard monthly Part B premium is \$135.50 in CY 2019, an increase of \$1.50 from \$134 in CY 2018. A statutory “hold harmless” provision applies each year to 70 percent of enrollees, limiting the annual rise in Part B premiums to no more than the Social Security cost of living increase. For these enrollees, any increase in Part B premiums must be lower than the increase in their Social Security benefits. Some beneficiaries also pay a higher Part B premium based on income: those with annual incomes above \$85,000 (single) or \$170,000 (married) will pay from \$189.60 to \$460.50 per month in CY 2019. The Part B deductible in CY 2019 is \$185 for all beneficiaries, an increase of \$2 from \$183 in CY 2018.

Part C

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

In CY 2020, Medicare Advantage enrollment will total approximately 24 million beneficiaries, or 42 percent of all Medicare beneficiaries who are enrolled in both Parts A and B. Enrollment in Medicare Advantage is growing nearly 50 percent faster than enrollment in traditional Medicare. CMS data confirm that 99 percent of Medicare beneficiaries have access to at least one Medicare Advantage plan in CY 2019. Additionally, Medicare Advantage supplemental benefits have increased while premiums have remained stable. Part C gross fee-for-service spending will total \$286.5 billion in FY 2020.

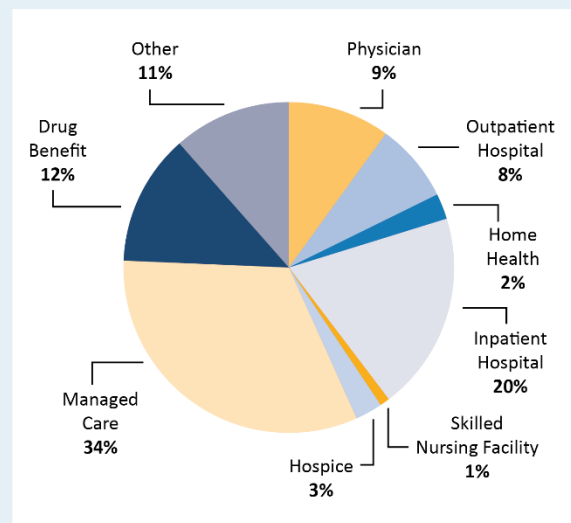
MEDICARE ADVANTAGE ENROLLMENT PROJECTED TO INCREASE BY 50 PERCENT FROM 2018-2029



Part D

Medicare Part D offers a standard prescription drug benefit with a CY 2019 deductible of \$415 and base beneficiary premium of approximately \$33. Enhanced and alternative benefits are also available with varying deductibles and premiums. Participating beneficiaries pay a portion of the cost of their prescription drugs. This portion varies based on whether the medication is generic or a brand name and the amount the beneficiary has already spent on medications that year. Low-income beneficiaries have varying degrees of cost-sharing, with co-payments ranging from \$0 to \$8.50 in 2019 and low or no monthly premiums. For CY 2020, CMS expects Medicare Part D enrollment to

**MEDICARE BENEFITS BY SERVICE, 2020
CURRENT LAW ESTIMATE: \$842.1 BILLION**



increase by 3.1 percent to 48.2 million, including 13.4 million beneficiaries who receive the low-income subsidy. CMS estimates total gross spending for Part D to be \$106.8 billion in FY 2020.

In CY 2019, of beneficiaries that have Part D coverage, approximately 54 percent are enrolled in a stand-alone Part D Prescription Drug Plan, 44 percent are enrolled in a Medicare Advantage Prescription Drug Plan, and 3 percent are enrolled in an employer plan. Of Medicare beneficiaries overall, approximately 77 percent of all Medicare beneficiaries receive prescription drug coverage through Medicare Part D or employer-sponsored retiree health plans, and a significant number through other creditable coverage, such as the Federal Employees Health Benefits Program.

Beneficiaries reach the Medicare Part D coverage gap, or “donut hole,” once their total drug spending exceeds an initial coverage limit (\$3,820 in total drug costs in CY 2019), and they stay in the coverage gap until they reach the threshold for qualified out-of-pocket spending (\$5,100 in out-of-pocket costs CY 2019), 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, but a combination of manufacturer discounts and gradually increasing federal subsidies have closed the gap over time. The Bipartisan Budget Act of 2018 increased manufacturer discounts from 50 to 70 percent, and closed the brand drug coverage gap one year ahead of schedule -- in CY 2019 instead of CY 2020. In CY 2019, non-low income subsidy beneficiaries who reach the coverage gap will now pay just 25 percent of the cost of covered Part D brand drugs and biologics and will pay 37 percent of the costs for all generic drugs in the coverage gap. In CY 2020 and beyond, beneficiaries will pay 25 percent of the costs for all covered Part D drugs during both the coverage gap and initial coverage phases of the benefit. Low-income subsidy beneficiaries are statutorily excluded from the coverage gap discount program because Medicare pays for the majority of their cost-sharing.

MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS

CMS contracts with Quality Improvement Organizations (QIOs) - experts in quality improvement - to ensure Medicare beneficiaries and their families receive high quality care and support CMS’s aims of

better health, better care and lower costs. The QIOs drive local change by partnering directly with Medicare providers, beneficiaries, families, and other organizations to support innovative approaches to improve quality, accessibility, and affordability, which translates 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 QIOs that work with providers and beneficiaries: Quality Innovation Network contractors and Beneficiary and Family Centered Care contractors. In 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.

	2018	2019	2020	Change 2020 +/- 2019
Aged 65 and over	50.7	52.4	54.1	+1.7
Disabled	8.8	8.7	8.6	-0.1
Total	59.6	61.1	62.7	+1.6

Source: CMS Office of the Actuary estimates

2020 LEGISLATIVE PROPOSALS

The FY 2020 Budget includes targeted Medicare proposals designed to improve value-based systems of care, exercise fiscal integrity, promote competition, reduce provider burdens, improve the appeals system, and address high drug prices. Together, this legislative package is expected to net savings to the Medicare Trust Funds of \$811 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 8 years, in part by ensuring Medicare payments are directly related to its health care financing role, financing certain payments to hospitals for graduate medical education and uncompensated care outside the Trust Fund and slowing their growth rate.

Improving Value-Based Systems of Care

Reprioritize Primary and Preventive Care in Medicare

Medicare's physician fee schedule does not adequately reimburse for primary care relative to specialty care due, at least in part, to challenges in reflecting clinician time and resources spent evaluating and coordinating ongoing patient care. Beginning in FY 2021, this proposal creates a risk-adjusted monthly Medicare Priority Care payment for providers who are eligible to bill for evaluation and management (E/M) services and who provide ongoing primary care to Medicare beneficiaries. The payment would be funded by a five percent annual reduction to the valuations of all non-E/M services and procedures under the Physician Fee Schedule. [No budget impact]

Expand Basis for Beneficiary Assignment for Accountable Care Organizations

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

Create a Consolidated Hospital Quality Payment Program

Medicare requires inpatient hospitals to participate in four quality reporting programs: the Inpatient Quality Reporting Programs, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Readmissions Reduction Program. This proposal establishes a new consolidated hospital quality payment program that combines and streamlines these four existing programs to drive quality improvement, lower health care costs, achieve transparency by publicly reporting performance information, and pay for value by making

value-based incentive payment adjustments. Additionally, given the importance of monitoring patient safety, this proposal would require hospitals, as a Medicare Condition of Participation, to accurately report hospital acquired infections data to the CDC's National Health Safety Network. These streamlined requirements support CMS's Patients Over Paperwork and Meaningful Measures Initiatives. [No budget impact]

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

The Physician Self-Referral Law (commonly referred to as the Stark Law) has been identified by the Department and the regulated industry as a significant impediment to care coordination, participation in alternative payment models, and the establishment of novel financial arrangements that further the goals of a value-based system. Effective CY 2021, the Department, in consultation with the HHS Office of Inspector General, will establish a new exception to the physician self-referral law for arrangements that arise due to participation in advanced Alternative Payment Models and identify the types of arrangements and the minimum risk levels and level of participation in the model required for such exceptions. Effective CY 2021, this proposal addresses the problem by establishing a new process for physicians to self-report inadvertent, technical non-compliance violations of the law and excluding 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]

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

Medicare currently has value-based purchasing programs in place for inpatient hospital services and several other settings, but not for outpatient hospital services and ambulatory surgical centers. Beginning in CY 2021, CMS will implement a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers, offering them incentives to improve quality and health outcomes. Under this proposal, two percent of payments would be linked to performance on quality and outcome measures. Total rewards and adjustments would be designed to be budget neutral. [No budget impact]

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

Under current law, Medicare bases payments for services furnished at outpatient hospital and ambulatory surgical centers on the setting of care rather than patient acuity. This proposal will risk-adjust payments to these facilities based on the severity of patients' diagnoses. These adjustments would be made in a budget neutral manner. This proposal will promote site neutrality in payments for similar services and similar patient characteristics at these facilities. [No budget impact]

Promoting Competition

Reform and Expand Durable Medical Equipment Competitive Bidding

Stakeholders raise two major concerns with the Medicare Durable Medical Equipment (DME) Competitive Bidding Program. First, DME suppliers can submit very low bids during the competition to win a Medicare contract and still get paid a higher price even though their low bid reduced prices for all other suppliers in the competition area. Second, current law requires that CMS use prices from urban DME competitions to inform fee schedule prices in rural areas, thereby undervaluing true costs in rural areas and threatening access to care. This proposal changes the way Medicare pays for DME under the competitive bidding program, from a single payment amount based on the maximum winning bid to the winning suppliers' own bid amounts. As a result, low bidders will be paid their low bid amount. The proposal also expands competitive bidding to additional geographic areas, including rural areas. In the event that fewer than two suppliers submit bids in a rural area, CMS will base prices on information from similar rural areas. Expanding competitive bidding will ensure prices for DME items and services in rural areas are based on competitions in those areas rather than on competitions in urban areas. [\$7.1 billion in Medicare savings and \$410 million in Medicaid savings over 10 years]

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

Medicare DME coverage excludes non-durable alternatives to DME. This proposal allows Medicare coverage for innovative non-durable medical equipment alternatives to treat and manage diabetes.

Payment for these alternative items would be subject to competitive bidding and capped at the payment rate for their DME counterpart. Allowing access to these alternatives makes it possible for beneficiaries to choose items and services that better suit their medical needs. [No budget impact]

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

Medicare beneficiaries in high-deductible health plans are currently prohibited from making tax-deductible contributions to their Health Savings Accounts (HSAs) or Medicare Savings Accounts (MSAs). This proposal allows beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs, subject to the annual HSA contribution limits determined by the Internal Revenue Service. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs and the ability to roll over funds from one MSA to another. Beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Individuals 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. This proposal would give Medicare beneficiaries greater flexibility to take control of their health care using tools that are currently available in the private market. [\$240 million in Medicare costs over 10 years]

Exercising Fiscal Stewardship

Modify Payments to Hospitals for Uncompensated Care

Medicare currently makes payments to hospitals for uncompensated care provided to non-Medicare beneficiaries. Effective FY 2021, this proposal 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 Medicare cost reports. The total amount of available uncompensated care payments will be equal to FY 2019 funding levels, grown annually by the Consumer Price Index for all Urban Consumers. Uncompensated care payments will be funded from the general fund of the Treasury rather than the Medicare Trust Fund. Empirically justified Disproportionate Share Hospital payments will not be changed. This proposal more closely aligns Medicare

payment policy with private insurers, who do not typically cover uncompensated care. [\$182.5 billion in Medicare savings over 10 years; this proposal would increase spending from general revenues by \$84.5 billion over 10 years, for a net savings to the federal government of \$98.0 billion over 10 years]

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

Medicare generally pays on-campus hospital outpatient departments substantially more than physician offices for the same services. Effective CY 2020, this proposal makes site neutral payments between on-campus hospital outpatient departments and physician offices for certain services such as clinic visits, eliminating the disparity between what Medicare pays in these settings for the same services. [\$131.4 billion in savings over 10 years]

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

Medicare payment for post-acute care service can differ substantially for similar beneficiaries depending on the setting, due to variation in supply and lack of evidence-based criteria regarding patient eligibility, the most appropriate setting, and level of care required. Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities will receive a lower annual Medicare payment update from FY 2020 to FY 2024 and, beginning in FY 2025, a unified post-acute care payment system would span all four post-acute care settings, with payments based on episodes of care and patient characteristics rather than the site of service. Payment rates would be budget neutral in FY 2025, risk adjusted, and set prospectively on an annual basis, with episode grouping and pricing based on the average cost for providing post-acute care services for a diagnosis, similar to the Diagnosis-Related Group methodology under the Inpatient Prospective Payment System (IPPS). This proposal would reduce costs, increase fairness, and give the Secretary the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate. [\$101.2 billion in savings over 10 years]

Pay Site Neutral Rates to All Hospital-Owned Physician Offices Located Off-Campus

Medicare pays most off-campus hospital outpatient departments higher rates than the Physician Fee

Schedule for the same services. These facility types include emergency departments, cancer hospitals, and grandfathered off-campus hospital outpatient departments billing under the Outpatient Prospective Payment System (OPPS) or under construction before November 2, 2015. This proposal requires all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule effective CY 2020. This change will promote site neutrality by aligning payments to hospital outpatient departments with payments to physician offices, regardless of hospital ownership or facility type. [\$28.7 billion in savings over 10 years]

Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria

Medicare pays a higher prospective payment rate to Long Term Care Hospitals (LTCHs) when admissions follow an acute care hospital stay with three or more days in an intensive care unit (ICU), or the LTCH provides at least 96-hours of mechanical ventilation services. Absent meeting these criteria, LTCHs receive a lower Medicare payment rate comparable to acute care hospitals under the IPPS. Effective FY 2020, this proposal raises the ICU stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care LTCHs provide. This change would promote site neutrality by basing payment on clinical characteristics and the needs of patients rather on location of care. [Savings of \$10.0 billion 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 2020, 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. [\$38.5 billion in savings over 10 years]

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

Currently, ESRD Networks are funded by withholding 50 cents from each treatment payment under the ESRD Prospective Payment System, unchanged since 1989. This proposal updates the amount from 50 cents to

\$1.50 and inflates that amount annually by the CPI-U to ensure funding is adequate for the networks to continue to carry out their work. [No budget impact]

Reducing Burden

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

Under the current structure of the Quality Payment Program, some clinicians who participate in advanced Alternative Payment Models may not be eligible for five percent incentive payments because they do not meet arbitrary thresholds. Effective CY 2020, the five percent bonus for clinicians in advanced Alternative Payment Models would be paid based on physician fee schedule revenues received through Models in which they participate rather than all Medicare physician fee schedule payments. This change directly rewards clinicians along a continuum based on their level of participation in advanced Alternative Payment Models, without subjecting clinicians to arbitrary participation threshold levels. [\$280 million in savings over 10 years]

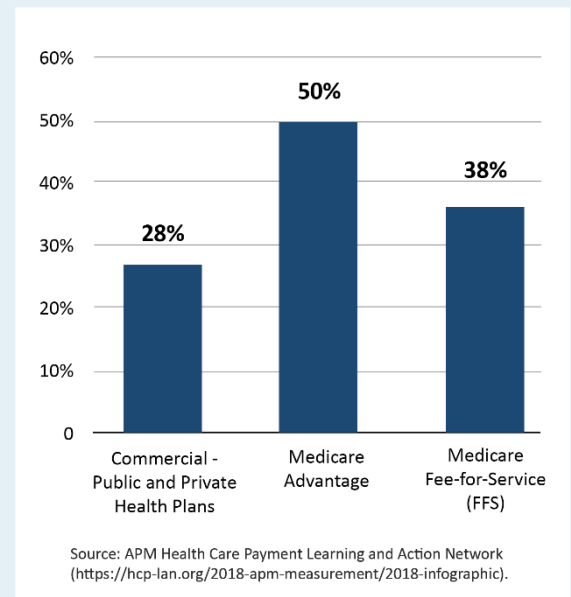
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment

Physicians must document a beneficiary's face-to-face encounter with a physician or a non-physician practitioner as a condition for Medicare payment for a DME order. This proposal allows CMS flexibility in the enforcement of the face-to-face requirement, eliminating this overly burdensome requirement for most Medicare providers and beneficiaries. [No budget impact]

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

Accreditation organizations currently do not make their survey reports and accompanying Plans of Corrections publicly available, and the Secretary is prohibited from disclosing accreditation surveys that are *not* home health agencies surveys or related to an enforcement action. This proposal would provide CMS with the authority to publish surveys for all accredited facilities, including hospitals, hospices, ambulatory surgical centers, outpatient physical therapy and speech-language pathology services, and rural health clinics. This change will increase transparency and accelerate value. [No budget impact]

MEDICARE EXCEEDS COMMERCIAL ALTERNATIVE PAYMENT MODELS (APM) PARTICIPATION IN 2017



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

Under current law, physicians must certify that all patients at critical access hospitals (CAH) are reasonably expected to be discharged or transferred within 96 hours of admission. The CAH is still eligible for Medicare payment if an individual patient's stay exceeds 96 hours, so long as the CAH maintains an annual average length of stay of 96 hours or less, which is a Medicare Condition of Participation. This proposal removes the 96-hour physician certification requirement, thereby eliminating the burden of this unnecessary requirement. [No budget impact]

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

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

facility choosing to be accredited by a CMS-approved accreditation organization, clarifying the current ambiguity over whether state survey agencies are required to survey these providers. [No budget impact]

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

The Merit-based Incentive Payment System (MIPS) is burdensome and overly complex, consisting of physician and other clinical level measures that are often not meaningful to clinicians who report them and do not help improve patient care. Effective CY 2022, this proposal alters the MIPS program by adopting a uniform set of broader claims calculated measures and simplifying beneficiary surveys to assess performance at the group practice level instead of the individual clinician level during the performance period to reduce burden and provide meaningful and comparable results to clinicians and patients. This proposal would use the budget-neutral payment adjustments under the 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. [No budget impact]

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

Current law is prescriptive about which measures to include in the ESRD Quality Incentive Program. Effective upon enactment, this proposal provides the Secretary with broad authority to add and remove measures to the ESRD Quality Incentive Program through rulemaking. CMS will submit all new measures to the designated pre-rulemaking entity as currently specified in statute. This change will align the ESRD Quality Incentive Program with CMS’s Meaningful Measures initiative, which seeks greater flexibility and less burden regarding the quality measures Medicare uses in its value-based payment systems. [No budget impact]

QUALITY PAYMENT PROGRAM – YEAR ONE PERFORMANCE RESULTS

Snapshot of Payment Adjustments for MIPS Eligible Clinicians in 2019

93% of MIPS eligible clinicians received a positive payment adjustment for their performance in 2017

- 71% earned a positive adjustment and an adjustment for exceptional performance
- 22% earned a positive payment adjustment only

95% overall avoided a negative payment adjustment for their performance in 2017

- 2% received a neutral adjustment (no increase or decrease)
- 5% received a negative payment adjustment

BURDEN REDUCTION IMPACT: PATIENTS OVER PAPERWORK

Burden reduction for health providers increases efficiencies and improves the patient care experience. Across rules finalized in 2017 and 2018, CMS projects an estimated savings of nearly: \$5.2 billion and a reduction of 53 million burden hours through 2021 – the equivalent of saving more than 6,000 years of burden hours over the next 4 years.

Total Projected Savings in 2018-2021 from Rules Finalized in 2017 and 2018

Provider Types	Savings	
	Dollars (millions)	Hours (thousands)
Accountable Care Organizations	\$4	45
Ambulatory Surgical Centers	\$1,400	915
Clinicians	\$15	17,500
End Stage Renal Disease	\$56	633
Home Health	\$496	8,400
Hospice	\$269	1,000
Hospitals	\$1,200	14,000
Long Term Care	\$497	6,600
Rural/Federally Qualified Health Centers	\$100	950

Improve the Medicare Appeals System

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

Change the Medicare Appeal Council's Standard of Review

Currently, when a party files a request for review of an Administrative Law Judge decision, the Medicare Appeal Council must review the decision *de novo*, from the beginning. This proposal changes the Council's standard of review from a *de-novo* to an *appellate-level* standard of review. Changing the Departmental Appeals Board's standard of review will increase adjudication capacity by up to 30 percent and further distinguish the Council's role as an administrative appellate body. [No budget impact]

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

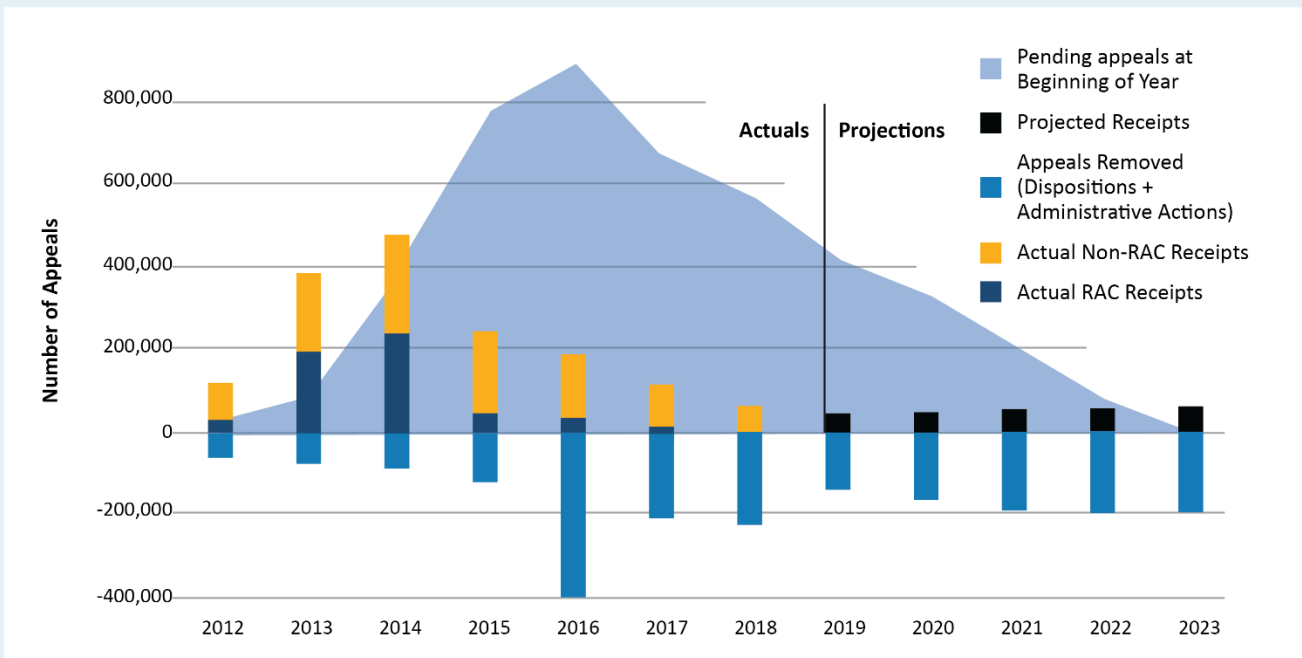
Currently, there are no administrative fees charged for filing a Medicare appeal, which has in some cases resulted in appellant's often filing non-meritorious appeals. This proposal establishes a post-adjudication user fee for all unfavorable Medicare appeals, other

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 will support a portion of the administrative costs required to adjudicate appeals and encourage those appellants who frequently file to more carefully assess their appeals before filing. [No budget impact]

Expedite Procedures for Claims with No Material Fact in Dispute

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

RISE AND PROJECTED FALL OF MEDICARE APPEALS BACKLOG AT OMHA FY2012-2023



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

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal increases the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is \$1,630 in calendar year 2019 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

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal allows the Office of Medicare Hearings and Appeals to use Medicare magistrates for appealed claims below the Federal District Court amount in controversy threshold, which is \$1,630 in calendar year 2019 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]

Limit Appeals When No Documentation is Submitted

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

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

The status quo allows new evidence to be submitted at the second level of appeals or above, decreasing the

efficiency of the Medicare appeals system and contributing to the backlog of pending appeals at Levels 3 and 4. 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

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

Medicare Legislative Proposals Discussed in Other Chapters

Medicare Drug Pricing Legislative Proposals

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First Blueprint*, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs. The FY 2020 Medicare legislative proposals work to achieve the Blueprint's goals through proposals to modernize the Medicare Part D prescription drug benefit, improve transparency and accuracy of payments for drugs under Medicare Part B, and better align the incentives of providers and health plans with those of beneficiaries and taxpayers. Please see the Lowering the Cost of Prescription Drugs chapter for proposal

descriptions. [\$67.2 billion in Medicare savings over 10 years]

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. [\$6.4 billion in Medicare savings over 10 years]

Legislative Proposals for Medicare-Medicaid Enrollees

The Budget includes four proposals to improve the quality and efficiency of care for Medicare-Medicaid, dually-eligible beneficiaries. See the Medicaid chapter for proposal descriptions. [\$210 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

Funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system does not target training to the types of physicians needed in the United States. The Budget includes a proposal to consolidate and better target federal spending for GME. See the Empowering States and Consumers to Reform Health Care chapter for a proposal description. [\$211.8 billion in Medicare savings over 10 years]

Reform Medical Liability

The Budget includes a set of proposals to reform medical liability to reduce medical malpractice costs and the practice of defensive medicine (see the Empowering States and Consumers to Reform Health Care chapter for proposal descriptions). [\$26.9 billion in net Medicare savings over 10 years]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven Medicare administrative proposals that the Department plans to implement in FY 2020 and save an estimated \$6 billion over ten years. These proposals do not require Congressional action. These proposals support the Administration's priorities of improving value-based systems of care, promoting competition, and exercising fiscal stewardship.

Improving Value-Based Systems of Care

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

It is currently not cost effective for providers to invest in some innovative technologies that could potentially save Medicare dollars over an episode of care. Under this proposal, the Center for Medicare & Medicaid Innovation would use existing authorities to identify bundled payment arrangements for certain high value devices. For example, these devices include technologies that could significantly reduce time and costs in a post-acute care setting but providers otherwise consider them impractical solely in the scope of Medicare payments to facilities. The proposal would require the device manufacturer to bear some or all of the risk. [No budget impact]

Improve Clarity and Transparency around Medicare Coverage Process

Some stakeholders find the process and standards for the Medicare coverage determination process lack clarity. This proposal requires CMS to issue additional guidance around the Medicare coverage process, including sub-regulatory guidance on the evidence standards that CMS utilizes in assessing coverage and the process to appeal coverage determinations, in an effort to improve clarity around Medicare coverage. [No budget impact]

Promoting Competition

Strengthen the Parallel Review Process to Streamline Medicare Coverage

The Parallel Review program is a collaborative effort between the Food and Drug Administration (FDA) and CMS that is intended to reduce the time between FDA approval of a drug or device and Medicare coverage of that item. This proposal strengthens the existing parallel review process to improve device manufacturer participation and increase transparency. [No budget impact]

Improve Medicare Beneficiary Access to Breakthrough Devices

There is currently no expedited pathway for Medicare beneficiaries to access innovative devices that have received FDA breakthrough designation. This proposal provides Medicare coverage of devices approved through the Breakthrough Device Program for

beneficiaries participating in clinical trials for up to four years from the date of FDA approval.

[No budget impact]

Add Additional Items to Durable Medical Equipment Competitive Bidding Program

The DME Competitive Bidding Program applies market-based competitive principles in setting prices for applicable items and services in Medicare. This proposal adds ventilators and orthotics to the next round of the competitive bidding program with implementation of prices beginning in 2021. This reform will ensure appropriate prices for these items and services, which will save money for taxpayers especially Medicare beneficiaries. [\$6.1 billion in Medicare savings over 10 years]

Exercising Fiscal Stewardship

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

Encounter data is a more accurate source of risk-adjustment data in Medicare Advantage, reflecting services rendered versus patient diagnoses that insurance companies submit. This proposal phases-in the use of encounter data for Medicare Advantage payment risk adjustments. In payment year 2020, CMS is proposing to calculate risk scores by adding 50 percent of the risk score using encounter data and fee-for-service diagnoses to 50 percent of the risk score using plan-reported Risk Adjustment Processing System and fee-for-service diagnoses. CMS would increase the

weighting of encounter data-based risk scores over subsequent years by moving to a risk score incorporating 75 percent of the encounter data/fee-for-service-based risk score in payment year 2021 and a risk score of 100 percent encounter data/fee-for-service-based risk score in payment year 2022. Using encounter data for risk-adjustment removes incentives for plans to inaccurately increase the severity of health conditions of their beneficiaries, improves Medicare payment accuracy, and reduces potential improper payments. [No budget impact]

Publicly Report Drugs with Significant Wastage Using Part B Claims Data

There may be a financial incentive for manufacturers to produce and providers to purchase drugs in larger packaged dosages than typically needed, because CMS pays for these discarded drugs and biologics up to the amount included in a package or vial, in addition to the amount administered to the beneficiary. Since January 1, 2017, providers and suppliers have been required to flag discarded drugs and biologics for CMS on their Part B claims. This proposal requires CMS to make public which Part B drugs have the highest reported drug wastage using data gathered from these claims. Publicly reporting this information will allow for a better understanding of which drugs would benefit from different packaging to reduce wastage. [No budget impact]



FY 2020 Medicare Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Medicare Legislative Proposals			
Improving Value-Based Systems of Care			
Reprioritize Primary and Preventive Care in Medicare	--	--	--
Expand Basis for Beneficiary Assignment for Accountable Care Organizations	--	-30	-80
Create a Consolidated Hospital Quality Payment Program	--	--	--
Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization	*	*	*
Implement Value-Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers	--	--	--
Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments	--	--	--
Promoting Competition			
Reform and Expand Durable Medical Equipment Competitive Bidding	--	-2,470	-7,110
Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes	--	--	--
Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts	--	50	240
Exercising Fiscal Stewardship			
Modify Payments to Hospitals for Uncompensated Care /1	--	-66,780	-182,460
Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services	-4,670	-45,980	-131,400
Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care	-1,210	-27,230	-101,150
Pay Site Neutral Rates to All Hospital-Owned Physician Offices Located Off-Campus	-1,100	-10,510	-28,660
Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria	-530	-4,190	-10,000
Reduce Medicare Coverage of Bad Debts	-410	-12,910	-38,510
Increase ESRD Networks Funding to Match Consumer Price Index	--	--	--
Reducing Burden			
Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models	-350	-620	-280
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment	--	--	--
Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations	--	--	--

FY 2020 Medicare Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission	--	--	--
Remove Timeframe for Initial Surveys for End Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018	--	--	--
Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System	--	--	--
Encourage Meaningful Measures for the End-Stage Renal Disease (ESRD) Quality Incentive Program	--	--	--
Improve the Medicare Appeals System			
Change the Medicare Appeal Council's Standard of Review	--	--	--
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals	--	--	--
Expedite Procedures for Claims with No Material Fact in Dispute	--	--	--
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review	--	--	--
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold	--	--	--
Limit Appeals When No Documentation is Submitted	--	--	--
Remand Appeals to the Redetermination Level with the Introduction of New Evidence	--	--	--
Require a Good-Faith Attestation on All Appeals	--	--	--
Medicare Interactions			
Drug Pricing Legislative Proposals	-230	-19,470	-67,160
Reduce Fraud, Waste, Abuse, and Improper Payments in Medicare	-450	-2,760	-6,460
Legislative Proposals for Medicare-Medicaid Enrollees	-20	-90	-210
Reform Graduate Medical Education Payments /2	-14,480	-89,640	-211,840
Rebase National Medicare & You Education Program User Fee /3	40	310	680
Reform Medical Liability	-70	-5,250	-26,895
Subtotal Outlays, Medicare Legislative Proposals	-23,480	-287,570	-811,295
Medicare Administrative Proposals			
Improving Value-Based Systems of Care			
Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations	*	*	*
Improve Clarity and Transparency around Medicare Coverage Process	--	--	--
Promoting Competition			
Strengthen the Parallel Review Process to Streamline Medicare Coverage	--	--	--
Improve Medicare Beneficiary Access to Breakthrough Devices	--	--	--

FY 2020 Medicare Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Add Additional Items to Durable Medical Equipment Competitive Bidding Program	--	-1,930	-6,080
Exercising Fiscal Stewardship			
Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters	--	--	--
Publicly Report Drugs with Significant Wastage Using Part B Claims Data	--	--	--
Reduce Fraud, Waste, and Abuse in Medicare	-15	-140	-370
Subtotal, Medicare Administrative Proposals	-15	-2,070	-6,450
TOTAL, Medicare FY 2020 Budget Proposals	-23,495	-289,640	-817,745

*Budget impact unavailable as of the publication date of the FY 2020 President's Budget.

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

Medicare Impact	--	50	240
General Revenue Treasury Impact	--	4,396	12,357
Total Impact	--	4,446	12,597

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

Medicare Impact	--	-66,780	-182,460
General Revenue Impact (CMS)	--	34,920	84,450
Total Impact	--	-31,860	-98,010

3/ The proposal to Rebase National Medicare & You Education Program User Fee has a projected net positive revenue impact for the Medicare Trust Funds of \$371 million over 10 years, comprised of \$1.05 billion in additional user fees offset by \$680 million in projected benefit spending. See proposal description in CMS Program Management chapter.

Program Integrity



	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Health Care Fraud and Abuse Control Program				
Discretionary	745	765	792	+27
Mandatory /1	\$1,298	\$1,330	\$1,410	+80
Subtotal, Health Care Fraud and Abuse Control Program	\$2,043	\$2,095	\$2,202	+107
Medicaid Integrity Program /1 /2	\$80	\$82	\$90	+8
Total, Budget Authority	\$2,123	\$2,177	\$2,292	+115

1/ The FY 2018 and FY 2019 mandatory base includes sequester reductions.

2/ Additional information on the Medicaid Integrity Program is included in the States Grants and Demonstrations chapter.

The Fiscal Year (FY) 2020 Budget strengthens the integrity and sustainability of Medicare and Medicaid by investing in the prevention of fraud, waste, and abuse, protecting beneficiaries, and eliminating wasteful spending. Two programs, the Health Care Fraud and Abuse Control (HCFAC) Program Account and the Medicaid Integrity Program, comprise the largest portion of the federal government investment in health care program integrity. The FY 2020 Budget provides \$2.3 billion in total mandatory and discretionary investments for the HCFAC and Medicaid Integrity Programs.

HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM

The HCFAC Program, established in 1996, serves as the primary federal program that addresses health care fraud and abuse through a coordinated effort between HHS and the Department of Justice (DOJ). It provides both discretionary and mandatory funding to address the full spectrum of health care fraud and abuse interventions, from prevention, detection, and reducing improper payments to investigations and prosecution.

Discretionary Health Care Fraud and Abuse Control

The Budget requests \$792 million in discretionary HCFAC funding, \$27 million above the FY 2019 enacted level. This includes \$317 million in base discretionary funds plus a discretionary cap adjustment of \$475 million, consistent with the Budget Control Act of 2011.

Of the \$792 million, CMS receives \$614 million, DOJ receives \$98 million, and the HHS Office of Inspector General (OIG) receives \$80 million.

CMS has shifted recent investments in HCFAC away from the “pay-and-chase” model to front-end prevention efforts. The program supports new and expanded efforts to reduce Medicare and Medicaid improper payment rates. For example, CMS will improve Medicaid data systems to better track fraud and abuse, expand Medicare fee-for-service targeted education and medical review, and strengthen oversight of Medicare Advantage. Activities balance fraud and abuse protections while limiting burden on providers.

Mandatory Health Care Fraud and Abuse Control

The Medicare Part A Trust Fund provides \$1.4 billion in mandatory HCFAC resources for FY 2020, allocated to the Medicare Integrity Program and other HCFAC partners. This funding supports efforts across HHS, OIG, DOJ, and the Federal Bureau of Investigation to combat health care fraud, waste, and abuse.

Return on Investment

Program integrity efforts are proven cost-effective investments for federal spending. Medicare Integrity Program prevention and detection efforts have consistently yielded a return of over \$10 billion in savings annually.

The three-year rolling average return-on-investment for HCFAC law enforcement activities is \$4 gained for every \$1 spent. In FY 2017 alone, these activities returned \$2.3 billion to the federal government, including \$1.4 billion returned to the Medicare Trust Funds and \$407 million in federal Medicaid recoveries returned to the Treasury.

MEDICAID INTEGRITY PROGRAM

Using HCFAC as a model, the Deficit Reduction Act of 2005 established the Medicaid Integrity Program as the nation's first program integrity effort focused on Medicaid. The mandatory appropriation for the Medicaid Integrity Program adjusts annually for inflation and will total \$90 million in FY 2020.

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

In FY 2018, CMS released a new program integrity strategy for Medicaid to address new program integrity challenges associated with the rapid increase in Medicaid spending in the last decade due in part to Medicaid expansion. The new initiatives in this strategy include the following:

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

Also included under 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 2018, these funding specialists partnered with states to avert or remove \$1.5 billion in payments that states could not justify.

2020 LEGISLATIVE PROPOSALS

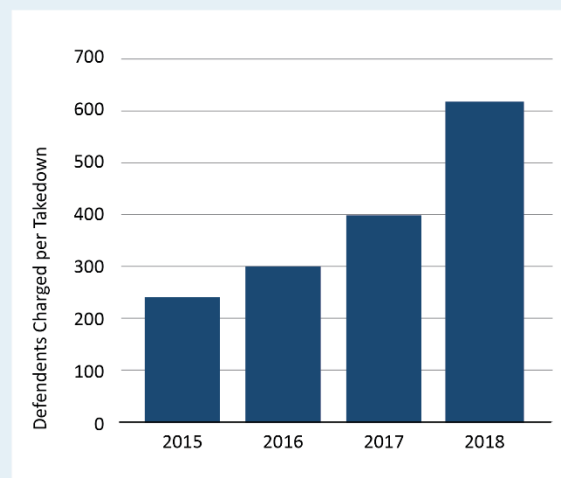
The FY 2020 Budget includes a comprehensive package of program integrity legislative proposals, saving \$19.6 billion over ten years, that strengthen fiscal stewardship in Medicare and Medicaid by: addressing opioid-related fraud and abuse; improving payment accuracy; enhancing provider and program oversight; and supporting law enforcement.

Addressing Opioids

Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Administration to Terminate Provider Prescribing Authority

CMS and the Drug Enforcement Administration (DEA) rely on provider data to detect and prevent abusive prescribing of controlled substances, but data reciprocity agreements do not exist between the two organizations.

HHS AND DOJ NATIONAL HEALTH CARE FRAUD AND OPIOID TAKEDOWNS



As evidenced by the chart above, coordinated efforts between DOJ and HHS result in increasing law enforcement takedowns of defendants committing opioid fraud. Under this proposal, CMS must report all Medicare revocation actions or preclusion list placements to the DEA that are based totally or in part on a pattern of abusive prescribing of controlled substances. In turn, the DEA could use this data to consider revocation of a DEA registration. [Budget impact not available]

Improving Payment Accuracy

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

Medicare cannot hold a practitioner financially accountable for improperly documenting ordered items or services. This proposal allows the Secretary to assess an administrative penalty on providers for ordering high-risk, high-cost items or services without proper documentation, such as diagnosis or encounter data. CMS would levy an administrative penalty of \$50 for Part B items/services and \$100 for Part A services. [No budget impact]

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

While prior authorization can be an effective tool for health care payers to support payment accuracy and reduce unnecessary utilization, current law restricts Medicare's ability to use this tool on all but a few fee-for-service items and services. This proposal extends the narrow existing authority to all Medicare fee-for-service items and services, specifically those that are at high risk for fraud and abuse. By allowing prior authorization on additional items and services, CMS can reduce Medicare improper payments. [\$6.3 billion in savings over 10 years]

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

The Medicare Payment Advisory Commission and the Government Accountability Office, have found that certain in-office ancillary services are prone to inappropriate physician self-referral and overutilization. Effective CY 2021, this proposal establishes a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. Patients would be attributed to the physician who provided the plurality of their evaluation and management (E/M) 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]

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

Despite their success in Fee-for-Service, Recovery Audit Contractors have found Medicare Parts C and D to be

an unattractive business model because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. To more efficiently use program integrity resources, this proposal removes the requirement for CMS to expand the Recovery Audit Program to the Medicare Parts C and D. The proposal also requires plan sponsors to report Part C and D fraud and abuse incidents and corrective actions. Given that the functions of the Part C and D Recovery Audit Programs are currently being performed through other program integrity mechanisms, this proposal creates programmatic and administrative efficiencies while strengthening fraud and abuse reporting. [No budget impact].

Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor

CMS currently absorbs all fees charged by the Department of the Treasury for the collection of most CMS overpayments. The proposal gives the Secretary authority to pass Treasury fees for CMS overpayment collections on to the debtor for certain programs. Specifically, CMS would increase the amount of the collection to account for Treasury's recovery fee and ensure the Medicare Trust Funds are fully repaid. [\$200 million in savings over ten years]

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

The Medicare Advantage improper payment rate was 8.10 percent in FY 2018 and overpayments were estimated at over \$9 billion. To improve Medicare Advantage payment accuracy, beginning in Calendar Year 2021, this proposal would confirm diagnoses submitted by Medicare Advantage Organizations for risk-adjustment with the medical record prior to CMS making risk-adjusted payments. The Secretary would be authorized to determine the threshold at which plans would be required to submit medical record documentation in support of the risk-adjustment and exclude certain types of plans. Confirming diagnoses before making risk-adjusted payments would improve payment accuracy in Medicare Advantage. [No budget impact]

Strengthen CMS's Ability to Recoup Medicaid Improper Payments

States are responsible for making correct beneficiary eligibility determinations to prevent misuse of taxpayer dollars. However, recent audits identified instances of states enrolling individuals in Medicaid who do not meet eligibility requirements, resulting in

overpayments to States. Current law and regulations restrict CMS's ability to recover these overpayments from states. This proposal gives CMS authority to collect overpayments from States that spend federal resources on ineligible or misclassified beneficiaries. Specifically, it would permit HHS to issue disallowances outside of the current improper payment rate measurement process and allow HHS and OIG to extrapolate findings on beneficiary eligibility to ensure federal recovery of incorrect eligibility determinations. Additionally, it strengthens CMS' ability to issue disallowances for beneficiary eligibility errors by eliminating the current three percent threshold for states' eligibility-related improper payments. In place of the current three-percent disregard, HHS would issue rulemaking specifying criteria for disallowances, including limiting disallowances to instances of monetary loss such as cases where ineligible individuals receive benefits. [\$4.4 billion in savings over 10 years]

Enhancing Provider and Program Oversight

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

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

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

The reasonable assurance period currently allows providers and suppliers who have been terminated from participation in Medicare for noncompliance with Federal requirements to reenter the program after a just a preliminary showing of compliance. This is allowed even under circumstances that conflict with Medicare's minimum reenrollment requirements and puts beneficiaries at an increased risk of harm. This proposal allows the Secretary to enforce an exception to Medicare's reasonable assurance period in cases of patient harm or neglect by removing providers from the program for a one-to-three year period. [No budget impact]

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

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

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

Currently, CMS lacks specific statutory authority to require records from Part B providers and suppliers in connection with an investigation or audit of drugs paid under Part D of the Medicare program. The proposal allows CMS to demand Part B records and information in support of Part D investigations and audits. Access to Part B records and information would allow CMS to complete more comprehensive Part D abusive prescribing investigations. [No budget impact]

Create Authority to Revoke or Deny Medicare Billing Privileges Based on Medical Board or Independent Review Organizations

The Secretary does not have authority to take administrative action against a provider based on a medical board's administrative action or Independent Review Organization determination, outside of a medical license suspension. The proposal allows the Secretary to take administrative action against physicians who have a prior medical board action(s) or an Independent Review Organization determination demonstrating that improper practitioner conduct led to patient harm. Examples of permissible administrative actions include revocation from Medicare or denial of billing privileges. [No budget impact]

Provide Flexibility for Enrolling Out-of-State Providers in Medicaid

Providers who render services to Medicaid beneficiaries who are visiting from another state face duplicative paperwork in order to receive payment from that state's Medicaid program. This proposal will

allow providers to receive payment for treating a Medicaid beneficiary from another state without enrolling in the home state of that Medicaid beneficiary as long as the provider is already enrolled in either Medicare fee-for-service or any state Medicaid program including, but not limited to, emergency and urgent care services. This proposal will improve the efficiency of provider payments while also improving beneficiary access to needed services. [\$9 million in costs over 10 years]

Streamline the Medicaid Terminations Process

States do not always remove bad actors from their Medicaid programs as quickly as is necessary to avoid continued fraud, waste, and abuse. This proposal enhances the existing Medicaid provider terminations statute in three ways. First, it defines appeals periods such that state Medicaid agencies will report terminations after the first level of appeal rather than waiting until all appeals have been exhausted. Second, it establishes reporting requirements for rescissions and reinstatements of terminated Medicaid providers. Third, it requires that states check the centralized Termination Notification Database before enrolling providers. [No budget impact]

Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments

The OIG has reported that Medicaid personal care services claims are at a high risk for fraud and has recommended CMS better screen such claims prior to payment. The Budget proposes requiring states to implement claims edits that will enable states to screen and automatically deny unusual personal care services claims, such as: claims for duplicative services; for services provided by personal care service attendants not meeting state qualification requirements; and for services rendered to individuals no longer eligible for Medicaid. [\$8.7 billion in savings over 10 years]

Consolidate Provider Enrollment Screening for Medicaid and CHIP

To protect Medicaid against ineligible and fraudulent providers, states are required to screen providers enrolling in Medicaid or CHIP according to their risk for fraud, waste, and abuse; however, providers enrolling in multiple state Medicaid or CHIP programs and managed care plans often face unnecessary and duplicative screening by states, federal programs, and managed care plans. This proposal requires providers receiving federal funding and enrolling in Medicaid or CHIP to undergo centralized CMS screening. State

Medicaid and CHIP Agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening. [No budget impact]

Extend Flexibility in Annual Open Payments Reporting Deadline

Many covered entities find the Open Payments reporting deadline burdensome with a limited time for review and corrections before publication. The proposal removes the statutory June 30th publication date for Open Payments data and provides the Secretary discretion to establish an alternative annual publication date that does not extend beyond October 1. This approach provides more time for impacted parties to review Open Payments data before it is released, ensuring reduced provider burden and improved accuracy of the Open Payments data. [No budget impact]

Require Physician Owned Distributors to Report in Open Payments

Currently, Physician Owned Distributors often sell or distribute implantable medical devices to other entities with whom they have a financial interest but are not required to report in the Open Payments Program, making it difficult for patients to recognize potential conflicts of interests. Effective calendar year 2020, this proposal requires that all Physician Owned Distributors report and identify themselves in the Open Payments program. This approach promotes increased transparency in response to a primary criticism of Physician Owned Distributors, that ownership may affect physicians' clinical decision-making, influencing them to perform unnecessary surgeries or choose a medical device in which they have a financial interest over one more appropriate for the patient. [No budget impact]

Supporting Law Enforcement and Fraud Reduction

Expand Medicaid Fraud Control Unit Review to Additional Care Settings

Medicaid Fraud Control Units receive cases of abuse and neglect in non-institutional settings that they cannot pursue due to legal restrictions. The current limitation on federal matching was established in 1978, at a time when Medicaid services were typically provided in institutional settings, and does not reflect the shift in delivery and payment for health services to home and community based settings. The Budget proposes to allow Medicaid Fraud Control Units to receive federal matching funds for the investigation or

prosecution of abuse and neglect of a beneficiary in non-institutional settings, such as home-based care. [Budget impact not available]

Clarify Authority for the Healthcare Fraud Prevention Partnership

Currently, the Healthcare Fraud Prevention Partnership operates under the authority established by the HCFAC Program, which limits allowable fraud and abuse activities to data sharing. This proposal establishes explicit authority for the Partnership and expands the scope of allowable activities beyond data sharing. The new authorities would allow the Partnership to address the full spectrum of fraud and abuse in the health care sector, including efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse. [No budget impact]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven program integrity administrative proposals that the Department plans to implement in FY 2020, saving \$568 million over the next ten years. These proposals do not require Congressional action. Each proposal supports the Administration's program integrity priorities of improving payment accuracy and oversight.

Improving Payment Accuracy

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

CMS estimates that almost 36 percent of Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) payments were improperly paid in FY 2018. By leveraging Medicare demonstration authority, this proposal tests whether using a benefits manager for serial durable medical equipment claims results in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring that beneficiaries were receiving the correct quantity of supplies or services for the appropriate period. [No budget impact]

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

As noted above, CMS estimates that almost 36 percent of Medicare DMEPOS payments were improperly paid in FY 2018. This proposal subjects additional DMEPOS item and services to prior authorization as a condition of Medicare payment. Prior authorization would be

applied to items with a high risk for improper payments, leading to improved payment accuracy. [\$300 million in savings over 10 years]

Address Improper Payments of Chiropractic Services through Targeted Medical Review

Recent legislation requires Medicare prior authorization for certain chiropractic services rendered by providers with aberrant billing patterns in an effort to reduce improper payments. . However, CMS has determined that implementing the prior authorization program as specified in the legislation would cost more to administer than it would save. Under this proposal, CMS would use Innovation Center authority to test whether more targeted medical review could effectively address improper payments in chiropractic services. [No budget impact]

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

CMS and other health care payers use prior authorization as a tool to reduce or eliminate unnecessary utilization of health care services. To address over-utilization in Medicare of low-value health services, CMS will explore options within their current authority to test prior authorization of low-value services. When implementing this proposal, CMS will consider patient access and other quality concerns, in an effort to reduce burden on patients while ensuring appropriate provisions of health care. [No budget impact]

Expand Medicare Advantage Risk Adjustment Data Validation Audits

Risk Adjustment Data Validation (RADV) contract audits support CMS program integrity and oversight in Medicare Advantage and perform as the primary corrective action for Medicare Advantage improper payments. This proposal expands the number of contract-level RADV audits. The number of RADV audits would increase annually, until the current level doubles in CY 2023. [No budget impact]

Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility

Current regulations restrict CMS's ability to issue disallowances related to beneficiary eligibility. This proposal will revise the regulations relating to Medicaid improper payment rate measurement, empowering CMS to issue disallowances to states with a beneficiary eligibility improper payment rate above the statutory

three percent threshold. [\$190 million in savings over 10 years]

Enhancing Provider and Program Oversight

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

Providers and suppliers that abuse the Medicare program evade revocation from the program by “reinventing” themselves under a new business’s corporate umbrella. This proposal expands the current authority to revoke or deny an individual’s and entity’s Medicare enrollment if they are affiliated with a sanctioned entity. This change will stop these abusive enrollment practices by allowing the Secretary to take administrative actions against entities that have owners, managing employees, officers, and/or directors that previously affiliated with sanctioned

Medicare entities. [\$70 million in savings to Medicare and \$8 million in savings to Medicaid over ten years]

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 to assign unique identifiers to personal care service attendants that will be listed on claims along with dates that attendants performed services in question. [No budget impact]

FY 2020 Program Integrity Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Legislative Proposals			
Address Opioids			
Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Agency to Terminate Provider Prescribing Authority	*	*	*
Improving Payment Accuracy			
<i>Medicare</i>			
Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation	-	-	-
Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste and Abuse	-430	-2,660	-6,260
Require Prior Authorization When Physicians Order Certain Services Excessively Relative to Their Peers	*	*	*
Improve Efficiency and Strengthen Program Integrity Efforts in Medicare Parts C and D	-	-	-
Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor	-20	-100	-200
Implement Targeted Risk-Adjustment Pre-Payment Review in Medicare Advantage	-	-	-
<i>Medicaid</i>			
Strengthen CMS’s Ability to Recoup Medicaid Improper Payments	-	-1,480	-4,420
Enhancing Provider and Program Oversight			
<i>Medicare</i>			
Prevent Fraud by Applying Penalties on Providers and Suppliers who Fail to Update Enrollment Records /1	-2	-13	-32
Ensure Providers that Violate Medicare’s Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Program	-	-	-
Require Reporting on Clearinghouses and Billing Agents when Medicare Providers and Suppliers Enroll in the Program	-	-	-
Require Providers and Suppliers to Produce Part B Records to Support Part D Investigations or Audits	-	-	-
Create Authority to Revoke or Deny Medicare Billing Privileges Based on Medical Board or Independent Review Organizations	-	-	-
<i>Medicaid</i>			
Provide Flexibility for Enrolling Out-of-State Providers in Medicaid	-	4	9
Streamline the Medicaid Terminations Process	-	-	-
Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments	-700	-3,830	-8,670
Consolidate Provider Enrollment Screening for Medicaid and CHIP	-	-	-
<i>Crosscutting</i>			
Extend Flexibility in Annual Open Payments Reporting Deadline	-	-	-
Require Physician Owned Distributors to Report in Open Payments	-	-	-

FY 2020 Program Integrity Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Supporting Law Enforcement and Fraud Reduction			
<i>Medicaid</i>			
Expand Medicaid Fraud Control Unit Review to Additional Care Settings	*	*	*
<i>Crosscutting</i>			
Clarify Authority for the Healthcare Fraud Prevention Partnership	-	-	-
Subtotal Outlays, Program Integrity Legislative Proposals	-1,152	-8,079	-19,573
Subtotal, Medicare Impact	-452	-2,773	-6,492
Subtotal, Medicaid Impact	-700	5,306	-13,081
Administrative Proposals			
Improving Payment Accuracy			
<i>Medicare</i>			
Address Excessive Billing for Durable Medical Equipment that Requires Refills on Serial Claims	-	-	-
Address Overutilization and Billing of Durable Medical Equipment, Prosthetics and Orthotics by Expanding Prior Authorization	-15	-120	-300
Address Improper Payments of Chiropractic Services through Targeted Medical Review	-	-	-
Reduce Utilization of Low-Value Health Services through Prior Authorization Demonstrations	-	-	-
Expand Medicare Advantage Risk Adjustment Data Validation Audits	-	-	-
<i>Medicaid</i>			
Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility	-	-60	-190
Enhancing Provider and Program Oversight			
<i>Crosscutting</i>			
Allow Revocation and Denial of Provider Enrollment Based on Affiliation with a Sanctioned Entity	-	-23	-78
<i>Medicare Impact (non-add)</i>	-	-20	-70
<i>Medicaid Impact (non-add)</i>	-	-3	-8
<i>Medicaid</i>			
Establish Unique Identifiers for Personal Care Service Attendants	-	-	-
Subtotal Outlays, Program Integrity Administrative Proposals	-15	-203	-568
Subtotal, Medicare Impact	-15	-140	-370
Subtotal Medicaid Impact	-	-63	-198
*Budget impact unavailable as of the publication date of the FY 2020 President's Budget. 1/ This proposal reflects new revenue collections to the Medicare Part A Trust Fund.			

Medicaid



	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Current Law				
Benefits /1	371,903	396,820	403,549	+6,639
State Administration	17,254	21,861	22,528	+667
Total Net Outlays, Current Law	389,157	418,681	425,986	+7,305
Proposed Law				
Legislative Proposals	-	-	-7,835	-7,835
Total Net Outlays, Proposed Law	389,157	418,681	418,151	-530

1/ Includes outlays from the Vaccines for Children Program, administered by the Centers for Disease Control and Prevention. Also reflects administrative proposal outlay impacts assumed in the baseline.

Medicaid provides medical assistance to millions of low-income and disabled Americans. In Fiscal Year (FY) 2018, more than one in five individuals were enrolled in Medicaid for at least one month in the United States. In FY 2019, over 76 million people on average in any given month are expected to receive health care coverage through Medicaid. CMS predicts that enrollment will increase in the future due to factors such as population growth.

HOW MEDICAID WORKS

States design, implement, and administer their own Medicaid programs based on guidelines established by the federal government. The federal government matches state expenditures based on the Federal Medical Assistance Percentage, which can be no lower than 50 percent. In FY 2019, the federal share of Medicaid outlays will be approximately \$418.7 billion. Without reforms, CMS’s Office of the Actuary estimates total federal and state Medicaid benefit spending will be \$1.1 trillion by FY 2029, comprising 3.2 percent of U.S. gross domestic product.

Currently, states must cover individuals who meet certain minimum categorical and financial eligibility standards. Medicaid beneficiaries include children; pregnant women; adults in families with dependent children; and the aged, blind, and/or disabled. Individuals must meet certain minimum income eligibility criteria that vary by category. States have the flexibility to extend coverage to higher income groups, including medically needy individuals, through waivers and amended state plans. Medically needy individuals do not meet the income standards of the above

mentioned categorical eligibility groups but incur large medical expenses and would otherwise qualify for Medicaid.

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

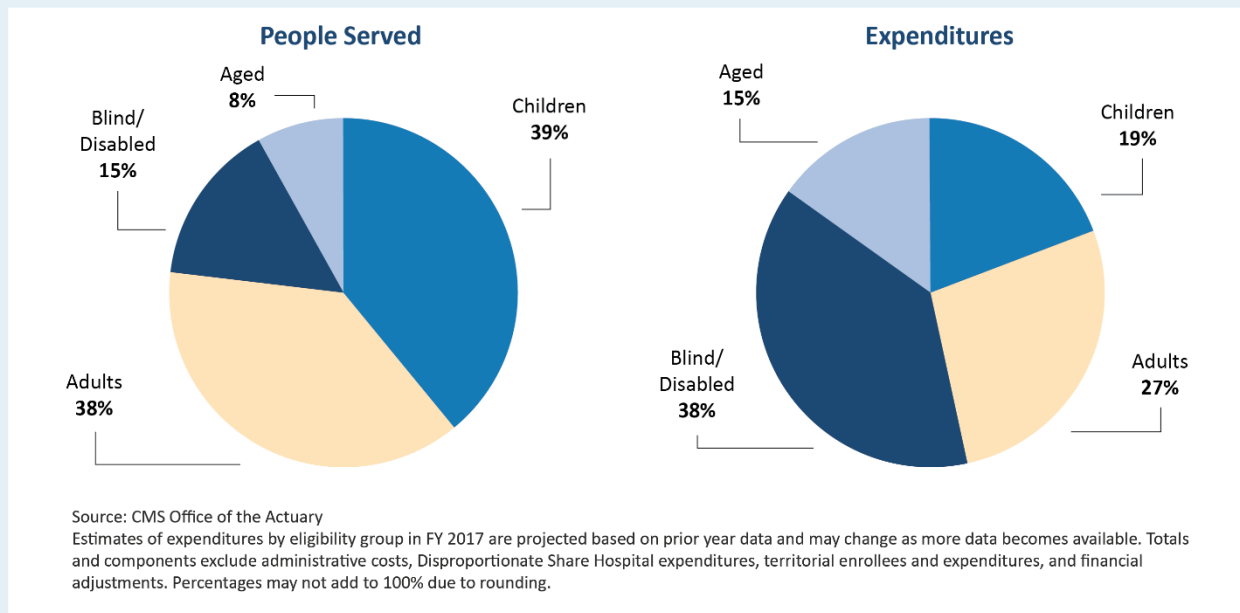
RECENT PROGRAM DEVELOPMENTS

Empowering Individuals through Community Engagement

Millions of able-bodied, working-age adults became eligible for Medicaid through the Obamacare Medicaid expansion. While medical coverage is important, public assistance programs trap many individuals in dependency. In addition to ensuring access to health care for Americans, the Trump Administration also prioritizes helping individuals obtain economic self-sufficiency.

In January 2018, the Administration announced its intention to break the cycle of poverty and dependence through approval of Section 1115 community engagement demonstrations. The demonstrations promote work or community engagement activities (e.g., volunteering, educational activities, or job training) for working-age, able-bodied adults to promote improved health and well-being. Since then, CMS approved community engagement demonstrations in eight states.

PERCENTAGE OF MEDICAID BENEFICIARIES VS. FEDERAL MEDICAL ASSISTANCE EXPENDITURES BY ELIGIBILITY GROUP



CMS remains committed to supporting states in their efforts to develop new and innovative solutions to improve their Medicaid programs and to provide individuals on Medicaid with better health, the ability to experience the dignity of a job and personal responsibility, and move individuals forward on the path to independence and greater well-being.

Designing Innovative Service Delivery Systems in Mental Health

In November 2018, as required by the 21st Century Cures Act of 2016, CMS published a State Medicaid Director letter discussing strategies under existing authorities for states to implement innovative service delivery system reforms for adults with serious mental illness, and children with serious emotional disturbance. Examples of these innovations include improving availability of behavioral health screenings and mental health and substance use disorder services in schools to identify and engage children with serious emotional disturbance sooner.

⁶ For more information, please see the State Medicaid Director letter: <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf>

⁷ Except where otherwise noted, estimates reflect gross savings to Medicaid. In some cases, savings will be

The letter explained a demonstration opportunity for states to receive federal financial support for treating Medicaid beneficiaries with these conditions during short-term acute care stays in psychiatric hospitals or in residential treatment facilities that qualify as an Institution for Mental Diseases.⁶

2020 LEGISLATIVE PROPOSALS⁷

The FY 2020 Budget provides additional flexibility and reduces administrative burden for states; puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and reducing waste; and refocuses Medicaid on populations the program was originally intended to serve—low-income families, the elderly, people with disabilities, children, and pregnant women. In total, the Budget includes net savings to Medicaid of \$1,482.7 billion over 10 years. Of this total, the Budget includes \$1,385.5 billion in savings to Medicaid related to the Empowering States and Consumers to Reform Health Care proposal (see related chapter for more information).

reduced when enacted in conjunction with the Empower States and Consumers to Reform Health Care proposal.

Increasing Medicaid Flexibility for States and Reducing Burden

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

Substance use is strongly associated with significant adverse health impacts for both mothers and infants. Opioid use during pregnancy and incidents of neonatal abstinence syndrome have increased dramatically in recent years. This proposal would make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. [\$245 million over 10 years]

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

State flexibility to charge copayments above the nominal statutory amounts for non-emergency use of the emergency department is limited to waiver requests, a burdensome and time-consuming process. The Budget proposes to provide states the option to use state plan authority to increase these copayments to encourage personal financial responsibility and proper use of health care resources. [\$1.6 billion in savings over 10 years]

Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers

States are required to submit unnecessary paperwork to renew managed care waivers in place for years. This proposal reduces burdensome federal reviews by allowing states to grandfather managed care authorities in waivers and demonstration programs under their state plans if there are no substantive changes and 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 is widespread in states, yet states must submit paperwork for re-approval of Medicaid managed care waivers every five years for programs involving dual-eligible individuals and every two years for Section 1915(b) waivers for all other Medicaid eligibility groups. This proposal eliminates the current five-year time limit for Section 1915(b) waivers to give the Secretary the flexibility to determine the appropriate approval timeframe for all Medicaid managed care enrolled populations. [No budget impact]

Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals

States may be forced to adjudicate duplicative appeals at the state Medicaid agency when another entity has already adjudicated the same case. This proposal reduces the burden on states by allowing them to meet the Medicaid fair hearing requirements for cases that have already been adjudicated by Exchange Appeal Entities or by the U.S. Department of Health and Human Services (HHS). Specifically, the requirement that state Medicaid agencies must provide the opportunity for a fair hearing would change to permit state Medicaid agencies to substitute a fair hearing before another state agency or HHS. [No budget impact]

Focusing Medicaid Eligibility on the Most Needy

Strengthen Work Requirements to Promote Self-Sufficiency

The Budget improves consistency between work requirements in federally funded public assistance programs, including Medicaid and Temporary Assistance for Needy Families (TANF), by requiring that able-bodied, working-age individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This would enhance service coordination for program participants, improve the financial well-being of those receiving assistance, and ensure federally funded public assistance programs are reserved for the most vulnerable populations. [\$130.4 billion in savings over 10 years]

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

Asset tests once allowed states to prioritize receipt of Medicaid for lower-income individuals by screening for assets and resources, such as savings accounts or vehicles. However, Obamacare's Modified Adjusted Gross Income (MAGI) eligibility rules eliminated asset tests for most children and able-bodied adults, leaving asset tests only for aged, blind, and disabled Medicaid beneficiaries. This proposal provides states the option to apply asset tests to populations determined financially eligible by the MAGI standard, such as able-bodied adults, so states can refocus Medicaid on the truly needy. This proposal also provides states with the option to apply asset tests just to individuals eligible through the MAGI standard who are receiving long-term care. [\$2.1 billion in savings over 10 years]

Reduce the Maximum Allowable Home Equity for Medicaid Eligibility

Some states have set home equity limits so high that individuals with the means to pay for their own long-term care qualify for Medicaid payment for that care, transferring what should be an individual or family responsibility to the taxpayers. This proposal removes states' authority to substitute a higher home equity limit than the statutory minimum. This approach focuses long-term care coverage on lower-income individuals without significant assets that could be liquidated to cover their long-term care. [\$6.7 billion in savings over 10 years]

Require Documentation of Satisfactory Immigration Status before Receipt of Medicaid Benefits

Currently, states must enroll individuals that claim they have, but cannot immediately provide, documentation of citizenship or satisfactory immigration status. After a reasonable opportunity period, the individuals must submit evidence of citizenship or satisfactory immigration status. This proposal requires individuals to prove Medicaid eligibility before they receive coverage. States may still elect to provide coverage during a reasonable opportunity period, but this proposal prohibits federal payments for medical assistance during this period. [\$2.3 billion in savings over 10 years]

Reducing Wasteful Spending in Medicaid

Address Inappropriate Financing of Medicaid State Share by Public Providers

In recent years, some units of government, including states and localities, have acquired ownership of privately operated medical facilities. These newly public health care providers generate state and local Medicaid matching payments, while being held harmless for these donations by states through increased Medicaid supplemental payments. This proposal will prohibit units of government from exploiting this financing mechanism. Closing this loophole will prevent states from inappropriately generating state share, to restrain Medicaid spending and improve equity in Medicaid funding between states. [Budget impact not available]

Prohibit Medicaid Payments to Public Providers in Excess of Costs

Medicaid payments for health care services are limited to what Medicare would have paid for the same service (referred to as the Upper Payment Limit), which in

some cases may exceed a public provider's actual cost of providing care to Medicaid patients. This proposal limits Medicaid reimbursement for health care providers operated by a unit of government to an amount not exceeding the actual cost of providing those services. This will prevent states from using supplemental payments to public providers to circumvent Medicaid matching requirements. [Budget impact not available]

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

Medicaid regulations require states to include all third party payments for Medicaid beneficiaries when calculating uncompensated care costs under the Medicaid Disproportionate Share Hospital (DSH) limits. Some providers continue to receive duplicate uncompensated care payments from other payers, such as private insurance or Medicare. This proposal would codify existing regulations to remove ambiguity for states and hospitals. This will strengthen CMS's ability to enforce existing federal regulations and prevent states from paying hospitals twice for the same care episode. [No budget impact]

Continue Medicaid Disproportionate Share Hospital Allotment Reductions

Current law reduces Medicaid DSH allotments between FY 2020 and FY 2025 to account for decreases in uncompensated care. The Budget continues Medicaid DSH allotment reductions for FY 2026 through FY 2029, since the new Market-Based Health Care Block Grants proposed in the Budget provide states with resources to maintain coverage for those previously covered by Obamacare. [\$25.9 billion in savings over 10 years]

Rescind Remaining Balances from the Medicaid Improvement Fund

The Medicaid Extenders Act of 2019 (P.L. 116-3) rescinded \$25 million from the Medicaid Improvement Fund, authorized for Medicaid administrative activities beginning in FY 2021. This proposal rescinds the remaining \$6 million balance from the fund. [\$6 million in savings over 10 years]

LEGISLATIVE PROPOSALS FOR MEDICARE-MEDICAID ENROLLEES

Reducing Wasteful Spending for Medicare-Medicaid Enrollees

Allow CMS Flexibility to Determine the Frequency of Program of All-Inclusive Care for the Elderly Program Reviews

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

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

Marketing materials provided by Dual Eligible Special Needs Plans to beneficiaries go through separate state and CMS review processes. This proposal allows for joint state and CMS review, while enhancing their ability to provide a uniform message to beneficiaries. Providing CMS with the ability to coordinate reviews with states based on a single submission of these marketing materials can improve the quality of products available to beneficiaries, while reducing the burden on health plans, states, and CMS. [No budget impact]

Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans

Medicare and Medicaid have different appeals processes in statute, resulting in different requirements related to timeframes and limits, amounts in controversy, and levels of appeals. This proposal provides HHS with the authority to streamline the appeals notification requirements for health plans that integrate payment and services for Medicare-Medicaid enrollees. It improves communications to beneficiaries so they do not receive conflicting instructions based on differing Medicare

and Medicaid requirements. It also 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 requires that CMS maintain a Special Enrollment Period (SEP) for full-benefit dually eligible beneficiaries who would like to make changes to their Medicare Advantage and Medicare prescription drug coverage outside of the annual enrollment period. This SEP has created unintended consequences, including aggressive targeting of dually eligible beneficiaries by enrollment agents, and decreased incentives for plans to invest in care coordination for this population. This proposal narrows the continuous SEP by allowing CMS to apply the same annual election process for both dually eligible and non-dually eligible beneficiaries, while preserving the ability for full-benefit dually eligible beneficiaries to use a SEP to opt into integrated care programs or change plans following auto-assignment into a Part D plan. This proposal protects full-benefit dually eligible beneficiaries from aggressive marketing targeted to low-income beneficiaries who currently have a continuous SEP, improves incentives to invest in care coordination for high-cost, often vulnerable beneficiaries, and reduces the administrative burden on health plans from beneficiary fluctuations between plans. [No budget impact to Medicaid, \$210 million in savings to Medicare over 10 years]

MEDICAID INTERACTIONS

Medicaid Drug Pricing Legislative Proposals

Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs. For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First* Blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs. The FY 2020 Medicaid legislative proposals work to achieve the Blueprint's goals by strengthening negotiation

and accountability to lower the costs of prescription drugs for states and the federal government. Please see the Lowering the Cost of Prescription Drugs chapter for proposal descriptions.

Empowering States and Consumers to Reform Health Care

Medicaid costs to states and the federal government are growing at an unsustainable rate and states do not have the flexibility they need to address the underlying drivers of these trends. The Budget supports the comprehensive Medicaid reform in the 2017 Graham-Cassidy-Heller-Johnson legislation, including allowing states a choice between a per-capita cap or a block grant, and repealing 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 innovation (see the Empowering States and Consumers to Reform Health Care chapter for a proposal description). [\$1.4 trillion in Medicaid savings over 10 years]

Reform Graduate Medical Education Payments

Current funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system ineffectively targets training to certain types of physicians that are necessary for the Nation. The Budget includes a proposal to consolidate and better target federal spending for GME (see the Empowering States and Consumers to Reform Health Care chapter for a proposal description). [\$21.3 billion in Medicaid savings over 10 years]

Reform Medical Liability

The Budget includes a set of proposals to reform medical liability to reduce medical malpractice costs and the practice of defensive medicine (see Empowering States and Consumers to Reform Health Care chapter for proposal descriptions). [\$46 million in net Medicaid savings over 10 years⁸]

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). [\$13.1 billion in Medicaid savings over 10 years]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven Medicaid administrative proposals that the Department plans to implement in FY 2020 and save an estimated \$53.4 billion over 10 years. These proposals support the Administration's priorities for Medicaid and do not require Congressional action.

Focusing Medicaid Eligibility on the Most Needy

Test Interventions to Improve Maternal Mortality and Morbidity

Maternal morbidity and mortality in the United States have been rising significantly in recent decades. Under the Center for Medicare and Medicaid Innovation authority, this proposal aims to explore a potential service delivery model to test interventions to improve maternal mortality and morbidity. [No budget impact]

Tighten Medicaid Child Support Enforcement Requirements

Not all state Medicaid agencies collect the information that state child support agencies need or share that information in a timely manner, impairing the ability of child support agencies to enforce child support requirements. Under this proposal, CMS and the Administration for Children and Families will issue joint guidance to State Medicaid Agencies and Child Support enforcement agencies outlining successful processes for cross-agency coordination, including collecting information from custodial parents, sharing data, and transmitting relevant information to child support agencies in a timely manner. As more custodial parents provide information aiding child support enforcement, it will ensure more children receive required support and will promote parents as the primary source of economic support for their children. [No budget impact]

Allow States the Flexibility to Conduct More Frequent Eligibility Redeterminations

Current regulations prohibit states from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on MAGI

⁸ Savings accounts for the interaction with the Empowering States and Consumers to Reform Health Care proposal.

financial eligibility. The Budget commits to using regulatory authority to allow states the option to conduct more frequent eligibility redeterminations for MAGI populations to ensure that Medicaid is focused on the most needy. [\$45.6 billion in savings over 10 years]

Reducing Wasteful Spending in Medicaid

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, including of opioids. 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, notably, to help increase oversight of opioid prescriptions and dispensing in Medicaid. [\$245 million in savings over 10 years]

Reduce the Federal Match Rate for Medicaid Eligibility Workers

Medicaid regulations and related subregulatory guidance implementing Obamacare increased the federal match rate for Medicaid eligibility workers to 75 percent by linking these costs to state system operation. This proposal would phase down this match rate to 50 percent by FY 2024. This will return federal reimbursement to historical levels and incentivize

states to administer their Medicaid programs in a more efficient and fiscally responsible way. [\$7.4 billion in savings over 10 years]

Improve Transparency of Medicaid Supplemental Payments

CMS does not currently have comprehensive provider-level data on Medicaid supplemental payments and how they are financed by states. To improve the transparency and oversight of Medicaid supplemental payments, the Budget commits to issuing a regulation requiring more complete and timely provider-level data on supplemental payments, including the financing of such payments. This approach will provide CMS more data to assess whether state payments to Medicaid providers are economical, efficient, and fall within the Upper Payment Limit. [No budget impact]

Increasing Medicaid Flexibility for States and Reducing Burden

Make Medicaid Non-Emergency Medical Transportation Optional

Under current regulations, states must provide Non-Emergency Medical Transportation (NEMT) to all Medicaid beneficiaries. States have requested additional flexibility from this requirement due to challenges containing NEMT costs and addressing program integrity concerns. The Budget commits to using regulatory authority to change the provision of this benefit from mandatory to optional to provide greater flexibility to states. [No budget impact]

FY 2020 Medicaid Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Medicaid Legislative Proposals			
Increasing Medicaid Flexibility for States and Reducing Burden			
Allow States to Extend Coverage for Pregnant Women with Substance Use Disorders to One Year Postpartum	25	120	245
Increase the Limit on Medicaid Copayments for Non-Emergency Use of the Emergency Department	-60	-570	-1,550
Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers	-	-	-
Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers	-	-	-
Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals	-	-	-
Focusing Medicaid Eligibility on the Most Needy			
Strengthen Work Requirements to Promote Self-Sufficiency	-8,300	55,600	-130,400
Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations	-50	-790	-2,110
Reduce the Maximum Allowable Home Equity for Medicaid Eligibility	-	-2,520	-6,650
Require Documentation of Satisfactory Immigration Status Before Receiving Medicaid Benefits	-190	-1,010	-2,310
Reducing Wasteful Spending in Medicaid			
Address Inappropriate Financing of Medicaid State Share by Public Providers	*	*	*
Prohibit Medicaid Payments to Public Providers in Excess of Costs	*	*	*
Clarify Medicaid Treatment of Third Party Payments for Disproportionate Share Hospital Allotments	-	-	-
Continue Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions	-	-	-25,920
Rescind Remaining Balances from the Medicaid Improvement Fund	-	-6	-6
Reducing Wasteful Spending for Medicare-Medicaid Enrollees (Medicaid Impact)			
Allow CMS Flexibility to Determine the Frequency of Program of All-Inclusive Care for the Elderly Program Reviews	-	-	-
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	-	-	-
Medicaid Interactions			
Drug Pricing Legislative Proposals (Medicaid Impact) /1	-151	-903	-2,087
Empower States and Consumers to Reform Health Care (Medicaid Impact) /2	1,280	-429,058	-1,385,515

FY 2020 Medicaid Budget Proposals

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Reform Graduate Medical Education Payments (Medicaid Impact) /2	-1,600	-9,000	-21,300
Reform Medical Liability (Medicaid Impact) /2 /3	-46	-46	-46
Reduce Fraud, Waste, Abuse, and Improper Payments (Medicaid Impact) /4	-700	-5,306	-13,081
Reform and Expand Durable Medical Equipment Competitive Bidding (Medicaid Impact) /5	-	-145	-410
Extend Special Immigrant Visa Program (Medicaid Impact) /6	8	74	142
Extend Reduced Pension for Certain Veterans and Survivors covered by Medicaid plans (Medicaid Impact) /7	-	-	571
Subtotal Gross Outlays, Medicaid Legislative Proposals	-9,785	-504,761	-1,590,427
Net Effect of All Medicaid Interactions /8	1,950	37,910	107,740
Subtotal Net Outlays, Medicaid Legislative Proposals	-7,835	-466,851	-1,482,687
Medicaid Administrative Proposals			
Focusing Medicaid Eligibility on the Most Needy			
Test Interventions to Improve Maternal Mortality and Morbidity	-	-	-
Tighten Medicaid Child Support Enforcement Requirements	-	-	-
Allow States the Flexibility to Conduct More Frequent Eligibility Redeterminations	-1,300	-17,600	-45,600
Reducing Wasteful Spending in Medicaid			
Require Minimum Standards in Medicaid State Drug Utilization Review Programs	-20	-105	-245
Reduce the Federal Match Rate for Medicaid Eligibility Workers	-	-2,116	-7,406
Improve Transparency of Medicaid Supplemental Payments	-	-	-
Program Integrity Administrative Proposals (Medicaid Impact)	0	-63	-198
Increasing Flexibility for States and Reducing Burden			
Make Medicaid Non-Emergency Medical Transportation Optional	-	-	-
Subtotal, Medicaid Administrative Proposals /9	-1,320	-19,884	-53,449
TOTAL, Medicaid FY 2020 Budget Proposals	-9,155	-486,735	-1,536,137

* Budget impact unavailable as of the publication date of the FY 2020 President's Budget.

1/ See Lowering the Cost of Prescription Drugs chapter for descriptions of these proposals.

2/ See Empowering States and Consumers to Reform Health Care chapter for descriptions of these proposals.

3/ Savings reduced to account for the interaction with the "Empowering States and Consumers to Reform Health Care" proposal.

4/ See Program Integrity chapter for descriptions of these proposals.

5/ See Medicare chapter for description of this proposal.

6/ This proposal is included in the Department of State's FY 2020 Budget Request.

FY 2020 Medicaid Budget Proposals

dollars in millions

2020

2020
-2024

2020
-2029

7/ This proposal is included in the Department of Veterans Affairs' FY 2020 Budget Request.

8/ The gross Medicaid savings from all proposals in this package would be reduced when enacted in conjunction with the Empower States and Consumers to Reform Health Care 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.

9/ These administrative actions are assumed to take effect in FY 2020 under current law.



Children’s Health Insurance Program

	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Current Law				
Children’s Health Insurance Program (CHIP)	17,282	18,434	16,882	-1,552
Child Enrollment Contingency Fund	0	200	0	-200
Total Outlays, Current Law	17,282	18,634	16,882	-1,752
Proposed Law				
CHIP Legislative Proposals	0	0	0	0
Total Outlays, Proposed Law	17,282	18,634	16,882	-1,752

The Balanced Budget Act of 1997 established the Children’s Health Insurance Program (CHIP), administered at the federal level by CMS, to provide coverage for children whose families have incomes too high to qualify for Medicaid but too low to afford private health insurance. Every state, the District of Columbia, and all five territories have approved CHIP state 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 and access to health care. Congress appropriates a capped funding amount for CHIP annually, which CMS then allocates to states and territories with an approved CHIP plan based on a formula set in law. Since Fiscal Year (FY) 2009, the amount of funding Congress appropriated for CHIP has exceeded the amount CMS can award to states and territories under the statutory formula.

States, including the 50 states, District of Columbia, and territories, have flexibility in designing their programs. They can implement CHIP by expanding Medicaid, creating a separate program, or combining both approaches. As of December 2018, there were 14 Medicaid expansion programs, 2 separate programs, and 40 combination programs among the states, the District of Columbia, and the territories.

States use a Modified Adjusted Gross Income standard to determine eligibility for coverage under a state’s CHIP program. The statute permits states to offer continuous eligibility for 12 months, regardless of changes in family income, and to enroll children who

are eligible for family coverage under a state employee health plan into CHIP.

States with an approved CHIP plan are eligible to receive an enhanced federal matching rate, which ranges from 65 to 85 percent. From FY 2016 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.

CHIP has several financing mechanisms to address potential state funding shortfalls. The Child Enrollment Contingency Fund supports states that predict a funding shortfall due to higher than expected enrollment. HHS invests the Contingency Fund in interest-bearing securities of the United States. Since its establishment in FY 2009, only three states have qualified for a Contingency Fund payment, totaling \$309 million. States are not required to spend Contingency Fund resources on CHIP activities.

In addition, HHS recoups unused state allotment funding to redistribute to states facing a funding shortfall if their current allotment is insufficient to meet program demand. Since 2012, CMS has redistributed \$1.7 billion to 30 states and territories. However, existing shortfall funding is limited and may not be sufficient to address future needs. The Children’s Health Insurance Program Reauthorization Act of 2009 established a CHIP Performance Bonus Fund for FYs 2009 through 2013 to provide payments to states that met five out of eight specific enrollment and retention activities. CMS’s authority to make payments from the Performance

Bonus Fund expired after FY 2013, leaving some funds unused.

In FY 2018, the CMS Office of the Actuary estimated that 9.8 million individuals received health insurance funded through CHIP allotments at some point during the year. CHIP enrollment throughout the year averaged approximately 7.0 million individuals.

RECENT PROGRAM DEVELOPMENTS

In 2018, Congress passed and the President signed the HEALTHY KIDS Act (P.L. 115-120) and the Bipartisan Budget Act of 2018 (P.L. 115-123), which both extended CHIP funding, and authorized the Child Enrollment Contingency Fund for 10 years through FY 2027. This 10-year extension is the longest period of CHIP funding and stability since its creation in 1997, which enables continued coverage of over 9 million children currently enrolled in CHIP.

The HEALTHY KIDS Act and Bipartisan Budget Act of 2018 also extended CHIP Express Lane Eligibility, the qualifying state option, and the expansion allotment adjustment. The Express Lane Eligibility option permits states to enroll children in Medicaid or CHIP based on findings, such as income, household size, or other eligibility factors, from other federal programs. Under the qualifying state option, certain states that significantly expanded Medicaid eligibility for children prior to the enactment of CHIP in 1997 may use CHIP allotment funding to finance the cost of children covered under Medicaid with incomes above 133 percent of the Federal Poverty Level. Qualifying states may elect to use their CHIP allotment funding to fund the difference between the CHIP Enhanced Federal matching rate and the Medicaid matching rate. The expansion allotment adjustment permits states with planned CHIP benefit or eligibility expansions to children to request increases to their allotments in even fiscal years.

Financing

The 23-percentage point increase in the CHIP enhanced federal matching rate phases down to 11.5 percentage points in FY 2020. CHIP returns to the traditional enhanced federal matching rate for FYs 2021 to 2027.

Payments from the Contingency Fund are currently authorized through FY 2027 for states that face a

funding shortfall based on greater than expected enrollment.

Eligibility and Coverage

States must maintain the same eligibility levels for all children covered under Medicaid and CHIP that were in place as of March 30, 2010, through September 30, 2019. For FYs 2020-2027, this requirement only applies to children in families with incomes up to 300 percent of the Federal Poverty Level.

Outreach and Enrollment

The Outreach and Enrollment Program provides grants and funds a national outreach and enrollment campaign to children who are eligible for, but not enrolled in, Medicaid and CHIP. Funding for the Outreach and Enrollment Program totals \$168 million for FYs 2018 through 2027.

Improving Quality

CHIP funds activities to improve child health quality in Medicaid and CHIP and to strengthen the quality of, and access to, children's health care. States use a variety of health care delivery and measurement approaches for both providers and patients. Funding for child health quality activities totals \$150 million for FYs 2018 to 2027. Beginning in FY 2024, states will be required to report on pediatric quality measures in the Child Core Set, which are currently optional.

2020 LEGISLATIVE PROPOSALS

Strengthen the CHIP Safety Net for States

The Budget proposes to bolster the safety net available to states experiencing funding shortfalls, while eliminating funding streams that do not support children's health. Beginning in FY 2021, the Budget would allow CMS to transfer unused annual appropriations to a Shortfall Fund that would be available for redistribution to states facing funding shortfalls. This would permit CMS to streamline funding mechanisms for states, make it easier for states to access needed funding when facing CHIP funding shortfalls, and ensure that shortfall funding is available to states and territories that need it for years to come. In addition, this proposal repeals the CHIP Performance Bonus Fund because CMS has not had the authority to make Performance Bonus payments since FY 2013. This proposal also repeals the Child Enrollment Contingency Fund because few states can

meet the restrictive eligibility criteria to qualify for a Contingency Fund payment when facing a funding shortfall. [No budget impact]

Children's Health Insurance Program



FY 2020 CHIP Proposals

	<i>dollars in millions</i>		
	2020	2020-2024	2020-2029
CHIP Proposals			
Strengthen the CHIP Safety Net	--	--	--
Total Outlays, CHIP Proposals	--	--	--



State Grants and Demonstrations

	<i>dollars in millions</i>			2020 +/- 2019
	2018	2019	2020	
Current Law Budget Authority				
Medicaid Integrity Program/1	80	82	90	+8
Money Follows the Person Evaluations/2	--	112	--	-112
Money Follows the Person Evaluations/2	--	1	--	-1
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	--	55	--	-55
Children's Health Insurance Program (CHIP) Outreach and Enrollment Grants	120	--	--	--
Total Current Law Budget Authority	200	250	90	-160
Current Law Outlays/3				
Medicaid Integrity Program/1	82	81	86	+5
Money Follows the Person Demonstration/2	381	360	470	+110
Money Follows the Person Evaluations	--	1	1	--
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	--	16	24	+8
Demonstration Programs to Improve Community Mental Health Services	1	3	3	--
Children's Health Insurance Program (CHIP) Outreach and Enrollment Grants/4	17	14	25	+11
Incentives for Prevention of Chronic Diseases in Medicaid/5	--	--	1	+1
Total Current Law Outlays	481	475	610	136

1/ Budget authority is adjusted annually by Consumer Price Index for All Urban Consumers. Outlays include some spending from prior year budget authority. Also described in the Program Integrity chapter.

2/ The Medicaid Extenders Act of 2019 (P.L. 116-3) amends the Deficit Reduction Act to provide \$112 million in FY 2019 for states with approved Money Follows the Person demonstrations to continue providing home and community-based long-term care services to individuals transitioning from institutions to community-based settings until FY 2021.

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/ See the CHIP chapter for additional information about this program.

5/ Outlays are from prior year budget authority.

CMS State Grants and Demonstrations funds diverse activities including: strengthening Medicaid program integrity, increasing the treatment capacity of providers participating under a State plan or waiver to provide substance use disorder treatment or recovery services, funding outreach activities to enroll children into Medicaid and the Children's Health Insurance Program (CHIP), and providing grants to states to prevent chronic diseases.

MEDICAID INTEGRITY PROGRAM

The Medicaid Integrity Program was established by the Deficit Reduction Act of 2005, which appropriated \$75 million annually. Congress later increased appropriations for inflation beginning in Fiscal Year (FY) 2011. While states have the primary responsibility for combating Medicaid fraud, waste, and abuse, the Medicaid Integrity Program plays an important role supporting state efforts by providing technical support to states and contracting with eligible entities to carry out activities such as agency reviews, audits, identification of overpayments, and education

activities. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the Health Care Fraud and Abuse Control program.

Please refer to the Program Integrity chapter for additional information.

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

The President recently signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which includes Medicaid provisions to address the opioids crisis.

The SUPPORT Act includes a \$55 million Medicaid demonstration project over 4.5 years. CMS will oversee efforts to increase substance use provider capacity, by providing an enhanced Medicaid match rate for select states. CMS may select at least 10 states to receive planning grants to assess their behavioral treatment and provider needs to improve provider networks treating substance use disorders. CMS may choose up to five (provided they meet specified criteria) of the 10 states to award planning grants to receive the enhanced federal match rate and implement the activities under this demonstration:

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

populations enrolled under the State plan or waiver.

CHIP OUTREACH AND ENROLLMENT GRANTS

Through grants and a national campaign, the Outreach and Enrollment Program improves outreach to, and enrollment of, children who are eligible for, but unenrolled in, Medicaid and CHIP, including American Indian or Alaska Native children. Funding supports family education about the availability affordable health coverage under Medicaid and CHIP, identifying children likely to be eligible for these programs, and assisting families with the application and renewal process. A total of \$168 million is available for outreach and enrollment grants through FY 2027. The Bipartisan Budget Act of 2018 requires that 10 percent of the funding from FYs 2024 to 2027 is set aside for evaluations and technical assistance.

Please refer to the CHIP chapter for additional information.

MONEY FOLLOWS THE PERSON DEMONSTRATION

This demonstration, recently extended through FY 2021 by the Medicaid Extenders Act of 2019, helps states support individuals to achieve independence. States are continuing to operate this demonstration with available funding, 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 Medicaid Extenders Act of 2019 (P.L. 116-3) also provides \$112 million in FY 2019 to states with approved Money Follows the Person demonstration projects to continue providing home and community-based long-term care services to individuals transitioning from institutions to community-based settings.

	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Innovation Center Obligations /1	\$931.2	\$1,021.7	\$1,400.0	+378.3
1/ FY 2018 numbers are actuals. FY 2019 and 2020 are estimates.				

The Center for Medicare and Medicaid Innovation (Innovation Center) tests innovative payment and service delivery models with the potential to preserve or enhance the quality of care and reduce Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP) spending. The Innovation Center operates under this statutory mandate in support of CMS’s goal of fostering an affordable, accessible health care system that puts patients first. Under current law, in Fiscal Year (FY) 2020, the Innovation Center will receive its second \$10 billion, ten-year appropriation.

INNOVATION CENTER MISSION AND VISION

To increase the transparency, responsiveness, and effectiveness of the Innovation Center’s work, CMS issued a Request for Information (RFI) in 2017. The RFI specifically asked for feedback on a new direction for the Innovation Center, to promote patient-centered care; test market-driven reforms to empower beneficiaries as consumers; improve price transparency; and increase choices and competition to drive quality, reduce costs, and improve outcomes.

CMS received over 1,000 responses to the RFI from a wide variety of individuals and organizations, health systems, physician groups, consumers, and private businesses. The responses provided valuable insight about possibilities for improving existing Innovation Center models, as well as ideas for transformative new models that empower beneficiaries with more choices and better health outcomes.

Based on these responses and other input from stakeholders, the Innovation Center reexamined its portfolio and began developing new models that put patients first, reduce unnecessary burden, increase efficiencies, and improve the patient experience.

VALUE-BASED TRANSFORMATION

Paying for value (outcomes and health vs. procedures and sickness) is a central premise of the Innovation Center’s work. The Innovation Center is developing

and testing models that complement HHS’s “four Ps” of driving toward value: Patients as Consumers, Providers as Accountable Patient Navigators, Paying for Outcomes, and Prevention of Disease Before It Occurs.

Patients as Consumers

Getting better value from our health system and paying for value requires empowering patients to be engaged and informed consumers. To achieve this, the Innovation Center is interested in integrating interoperability and promotion of patients’ timely and secure access to their health information into its models and will pursue opportunities to do so. CMS is considering models with elements that allow patients to make the right choices for themselves and their health by improving their access to information about pricing and alternative therapies.

Providers as Accountable Patient Navigators

In the shift toward value, empowered patients will still need physicians to help them navigate the health care system, and HHS needs to give those physicians the right incentives to guide patients in making choices that will lead to good outcomes. In developing models, the Innovation Center is pursuing opportunities for larger, more sophisticated physician practices that are ready to take significant risk for total patient outcomes to do so. At the same time, the Innovation Center is seeking to provide flexibility for smaller practices to ensure they are able to participate, while helping them move toward value-based payments. CMS is also considering models that empower providers in high-cost specialty areas that are in need of patient-centered reforms.

Paying for Outcomes

The U.S. health care payment system is overly complex and often does not create sufficient incentives for higher-quality, lower-cost care. The Innovation Center closely monitors and evaluates its models to ensure that the incentives are driving better outcomes and not

just more volume. An Alternative Payment Model (APM) is a payment approach that creates added incentives to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Payment for value, as measured through outcomes, is the central premise of every model the Innovation Center tests.

Prevention of Disease Before it Occurs

The best way to improve health and lower costs is to prevent disease before it occurs. The Innovation Center supports this goal by developing models that help to break down the silos between medical care, nutrition, transportation, housing, and other social supports in an effort to consider an individual's health holistically and prevent disease. For example, the Accountable Health Communities Model addresses a critical gap between clinical care and community services in the current health care delivery system by testing whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries reduces health care costs and utilization.

INNOVATION CENTER MODELS

To date, the Innovation Center has launched 38 models, including Accountable Care Organization (ACO) models; episode-based payment initiatives; primary care transformation; initiatives focused on the Medicaid, CHIP, and dually eligible populations; initiatives to accelerate the development and testing of new payment and service delivery models; and initiatives to speed the adoption of best practices. The Innovation Center also implements demonstrations established through statute.

Model Evaluations and Results to Date

The Innovation Center uses independent evaluators to routinely and rigorously assess the impact of each model on quality and expenditures. The evaluations include advanced statistical methods and carefully selected comparison groups to ensure that models deemed to be successful represent true opportunities for high-value investments of taxpayer dollars. The Innovation Center recently reviewed and synthesized evaluation results across multiple models to identify best practices for future model design in three key areas: primary care, episode-based payments, and state-based models. Findings from

these models revealed that: (1) the Innovation Center's primary care initiatives improved practices' efforts to become Patient-Centered Medical Homes or advanced primary care practices; (2) episode payment models led to reductions in utilization and gross Medicare expenditures for many episode types, with limited impact on quality or functional status outcomes; and (3) state-based model tests leveraged CMS investments in infrastructure and technical assistance, which then encouraged health care providers to gain experiences and resources needed to enable them to take on higher risk.

Expanded Models

The statute provides the Secretary authority to expand the duration and scope of a model being tested through rulemaking, including nationwide implementation. To exercise this authority, the Secretary, working with the Chief Actuary at CMS, must determine that expansion would either reduce spending without reducing quality of care or improve quality of care without increasing spending. To date, the Pioneer ACO Model, which supported experienced providers to coordinate care for patients across care settings, and the Medicare Diabetes Prevention Program, which helped prevent the onset of type 2 diabetes among pre-diabetic Medicare beneficiaries, were certified for expansion using this authority. Congress may also choose to codify successful models.

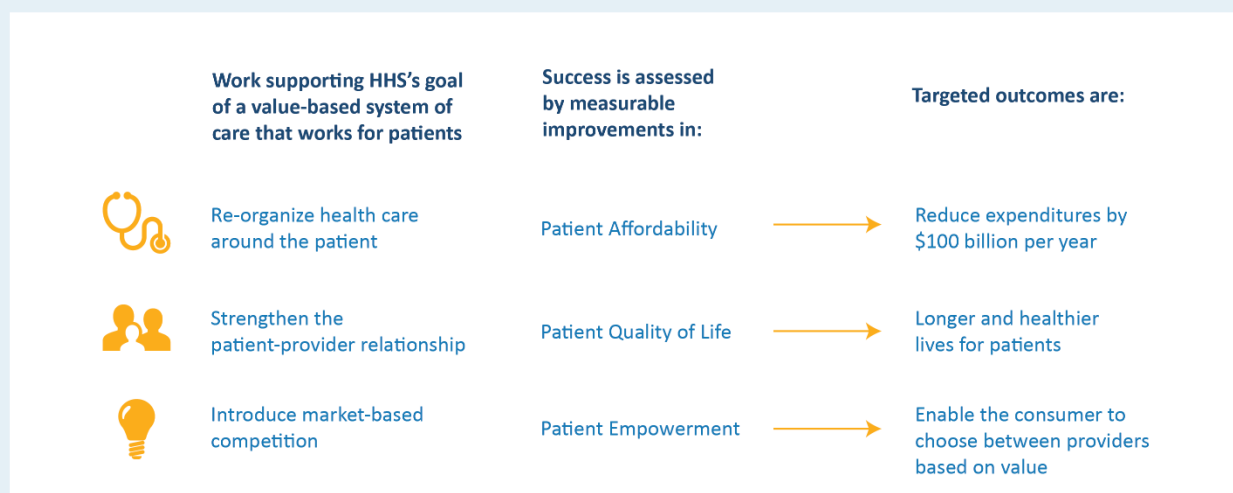
NEW INITIATIVES

Since January 2018, the Innovation Center has launched a number of bold, new models designed to provide better care at a lower cost and aligned with the "four Ps" of value-based transformation.

Emergency Triage, Treat, and Transport (ET3) Model

The ET3 model removes existing barriers to beneficiaries receiving the right care, in the right place, at the right time, in order to reduce expenditures and enhance quality of care. It tests new Medicare payments and care delivery options for ambulance suppliers and providers who partner with qualified

INNOVATION CENTER SUPPORTING VALUE-BASED TRANSFORMATION



health care practitioners to deliver treatment in place or with alternative destination sites, such as urgent care or behavioral health clinics. The model will begin January 1, 2020 and run for five years.

Medicare Advantage Value Based Insurance Design (MA VBID) Model

The existing MA VBID model tests the impact of allowing MA organizations to develop plan benefit designs that are targeted to specific groups of enrollees based on chronic conditions. The Bipartisan Budget Act of 2018 updated the MA VBID model to allow plans in all 50 states and territories to apply beginning in 2020, and extended participation to more Medicare Advantage plan types, including all Special Needs Plans. In January 2019, the Innovation Center announced the addition of new flexibilities for health plans to the MA VBID model, including targeted supplemental benefits based on beneficiaries' socioeconomic status, health conditions, or both; expanding the scope of rewards and incentives programs; greater use of telehealth; requirements for wellness and health care planning (advanced care planning); and an integrated hospice benefit. These new additions will be available beginning in plan year 2020, and in 2021 for the integrated hospice benefit. The model will run for another five years, through 2024.

Part D Payment Modernization Model

To address the high costs of prescription drugs, CMS will test the impact of modernized program design and incentives in Part D. This model tests whether increased plan sponsor liability for Part D catastrophic

spending, coupled with greater programmatic flexibilities and formulary management tools, including a Part D rewards and incentives program, will reduce expenditures and improve quality of care for Medicare beneficiaries. CMS is currently accepting applications from Part D sponsors to participate in this model, which is scheduled to begin in plan year 2020. Participants with drug costs below the spending target benchmark will be eligible for performance based payments, while participants with drug costs exceeding the benchmark will be penalized.

Integrated Care for Kids Model (InCK)

By integrating behavioral and physical health care, the InCK model aims to support states and local providers as they address the needs of pediatric Medicaid and CHIP beneficiaries with significant health needs. The InCK model tests whether the combination of a local service delivery model that coordinates integrated behavioral, physical, and complementary child health services, and a state-specific payment model that supports the coordination of those integrated services, reduces health care expenditures and improves the quality of care for this population. The model aims to prevent opioid misuse and improve outcomes for children affected by family opioid misuse and will run between January 1, 2020 and December 31, 2026.

Maternal Opioid Misuse (MOM) Model

The MOM model aims to improve quality of care for pregnant and postpartum Medicaid beneficiaries with opioid use disorder through state delivery system innovations. It tests sustainable coverage and payment

strategies supporting the coordination of clinical care and the integration of services essential for health, wellbeing, and recovery; expands access, service-delivery capacity, and infrastructure based on state-specific needs; and improves quality of care and reduces costs for mothers and infants. This model will run from January 1, 2020 through December 31, 2024.

***Bundled Payments for Care Improvement (BPCI)-
Advanced Model***

BPCI Advanced aims to align incentives for participating health care providers to reduce expenditures and improve quality of care for Medicare beneficiaries. It is an episode payment model that builds on the original BPCI models to test bundled payments for 32 clinical episodes that would typically include care furnished in acute and post-acute settings. These episodes were

selected based on opportunities for cost savings and quality improvement, sufficient volume for evaluation, and a goal to include a variety of clinical services, specialties, and beneficiary types. The model qualifies as an Advanced APM under the Quality Payment Program. The model runs from October 1, 2018 through December 31, 2023.

**INNOVATION CENTER DEMONSTRATIONS DISCUSSED
IN OTHER CHAPTERS**

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

Program Management



	<i>dollars in millions</i>			2020
	2018	2019	2020	+/- 2019
Discretionary Administration				
Program Operations	2,815	2,824	2,390	-435
Federal Administration	733	733	748	+15
Survey and Certification	397	397	442	+45
Research /3	20	20	--	-20
Subtotal, Discretionary Budget Authority	3,965	3,975	3,579	-395
Mandatory Administration /1				
Medicare Improvements for Patients and Providers Act	3	3	3	--
Protecting Access to Medicare Act (2014)	6	9	10	--
Improving Medicare Post-Acute Care Transformation (2014)	17	17	6	-11
Medicare Access and CHIP Reauthorization Act	152	108	20	-88
21 st Century Cures Act	11	--	--	--
SUPPORT Act	--	3	--	-3
Bipartisan Budget Act	13	12	--	-12
Subtotal, Mandatory Administration	202	152	39	-113
Reimbursable Administration				
Medicare and Medicaid Reimbursable Administration /2	372	551	594	+43
Exchange-Related Reimbursable Administration /1	1,700	1,853	1,842	-11
Risk Corridor Collections	22	--	--	--
Subtotal, Reimbursable Administration	2,094	2,404	2,436	+32
Total Program Management Program Level, Current Law	6,260	6,531	6,055	-476
Proposed Law				
Survey and Certification Revisit and Complaint Investigation Fee /4	--	--	--	--
Rebase National Medicare & You Education Program User Fee /4	--	--	--	--
Program Management Implementation Funds (mandatory)	--	--	200	+200
Subtotal, Proposed Law	--	--	200	+200
Total Program Management Program Level, Proposed Law	6,260	6,531	6,255	-276

- 1/ Includes user fees charged to issuers in Federally-facilitated Exchanges, State-based Exchanges on 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/ Research funding is being requested as part of the Program Operations funding in FY 2020.
- 4/ Collections from the proposed user fee would begin in FY 2021.

The Fiscal Year (FY) 2020 discretionary Budget requests \$3.6 billion for CMS Program Management which will enable CMS to continue to effectively administer Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). The FY 2020 Budget reflects CMS’s priorities to: empower States and provide them with greater flexibility; modernize programs to address

the changing needs of the people CMS serves; leverage innovation and technology to drive better care for Americans, and strengthen the integrity and sustainability of Medicare and Medicaid by investing in activities to prevent fraud, waste, and abuse.

PROGRAM OPERATIONS

The Budget requests \$2.4 billion for Program Operations and funds essential payment, information technology, and outreach activities for Medicare, Medicaid, CHIP, and private insurance programs. Priority activities for FY 2020 include:

Medicare Contractor Operations

Approximately 36 percent, or \$866 million, of the FY 2020 Program Operations request supports ongoing Medicare contractor operations. This includes processing 1.3 billion Medicare Part A and B claims, enrolling providers in the Medicare program, reimbursing providers, processing 2.3 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 \$86 million to timely process approximately 264,000 second level appeals. CMS actively supports the Department's effort to improve the Medicare appeals process and address the pending backlog of appeals at the Administrative Law Judge and Departmental Appeals Board levels. The Budget funds initiatives to decrease the number of new appeals entering the system and address pending appeals in the backlog.

Information Technology Systems and Support

The Budget includes \$440 million for information technology systems, including cybersecurity, allowing the agency to protect the valuable consumer health data of millions of Americans from outside threats. The Budget will continue an initiative, started in FY 2018, that enables seniors to access and navigate the Medicare program more seamlessly, provides new personalized tools to improve the customer experience, and helps beneficiaries make health care decisions that are best for them.

Medicaid and CHIP Operations

The Budget requests \$103 million for administrative activities to improve Medicaid and CHIP program operations. This includes the modernization of data systems and continued development of a scorecard for state Medicaid and CHIP programs to track the extent to which states achieve tangible results that improve the lives of beneficiaries.

Exchanges

The Budget expands the use of Exchange user fees to cover all Federal administrative expenses associated with operating the Exchanges. The program level for Exchanges totals \$1.3 billion, all of which will be funded by Exchange user fees with the exception of \$6 million from the Health Care Fraud and Abuse Control appropriation. Expanding the use of user fees for Federal administrative expenses will make the Exchanges more financially self-sustaining.

THE MEDICAID AND CHIP (MAC) SCORECARD

The MAC Scorecard is a searchable, web based reporting platform displaying data on:



Medicaid health outcomes



Quality of care



Access to care



Federal and state administrative performance and efficiency

This initiative reflects the Administration's commitment to transparency and accountability in welfare programs. CMS successfully completed MAC Scorecard 1.0 in June 2018 and will add additional quality and program integrity measures in subsequent versions with the goal of releasing an annual MAC Scorecard every fall that aligns with the annual Child and Adult Core Set measures publishing cycle.

Medicare Quality Improvement and Value-Based Transformation

The Budget includes \$175 million to support Medicare quality improvement and value-based activities previously funded by the Quality Improvement Organization mandatory appropriation to support increasing patient safety, making communities healthier, better coordinating post-hospital care, and improving clinical quality. This is the second-year of a five-year transition of quality improvement and value-based transformation support activities from the mandatory Quality Improvement appropriation to CMS Program Management.

FEDERAL ADMINISTRATION

The FY 2020 Budget requests \$748 million for CMS Federal administrative costs. At this level CMS will have staff to support core Medicare, Medicaid, and CHIP operations. The request includes \$15 million for personnel costs, previously funded by the Quality Improvement Organization mandatory appropriation, to support Medicare quality improvement and value-based transformation initiatives. This is the second-year of a five-year transition of personnel costs from the mandatory Quality Improvement Organization Improvement appropriation to CMS Program Management.

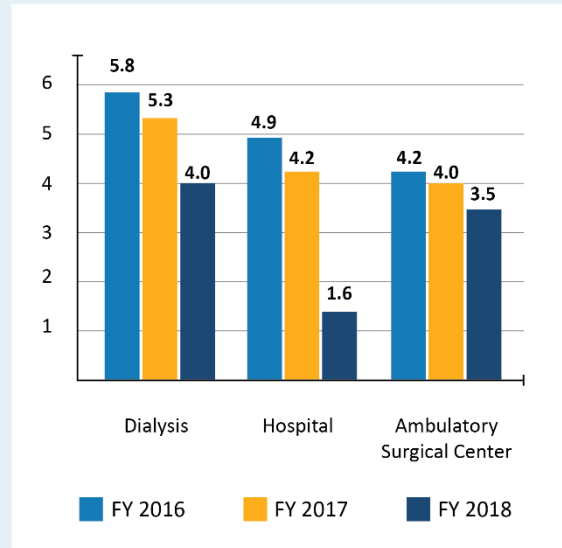
SURVEY AND CERTIFICATION

The FY 2020 Budget requests \$442 million for Survey and Certification, a \$45 million increase. The increased funding will enable CMS to maintain non-statutory survey frequency levels. The volume and cost of surveys have increased due to the growing number of participating facilities, higher levels of complaints, and increasing costs to conduct surveys.

Approximately 90 percent of the request will go directly to State survey agencies to perform health and safety oversight of Medicare certified providers. CMS expects states to complete over 21,000 initial surveys and re-certifications and over 60,000 visits in response to complaints in FY 2020. Surveys include mandated Federal inspections of long-term care facilities (i.e., nursing homes), home health agencies, hospices, and federal inspections of other key facilities. All facilities participating in the Medicare and Medicaid programs must undergo inspection when entering the program and on a regular basis thereafter.

The Budget proposes to levy a fee on Medicare-certified health care facilities to cover a portion of the costs of substantiated complaint surveys as well as revisit surveys that occur as a result of deficiencies found during an initial certification, recertification, or substantiated complaint visit. The fees would be set through rulemaking. This authority would enable CMS to more regularly revisit poor performing facilities, while creating an incentive for facilities to correct deficiencies and ensure quality of care. Indian Health Service facilities would be exempt from these fees. The Budget assumes collections beginning in FY 2021.

NATIONAL AVERAGE NUMBER OF DEFICIENCIES PER SURVEY



The Budget requests two-year budget authority for the Survey and Certification program. This approach increases administrative flexibility, enhances oversight and quality of care, and ensures that funds are available early enough in the state fiscal year to enable more effective planning, staffing, and funding of survey agencies to accomplish federally mandated survey workloads. This approach is particularly important since many states operate on fiscal years that are different from the Federal fiscal year. This proposal will further facilitate CMS's existing ability to reallocate funding between states when appropriate.

NATIONAL MEDICARE EDUCATION PROGRAM

The budget funds the National Medicare Education Program at \$385 million, including \$265 million in budget authority. CMS is committed to ensuring that beneficiaries have access to the educational materials and tools they need to find accurate and up-to-date information on their coverage options and covered benefits. The Budget requests \$273 million, including \$184 million in budget authority, to support the 1-800-MEDICARE call center, which provides beneficiaries with access to customer service representatives trained to answer questions about the Medicare program. The request will support an estimated 23 million calls with an average-speed-to-answer of approximately 5 minutes. Beneficiaries can also use 1-800-MEDICARE to report instances of possible fraud or abuse.

The Budget includes \$61 million, including \$31 million in budget authority, for beneficiary materials, the majority going to the printing and distribution of the *Medicare & You* Handbook.

2020 LEGISLATIVE PROPOSALS

Rebase National Medicare Education Program User Fee

Despite growing enrollment in Medicare Advantage and Part D plans, the amount of user fees these plans pay to support beneficiary outreach and enrollment assistance through the National Medicare Education Program has not kept pace due to an outdated statutory cap. This proposal allows CMS to assess an increased amount of user fees, starting in FY 2021, from Medicare Advantage and Part D plans to more equitably support outreach and enrollment assistance activities. [\$1.1 billion in additional user fees over 10 years]

Modernize Medicare Beneficiary Education Requirements

CMS is required to mail Medicare education materials to beneficiaries on an annual basis. This proposal provides the Secretary with increased flexibility to determine how to most efficiently and effectively communicate Medicare benefits information included in the *Medicare & You* Handbook with beneficiaries, including through electronic means instead of paper copies, in some cases. Offering digital alternatives will improve the efficiency of CMS Beneficiary Education activities. [No mandatory budget impact]

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

State Survey Agencies are required to survey all skilled nursing facilities every 12 months, with no greater than 15 months between surveys, regardless of a facility's Five Star Quality Rating. Effective FY 2020, this proposal gives the Secretary authority to adjust statutorily required survey frequencies for top-performing skilled nursing facilities and reinvest resources to strengthen oversight and quality improvement for poor performing facilities. This approach allows the frequency of nursing home surveys to be based on risk to health and safety, which reduces burden on high-performing facilities. [No budget impact]

NATIONAL MEDICARE EDUCATION PROGRAM FY 2020 PROGRAM LEVEL (DOLLARS IN MILLIONS)

Activity	2019	2020
Beneficiary Materials (e.g., Handbook)	70.8	61.1
1-800-MEDICARE and Beneficiary Claims Contact Center	243.5	273.1
Internet	36.6	27.8
Community-Based Outreach	3.0	3.0
Program Support Services/National Ad Campaign	25.9	19.6
Total NMEP Program Level	379.9	384.6

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

Provide Mandatory Resources for Implementation

The Budget includes a comprehensive package of CMS legislative proposals to carry out Administration reforms to the Medicare, Medicaid, and CHIP program. This proposal provides \$200 million in mandatory Program Management funding to implement these legislative proposals.

Administration for Children And Families: Overview



	dollars in millions			2020 +/-
	2018 /1	2019	2020	2019
Mandatory				
Budget Authority /2	34,982	35,089	33,794	-1,295
Discretionary				
Budget Authority /3	22,997	23,210	18,327	-4,883
Total ACF Budget Authority	57,979	58,299	52,121	-6,178

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.

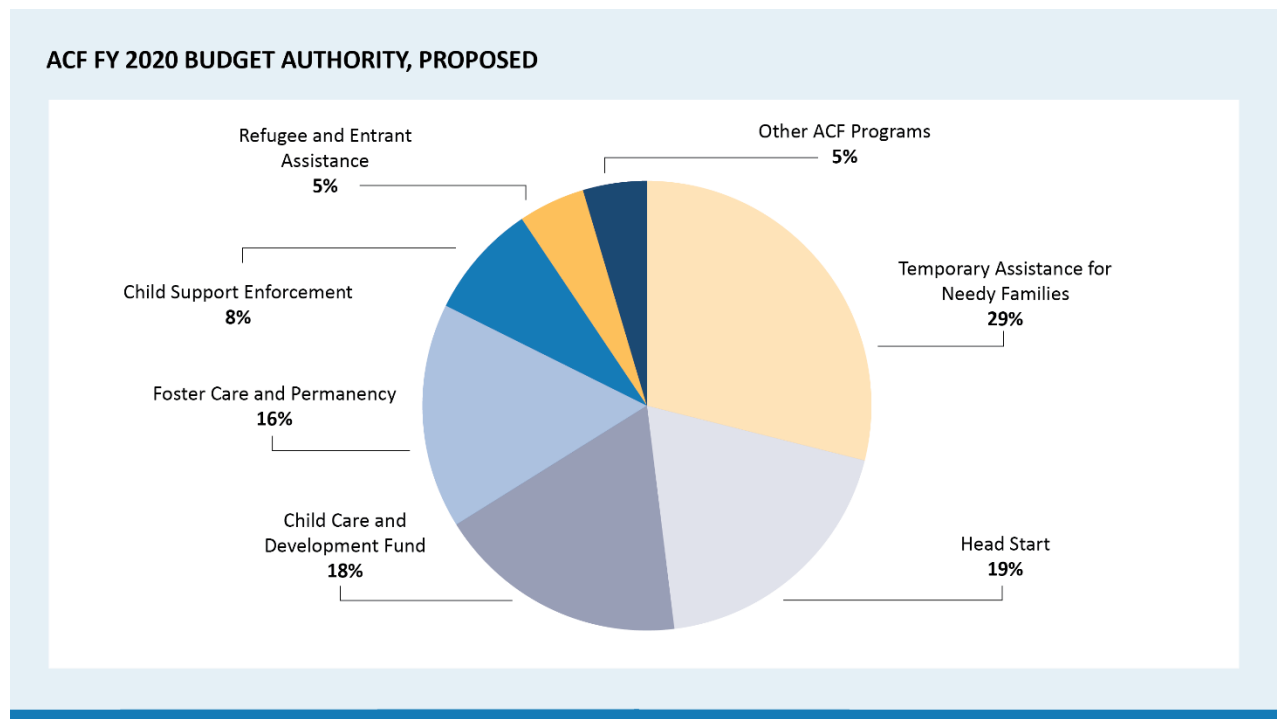
2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.

3/ FY 2018 does not include \$650 million for Head Start hurricane related funding provided by the Bipartisan Budget Act of 2018. Within the Refugee and Entrant Assistance Appropriation, FY 2018 does not include an offset of -\$10 million from offsetting collections from federal sources.

The Administration for Children and Families fosters health and well-being by providing federal leadership, partnership and resources for the compassionate and effective delivery of human services.

The Fiscal Year (FY) 2020 Budget requests \$52.1 billion for the Administration for Children and Families (ACF). ACF works in partnership with states, tribes, and communities to provide critical assistance to families and children, helping them achieve a path to success.

The Budget supports working families and promotes upward economic mobility through programs such as Head Start, Child Care, Child Support Enforcement, and Temporary Assistance for Needy Families. These programs promote personal responsibility, economic independence, productivity, and well-being by helping parents enter the workforce, care for their children, and form strong social networks and family bonds. ACF’s child welfare programs promote safety, well-being, and permanency through foster care, reunification, adoption, and efforts to prevent child maltreatment.



Administration for Children and Families: Discretionary



	<i>dollars in millions</i>			2020 +/-
	2018/1	2019	2020	2019
Early Childhood Programs				
Head Start	9,839	10,063	10,063	--
Child Care Block Grant (discretionary)	5,213	5,276	5,276	--
Subtotal, Early Childhood Programs	15,299	15,339	15,339	--
Programs for Vulnerable Populations				
Runaway and Homeless Youth	126	127	119	-8
Child Abuse Programs	158	158	158	--
Child Welfare Programs	326	326	326	--
Promoting Safe and Stable Families (discretionary)	100	100	60	-40
Adoption Incentives	75	75	38	-37
Chafee Education & Training Vouchers	43	43	43	--
Native Americans	54	55	52	-3
Family Violence Prevention and Services Programs	168	175	175	--
Subtotal, Programs for Vulnerable Populations	1,049	1,059	971	-88
Refugee Programs				
Unaccompanied Alien Children	1,570	1,303	1,303	--
Transitional and Medical Services	245	354	319	-35
Refugee Supportive Services	202	207	151	-56
Survivors of Torture	11	14	14	--
Victims of Trafficking (Foreign and Domestic)	24	27	17	-10
Subtotal, Refugee Programs	2,051	1,905	1,804	-101
Discontinued Programs				
Low Income Home Energy Assistance	3,640	3,690	--	-3,690
Community Services Block Grant	715	725	--	-725
Preschool Development Grants	248	250	--	-250
Other Community Services Programs	28	29	--	-29
Subtotal, Discontinued Programs	4,383	4,694	--	-4,694
Other ACF Programs				
Social Services Research & Demonstration	7	7	7	--
Disaster Human Services Case Management	2	2	2	--
Federal Administration	205	205	205	--
Subtotal, Other Programs	213	213	213	--
Total Discretionary Budget Authority	22,997	23,210	18,327	-4,883
Full-Time Equivalents	1,261	1,469	1,443	-26

1/ Reflects FY 2018 Enacted, post required and permissive transfers and rescissions.

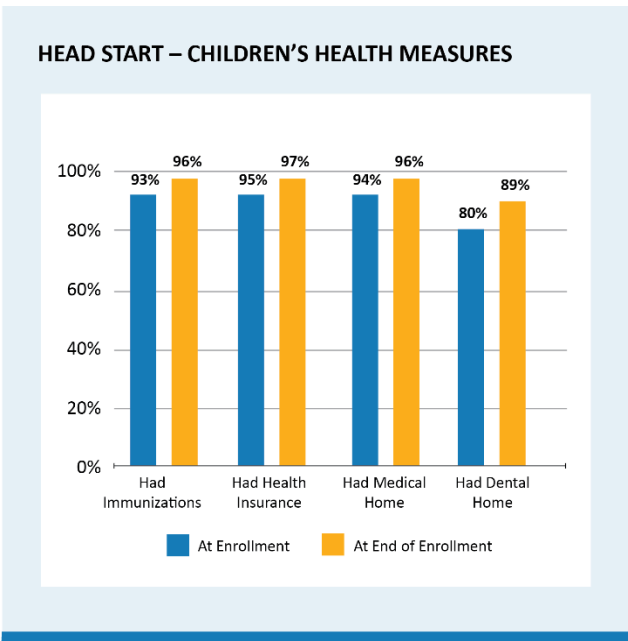
The Administration for Children and Families (ACF) provides services primarily through states, tribes, and local governments, as well as private, non-profit, faith-based, and community-based organizations. ACF human and social services programs promote the economic and social well-being of children, families, individuals and communities. Recipients have wide latitude to decide how to provide services and who receives them based on their unique local needs. The Fiscal Year (FY) 2020 Budget requests \$18.3 billion.

WORK SUPPORTS FOR FAMILIES

The Administration continues to prioritize programs that promote upward economic mobility for parents and enhance their children’s early care and education. These programs support low-income Americans, including vulnerable children and their parents, with the goal of personal responsibility and self-sufficiency.

Head Start

Head Start promotes school readiness for infants and children up to five years of age from low-income families by enhancing cognitive, social and emotional development. Head Start programs offer a variety of service models to meet the needs of the local community. The Budget invests \$10.1 billion, including \$805 million for Early Head Start-Child Care Partnerships. With this investment, Head Start will serve an estimated 871,000 children.



Head Start programs also work with families to help

ensure children have access to needed services and resources. The number of children who received immunizations increased over the 2016-2017 program year. More families also had health insurance and medical and dental homes for their children at the end of the 2016-2017 program year than at the beginning.

Child Care and Development Block Grant

The Budget provides \$5.3 billion for the Child Care and Development Block Grant, and \$4.2 billion in mandatory child care funding for a total investment of \$9.5 billion. This program provides low-income working families financial assistance for childcare and supports efforts to improve the quality of early care and education. The Budget proposes new incentives for states to recover improper child care payments and eliminates the duplicative requirement for a national child care hotline because every state now maintains a child care hotline.

SERVING VULNERABLE CHILDREN AND FAMILIES

The Budget supports services specifically assisting vulnerable children and families, including runaway and homeless youth and victims of child abuse and family violence.

Runaway and Homeless Youth

Each year thousands of youth experience homelessness, making them more vulnerable to violence and substance abuse. In 2017, the Department of Housing and Urban Development identified more than 40,500 youth under the age of 25 who were on their own and experiencing homelessness. The Budget provides \$119 million to support 587 programs across the country serving as a lifeline for homeless youth through emergency shelters and transitional living programs. The Budget proposes to update definitions to support trafficked youth and to create performance-based contracting demonstrations aimed at improving outcomes.

Child Abuse Prevention

ACF provides formula grants to states to improve the investigation of child abuse, train child protective service workers, and support community-based efforts to prevent child abuse and neglect. These funds also support state plans for safe care of infants affected by substance use disorders and for their parents and caregivers. ACF also shares critical research findings and lessons learned to improve child outcomes across the country, for example, demonstrating how child

welfare agencies can work with local housing authorities to decrease family separation due to lack of adequate housing.

Promoting Child Welfare

To promote child welfare, the Budget supports at-risk families and enables children to remain safely with their families or to be safely reunified in a timely manner. When it is not possible for a child to safely remain with his or her family, ACF works to remove barriers to adoption, provide incentive awards to states that increase the adoption of children in their foster care programs, and provide education and training vouchers to help foster care youth become self-supporting.

Administration for Native Americans

The Budget includes \$52 million for the Administration for Native Americans to award competitive grants to promote social and economic development, preserve native languages, and protect local environments. ACF awards the grants to federally recognized tribes, American Indian and Alaska Native organizations, Native Hawaiian organizations, and Native populations in U.S. Pacific territories.

Family Violence Prevention and Services

The Budget provides \$175 million for Family Violence Prevention and Service Programs. This funding provides services to prevent family violence, domestic violence, and dating violence. It provides immediate shelter and support services for adult and youth victims. This total includes \$10 million for the National Domestic Violence Hotline providing 24/7 crisis intervention, emotional support, counseling, safety planning, and resources to people experiencing domestic or dating violence.

REFUGEES, ENTRANTS, AND UNACCOMPANIED ALIEN CHILDREN

Unaccompanied Alien Children

ACF has the responsibility to provide shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other law enforcement authorities. ACF provides care for these children and identifies suitable sponsors, usually parents or other relatives, to care for them while their immigration cases proceed. While in ACF's care, children receive physical and mental health care, education, and recreation. Most children receive care through a network of permanent facilities, which are

state-licensed and operated by grantees under the close supervision of ACF staff. ACF also operates temporary shelters in response to periodic rapid increases in the number of unaccompanied alien children requiring care.

The number of unaccompanied alien children requiring care is inherently unpredictable. Funding needed for this program has exceeded the program's appropriated funds in five of the last seven fiscal years. To ensure adequate shelter capacity and care in FY 2020, the Budget proposes a mandatory contingency fund providing up to \$2 billion in additional resources over a three-year period.

Refugees and Other New Arrivals

ACF assists refugees and other eligible new arrivals to help them become self-supporting and assimilate to life in the United States through networks of nonprofits and state and local governments. New arrivals can receive up to eight months of financial support and medical assistance until they find employment. ACF provides transition support services, including English as a second language education, job training, case management, and counseling.

The FY 2020 estimate of eligible new arrivals is 93,000, including 30,000 refugees and 63,000 other new arrivals eligible for refugee benefits. The Budget includes \$319 million for transitional and medical services and \$151 million for refugee support services.

Victims of Trafficking

The Budget includes \$17 million for victims of trafficking to screen and identify victims and to provide victims with services, including case management, emergency assistance, and medical services. In coordination with the Department of Justice's Office of Victims of Crime, ACF serves both foreign national and U.S. citizens or permanent residents who are victims of trafficking. In addition, ACF funds a National Human Trafficking Hotline and works to raise awareness to prevent human trafficking.

EVALUATION AND INNOVATION

Research and Demonstration

Program evaluation and the use of data and evidence are critical for ACF and its partners to improve service delivery and increase program effectiveness. Some programs, such as the Office of Head Start and the Office of Child Care, have dedicated research and

program evaluation funding, but many other programs do not. The Budget maintains funding for Social Services Research and Demonstration, allowing ACF to study programs which lack dedicated research and evaluation funds and for research into areas that affect multiple programs.

Federal Administration

Federal administration funds pay for staff and administrative costs of the majority of ACF's programs.

Examples of administrative expenses include program management and required oversight, office space, and the development and maintenance of information technology systems. By increasing efficiency, ACF has managed recent program expansions, such as those included in the Family First Prevention Services Act, without increasing administrative funding. The Budget request for federal administration is \$205 million.

Administration for Children and Families: Mandatory



	<i>dollars in millions</i>			2020 +/- 2019
	2018 /1	2019	2020	
Current Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	2,917	0
Child Support Enforcement and Family Support	4,395	4,322	4,290	-32
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,138	8,301	8,548	+247
Promoting Safe and Stable Families (mandatory only)	480	489	345	-144
Social Services Block Grant	1,672	1,680	1,700	+20
Temporary Assistance for Needy Families (TANF) /2	16,737	16,737	16,739	+2
TANF Contingency Fund	608	608	608	0
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Budget Authority	34,982	35,089	35,185	+96
Proposed Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	4,212	+1,295
Child Support Enforcement and Family Support	4,395	4,322	4,340	+18
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,138	8,301	8,579	+278
Promoting Safe and Stable Families (mandatory only)	480	489	565	+76
Social Services Block Grant	1,672	1,680	85	-1,595
Temporary Assistance for Needy Families (TANF) /2	16,737	16,737	15,237	-1,500
TANF Contingency Fund	608	608	0	-608
Refugee and Entrant Assistance (mandatory only)	--	--	738	+738
Total, Proposed Law Budget Authority	34,982	35,089	33,794	-1,295
1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.				
2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.				

The Fiscal Year (FY) 2020 Budget requests \$33.8 billion in budget authority for the Administration for Children and Families (ACF) mandatory programs, with an estimated \$33.1 billion in outlays. ACF promotes the economic and social well-being of families, children, individuals, and communities through mandatory programs, including:

- Child Care Entitlement to States,
- Child Support Enforcement,
- Foster Care,
- Adoption Assistance,
- Guardianship,
- Independent Living,
- Promoting Safe and Stable Families, and

- Temporary Assistance for Needy Families (TANF).

ACF's proposals support the priorities of the Department and the Administration and focus on reducing poverty by increasing employment opportunities, creating economic mobility and strong social networks, increasing efficiency in human services programs, and addressing the impact of opioid misuse on families and children.

CHILD CARE ENTITLEMENT TO STATES

Program Description

The Budget includes \$3.6 billion for the Child Care Entitlement to States, an increase of \$743 million over FY 2019. The Child Care Entitlement to States provides mandatory funding to states and tribes for child care. The program requires states to spend at least 70 percent of mandatory child care funding on families receiving TANF, transitioning from TANF, or at risk of becoming eligible for TANF. In FY 2020, states must spend a minimum of nine percent of all child care funds, including the discretionary Child Care and Development Block Grant (CCDBG) to improve the quality and availability of healthy and safe child care for all families. Together with CCDBG, the Child Care Entitlement program helps families access and afford child care.

Legislative Proposals

The Budget requests \$216 million for the Child Care Entitlement to States, an increase of \$2.2 billion over 10 years. The Budget proposes a new, one-time \$1 billion fund for competitive grants to states to increase child care services for underserved populations and stimulate employer investment in child care.

CHILD SUPPORT ENFORCEMENT AND FAMILY SUPPORT PROGRAMS

Program Description

The Budget includes \$4.4 billion for the Child Support Enforcement program, a current law increase of \$121 million over FY 2019. The Child Support Enforcement program is a joint federal, state, tribal, and local partnership operating under title IV-D of the Social Security Act. It allows children to count on their parents for the financial, emotional, and medical support that they need to be healthy and successful, even when the parents live in separate households. The program functions in 54 states and territories, and 62 tribes. The Federal Child Support Enforcement program ensures economic and emotional support for children from both parents by locating noncustodial parents, establishing paternity, and establishing and enforcing child support orders.

Legislative Proposals

The FY 2020 Budget requests \$4.4 billion for Child Support Enforcement and Family Support Programs.

The Administration will also work to improve child support cooperation with other public assistance programs, such as Medicaid and the Supplemental Nutrition Assistance Program.

As part of the Administration's commitment to promoting work and self-sufficiency, the Budget includes a proposal, Get Noncustodial Parents to Work, allowing states to use up to two percent of their child support expenditures to require work activities for all noncustodial parents who owe overdue child support. This proposal will increase regular child support collections, enable noncustodial parents to provide for their children through increased engagement in work activities, and offer families a pathway towards economic independence.

Parenting time, or visitation, is the time a noncustodial parent spends with the child. Research shows that when noncustodial parents engage in their children's lives, they are more likely to meet their financial obligations. Several studies show that joint custody and access and visitation programs correlate with increased parent-child contact and child support payments. To improve parent-child relationships and outcomes for children, the Budget increases federal funding by \$34 million over 10 years for states to include parenting time provisions when establishing child support orders, at state option.

The Budget saves \$1.2 billion over 10 years by creating a technology enhancement and replacement fund to acquire a next-generation child support system and make it available to states. This proposal maximizes proven technology, rather than separate systems developed by each state, to increase system security and integrity. The new technology enhancement and replacement fund would also create savings and cost efficiencies for states and the federal government, resulting in better service delivery to child support customers. Leveraging reusable technology provides a cost effective solution to the widespread and pressing issue of replacing aging child support systems.

The Child Support account includes the Repatriation program providing temporary assistance, through service loans, to eligible repatriates referred from the U.S. Department of State. The Budget proposes to increase the annual ceiling on the amount of temporary assistance from \$1 million to \$10 million. This will allow HHS to improve responsiveness when repatriated individuals do not have resources for needs

such as temporary housing, meals, health care, or transportation.

CHILDREN’S RESEARCH AND TECHNICAL ASSISTANCE

Program Description

The FY 2020 Budget includes \$12 million in Children’s Research and Technical Assistance for child support program training and technical assistance, an increase of \$1.5 million over FY 2019. The Budget includes \$25 million to operate the Federal Parent Locator System (FPLS), an increase of \$0.8 million over FY 2019. Federal law authorizes and appropriates funds for Children’s Research and Technical Assistance, which supports training and technical assistance to states on child support enforcement activities and the operation of the FPLS to assist state child support agencies in locating noncustodial parents.

Legislative Proposals

The Budget includes a package of proposals to provide access to the National Directory of New Hires (NDNH) – a federal database of employment and unemployment insurance information administered by the Office of Child Support Enforcement within HHS – for evidence and program integrity purposes, while ensuring privacy and security safeguards. Program integrity proposals include strengthening eligibility verification and/or reducing improper payments and evidence-building proposals include providing access for statistical agencies and evaluation offices, as well as access for State agencies. If enacted, these proposals would eliminate duplicative efforts to collect the same employment and earnings data already in NDNH and improve government efficiencies.

FOSTER CARE AND PERMANENCY

Program Description

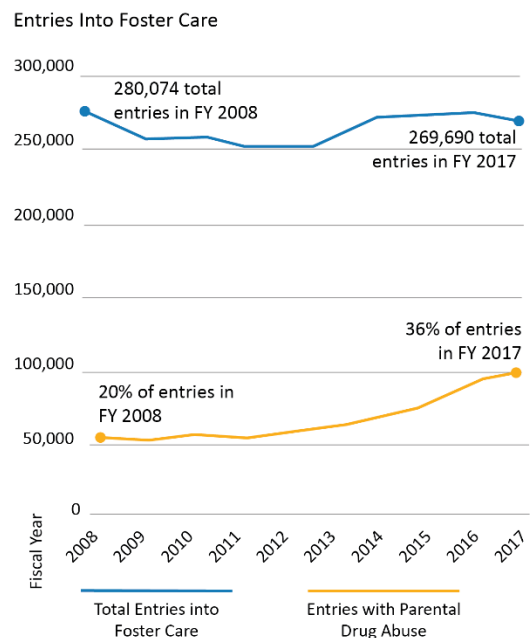
The Budget includes \$8.4 billion for the Foster Care, Adoption Assistance, Guardianship Assistance, and Independent Living programs, a current law increase of +\$559 million over FY 2019. These programs provide safety and permanency for children separated from their families, support services to prevent child maltreatment and the need for foster care, and prepare older youth in foster care for independence. The additional funding relative to FY 2019 will support the increased number of children participating in the Foster Care and Permanency program.

Funding goes primarily to:

- states as a partial reimbursement payment for board and care of eligible children in foster care,
- payments to families related to adoption and guardianship, and
- the Chafee Foster Care Program for Successful Transition to Adulthood, which assists current and former foster youth up to age 21 in obtaining education, employment, and life skills for self-sufficiency and successful transition to adulthood.

IMPACT OF PARENTAL DRUG ABUSE ON FOSTER CARE

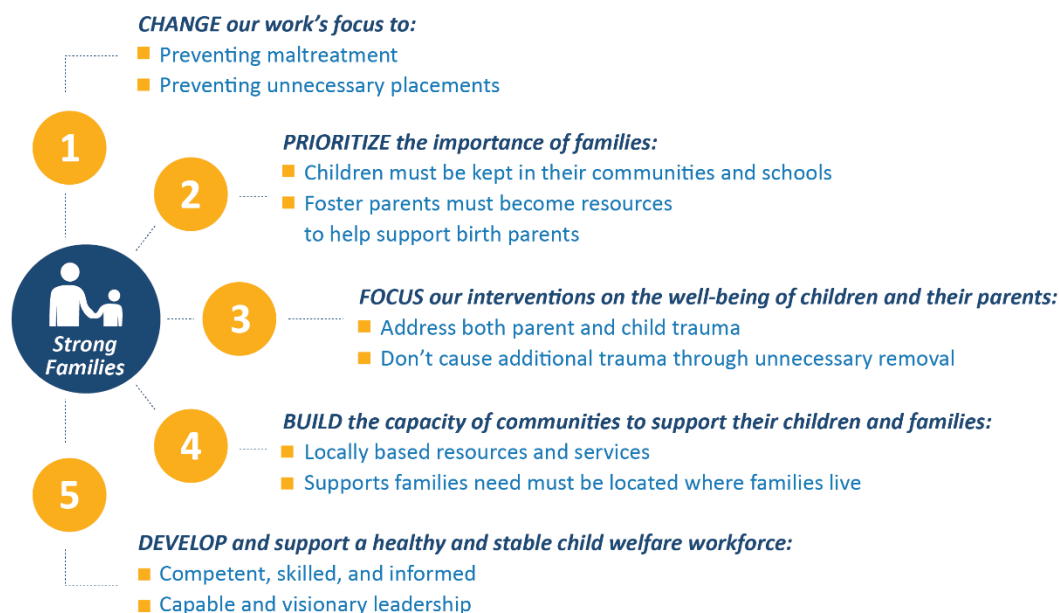
Parental Drug Abuse as a Circumstance Associated with Removal has increased in absolute numbers and as a percentage of all entries into foster care.



Source: U.S. Department of Health and Human Services, Adoption and Foster Care Analysis Reporting System (AFCARS), as of September 4, 2018.

In February 2018, Congress enacted the Family First Prevention Services Act (Family First Act) (P.L. 115-123). This important law allows federal funding for evidence-based prevention services for up to 12 months for children who are at risk of entering foster care, pregnant or parenting foster youth, and their parents or kin caregivers. Federal funding is available without regard to whether the child meets

THE CHILDREN'S BUREAU'S VISION FOR CHANGING NATIONAL CHILD WELFARE PRACTICE



title IV-E income eligibility standards. The funds can be used for mental health and substance abuse services, including opioid misuse, and for in-home parent skill-based programs. The Family First Act restricted federal funding for congregate foster care, often called group homes, in favor of family foster homes. Unless a state exercises the option to delay, beginning in FY 2020, federal funding will not pay for new congregate care after 14 days, except in limited circumstances with ongoing documentation and judicial review requirements.

The Family First Act provides an opportunity to re-examine the child welfare system and how it can focus on the well-being of children, strengthen families and communities, prevent the need for foster care, reunify families, and provide permanency through adoption or guardianship when reunification is not possible. ACF's child welfare proposals support Family First Act implementation and will improve child welfare outcomes, prevent the need for foster care, and address the opioid crisis.

Legislative Proposals

The Promote Family Based Care proposals will increase the availability of family foster homes for children with more severe behavioral, physical, or emotional needs by allowing federal reimbursement for salaries for

foster parents to care for these children. As states implement the Family First Act's funding restrictions on congregate care placements, they will need to develop alternate foster care options. This proposal invests \$357 million over 10 years, including \$7 million for technical assistance and oversight of activities related to the Family First Act (supplementing the \$1 million already enacted).

Preventing entry into foster care is key to avoiding unnecessary trauma, disrupting intergenerational cycles of maltreatment, and achieving better outcomes for children and families. The cost-neutral proposal to Create a Child Welfare Flexible Funding Option builds on the Family First Act by expanding resources available for preventive services, regardless of eligibility for foster care. It would allow federal funds to reimburse spending on any of the purposes or services authorized for child welfare spending under titles IV-E and IV-B of the Social Security Act beyond the costs of foster care, adoption, guardianship, and for services authorized by the Family First Act. This approach would empower states to invest broadly in services that promote permanency and stability for children and to focus more resources on preventing child maltreatment before it occurs.

The Flexible Funding Option would provide additional flexibility in the type and duration of intervention services offered by states. This includes a focus on preventive services which help states address differing needs in areas faced by the severity of the opioid crisis and its impact on families and children. The Flexible Funding Option would remove burdensome and overly prescriptive title IV-E eligibility requirements and the need to participate in eligibility reviews, further increasing the resources available to provide valuable services to improve child well-being. The federal government would continue to monitor states' performance through Child and Family Services Reviews.

The Budget proposes a demonstration project to offer incentives to states to improve performance on Child and Family Services Reviews and reinvest penalties for poor performance in child welfare pursuant to an improvement plan. The incentives component adds a 10-year investment of \$110 million.

PROMOTING SAFE AND STABLE FAMILIES

Program Description

The Budget includes \$510 million for the mandatory portion of the Promoting Safe and Stable Families program for FY 2020, an increase of \$42 million over FY 2019. These formula grants to states provide services to families, address child safety at home, and provide supportive services for reunifying and adoptive families. Funding supports Court Improvement Program grants to state and tribal courts to improve child welfare proceedings and Regional Partnership Grants, a competitive grant program that addresses the child welfare impact of substance abuse, including opioids. In recent years, parental substance abuse has grown as a circumstance associated with entry into foster care.

Legislative Proposals

The Budget increases funding for the Court Improvement Program by \$280 million to help courts improve and transition to the new requirements of the Family First Act, such as reviewing congregate care placements and providing training for judges, attorneys, and legal personnel working in child welfare cases. The Budget also increases funding to expand Regional Partnership Grants by \$368 million to serve more communities, especially rural communities affected by opioid misuse.

Promoting Safe and Stable Families includes the Personal Responsibility Education Program and the Sexual Risk Avoidance Education Program (formerly known as Abstinence Education). The Personal Responsibility Education Program provides formula grants to states and competitive grants to tribes and local organizations to educate adolescents on pregnancy prevention, sexually transmitted diseases, and adulthood preparation subjects such as healthy relationships and financial literacy. The Sexual Risk Avoidance Education Program provides formula grants to states and territories and competitive grants to local organizations for projects that educate youth on the health benefits of avoiding non-marital sexual activity. Programs focus on youth who are homeless, in foster care, live in rural areas or areas with high teen birth rates, or come from racial or ethnic minorities with disparities in teen birth rates. The Budget proposes a one-year reauthorization of each program at their current levels of \$75 million in mandatory funding per year.

SOCIAL SERVICES BLOCK GRANT

Program Description

Under current law, the Budget includes \$1.8 billion for the Social Services Block Grant (SSBG) appropriation account, which includes funding for SSBG and the Health Profession Opportunity Grants (HPOG) programs. SSBG provides support for a broad array of social services for children and adults. HPOG provides grants to support demonstration projects that provide Temporary Assistance for Needy Families (TANF) program recipients and other low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand.

Legislative Proposals

The Budget eliminates funding for the SSBG. The Administration's goal is to support welfare programs that effectively help low-income families move to independence through paid employment, and focus limited taxpayer dollars on program outcomes, not inputs, to ensure effectiveness in helping low-income families. A 2011 Government Accountability Office report noted that the SSBG Grant is fragmented, provides duplicative or overlapping services, and has limited accountability. The program has not demonstrated effectiveness in improving economic and social well-being. Recognizing that the SSBG is

sometimes used to provide rapid and flexible funding for disaster relief, the Budget maintains the program's authorization for possible future use in emergencies.

The Budget proposes a one-year extension for current HPOG grantees, at the current level of \$85 million in mandatory funding per year, to allow for continued evaluation and improvement.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

Program Description

The Budget includes \$15.1 billion for the TANF program, a current law decrease of \$1.4 billion from FY 2019. The TANF block grant provides 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 flexibility in determining how to use their TANF dollars to meet their citizens' needs and get them back on their feet.

Legislative Proposals

The Budget proposes \$15.1 billion for TANF State and Territory Family Assistance Grants. This funding level builds on the successes of welfare reform and re-focuses TANF 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. Over time, states have spent less on basic assistance and work, education, and training activities that help families achieve economic independence. Many states have taken advantage of provisions in the law that allow them to reduce their level of effort in engaging TANF recipients in work.

To address these challenges, the Budget 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 proposes to simplify TANF's work participation rate and target federal and state funding to needy families to end state gaming of the program.

Statutory limits on TANF reporting and significant differences between state TANF programs make it impossible for HHS to report an improper payment rate as required under current law. The Budget proposes to resolve this problem by giving ACF authority to collect quantitative and qualitative program integrity information from TANF programs, which will lay the groundwork for the data collection efforts needed to provide information on states' improper payments requirement. Using this information, HHS will prepare and submit to OMB a report on state efforts to promote payment integrity and accuracy within their TANF cash assistance programs.

The Healthy Marriage Promotion and Responsible Fatherhood (HMRF) Grants promote and encourage healthy marriage and relationships, positive father and family interactions, and other activities that foster social and economic security. Funding for these grants expires at the end of FY 2019. The Budget proposes a 5-year reauthorization of the HMRF program with technical improvements to create greater flexibility in funding awards to eligible entities.

UNACCOMPANIED ALIEN CHILDREN

The Budget provides up to \$2 billion in mandatory funding for an Unaccompanied Alien Children Contingency Fund. Please see the Unaccompanied Alien Children section of the ACF Discretionary chapter for a program description.

Administration for Children and Families: Mandatory



FY 2020 ACF Mandatory Outlays

	<i>dollars in millions</i>			2020 +/-
	2018 /1	2019	2020	2019
Current Law Outlays				
Child Care Entitlement to States	2,358	2,819	3,296	+477
Child Support Enforcement and Family Support	4,137	4,235	4,307	+72
Children's Research and Technical Assistance	41	43	37	-6
Foster Care and Permanency	8,581	7,876	8,404	+528
Promoting Safe and Stable Families (mandatory only)	425	468	485	+17
Social Services Block Grant	1,587	1,619	1,844	+225
Temporary Assistance for Needy Families (TANF) /2	16,415	16,536	16,219	-317
TANF Contingency Fund	666	597	608	+11
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Outlays	34,209	34,191	35,197	+1,006
Proposed Law Outlays				
Child Care Entitlement to States	2,358	2,819	3,562	+743
Child Support Enforcement and Family Support	4,137	4,235	4,356	+121
Children's Research and Technical Assistance	41	43	37	-6
Foster Care and Permanency	8,581	7,876	8,435	+559
Promoting Safe and Stable Families (mandatory only)	425	468	510	+42
Social Services Block Grant	1,587	1,619	487	-1,132
Temporary Assistance for Needy Families (TANF) /2	16,415	16,536	15,142	-1,394
TANF Contingency Fund	666	597	63	-534
Refugee and Entrant Assistance (mandatory only)	--	--	480	+480
Total, Proposed Law Outlays	34,209	34,191	33,070	-1,121

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.

2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.

Administration for Children and Families: Mandatory



FY 2020 ACF Mandatory Budget Proposals, Outlays

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Proposed Law Outlays			
Increase the Child Care Entitlement to States	216	1,080	2,160
Build the Supply of Child Care	50	1,000	1,000
Subtotal, Child Care (mandatory) (non-add)	266	2,080	3,160
Get Noncustodial Parents to Work /1	13	97	275
Fund States to Provide Parenting Time Services	1	11	34
Strengthen Child Support Enforcement and Establishment /2	--	--	--
Create a Technology Enhancement and Replacement Fund	35	-196	-1,185
Subtotal, Child Support Enforcement (non-add)	49	-88	-876
Increase the Repatriation Ceiling	0	4	9
Expand Access to National Directory of New Hires (NDNH)	--	--	--
Subtotal, Children's Research and Technical Assistance (non-add)	--	--	--
Promote Family Based Care	14	141	357
Create Child and Family Services Review Incentives	--	23	110
Create Child Welfare Flexible Funding Option	--	--	--
Interaction with Zero-Fund the Social Services Block Grant	17	104	214
Subtotal, Foster Care and Permanency (non-add)	31	268	681
Modernize and Expand the Court Improvement Program	9	125	280
Expand Regional Partnership Grants	11	162	368
Reauthorize the Personal Responsibility Education Program	3	73	73
Reauthorize Sexual Risk Avoidance Education	2	75	75
Subtotal, Promoting Safe and Stable Families (mandatory) (non-add)	25	435	796
Zero-Fund the Social Services Block Grant to States and Territories	-1,360	-8,092	-16,592
Reauthorize Health Profession Opportunity Grants	3	83	85
Subtotal, Social Services Block Grant (non-add)	-1,357	-8,009	-16,507
Reduce the TANF Block Grant	-1,099	-7,230	-15,284
Eliminate the TANF Contingency Fund	-545	-2,977	-6,017
Improve TANF by Strengthening Focus on Work and Families	--	--	--
Remake the Safety Net through Opportunity and Economic Mobility Demonstrations	22	300	500

	<i>dollars in millions</i>		
	2020	2020 -2024	2020 -2029
Provide for Alternative Improper Payments Reporting for the TANF Program	--	--	--
Reauthorize Healthy Marriage and Responsible Fatherhood	--	--	--
Child Support Enforcement Reform Proposals (TANF Impact)/3	-10	-85	-226
<i>Subtotal, Temporary Assistance for Needy Families (TANF) (non-add)</i>	-1,632	-9,992	-21,027
Establish an Unaccompanied Alien Children Contingency Fund	480	734	738
<i>Subtotal, Refugee and Entrant Assistance (mandatory) (non-add)</i>	480	744	738
Total Outlays, ACF Mandatory Legislative Proposals	-2,138	-14,568	-33,026

1/ The proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-\$16 million over 10 years) and the Supplemental Security Income program (-\$117 million over 10 years). Outlay impacts from Federal Offsetting Collections related to recoveries to the TANF program are shown in the TANF section.

2/ The Strengthening Child Support Enforcement and Establishment proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-\$107 million over 10 years) and the Supplemental Security Income program (-\$382 million over 10 years). Outlay impacts from Federal Offsetting Collections related to recoveries to the TANF program are shown in the TANF section.

3/ These estimates reflect outlay impacts of Child Support proposals from Federal Offsetting Collections related to recoveries to the TANF program.

Administration for Community Living



	<i>dollars in millions</i>			2020 +/- 2019
	2018/1	2019	2020	
Health and Independence Services				
Home & Community-Based Supportive Services	384	385	385	--
Nutrition Services	892	907	907	--
Native American Nutrition & Supportive Services	33	34	34	--
Preventive Health Services	25	25	25	--
Chronic Disease Self-Management /2	8	8	--	-8
Falls Prevention /2	5	5	--	-5
Aging Network Support Activities	12	17	12	-6
Subtotal, Health and Independence	1,359	1,381	1,362	-19
Caregiver Services				
Family Caregiver Support Services	180	181	151	-31
Native American Caregiver Support Services	10	10	8	-3
Alzheimer's Disease Program	23	24	19	-4
Lifespan Respite Care	4	4	3	-1
Subtotal, Caregiver Services	217	219	181	-38
Protection of Vulnerable Older Adults				
Long Term Care Ombudsman Program	17	17	16	-1
Prevention of Elder Abuse & Neglect	5	5	5	--
Senior Medicare Patrol Program (HCFAC)	18	18	18	--
Elder Rights Support Activities	16	16	14	-2
Subtotal, Protection of Vulnerable Older Adults	55	56	53	-3
Disability Programs, Research and Services				
State Councils on Developmental Disabilities	76	76	56	-20
Developmental Disabilities Protection and Advocacy	41	41	39	-2
Projects of National Significance	12	12	1	-11
University Centers for Excellence in Developmental Disabilities	41	41	33	-8
Nat'l Institute on Disability, Independent Living, & Rehab. Research	105	109	90	-19
Independent Living	113	116	109	-8
Traumatic Brain Injury	11	11	9	-2
Limb Loss Resource Center	3	4	--	-4
Paralysis Resource Center	8	9	--	-9
Subtotal, Disability Programs, Research and Services	409	418	337	-81
Consumer Information, Access and Outreach				
Voting Access for People With Disabilities (HAVA)	7	7	5	-2
Aging and Disability Resource Centers	8	8	6	-2
State Health Insurance Assistance Program	49	49	36	-13
Assistive Technology	36	36	32	-4
Medicare Improvements for Patients and Providers Act	38	38	38	--
<i>Current Law Mandatory</i>	38	38	--	-38
<i>Proposed Law Mandatory</i>	--	--	38	+38
Subtotal, Consumer Information, Access and Outreach	138	138	117	-21
Other Programs, Total, and Less Funds From Other Sources				
Program Administration	41	41	39	-2

	<i>dollars in millions</i>			2020 +/- 2019
	2018/1	2019	2020	
Total, Program Level	2,219	2,253	2,088	-164
Less Funds from Other Sources	83	81	18	--
Total Discretionary Budget Authority	2,136	2,169	2,033	-137
Full-Time Equivalents	188	198	189	-9

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.

2/ The FY 2020 Budget consolidates the Chronic Disease Self-Management and Falls Prevention Programs into the Preventive Health Service Program.

The Administration for Community Living maximizes the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.

The Administration for Community Living (ACL) works with states, localities, tribal organizations, nonprofit organizations, businesses, and families to help older adults and people of all ages with disabilities live independently and participate fully in their communities. ACL also invests in innovation, research, and education to improve the quality and availability of services for older adults and people with disabilities.

The Fiscal Year (FY) 2020 Budget requests \$2 billion for ACL. This total includes \$2 billion in discretionary budget authority and \$56 million in mandatory funding. The Budget prioritizes nutrition assistance and other key direct service programs. These direct service programs help seniors remain independent, assist and support families and caregivers, and empower individuals with disabilities to live independent lives and fully integrate into their communities.

PROMOTING ELDERS’ HEALTH, SAFETY, AND COMMUNITY LIVING

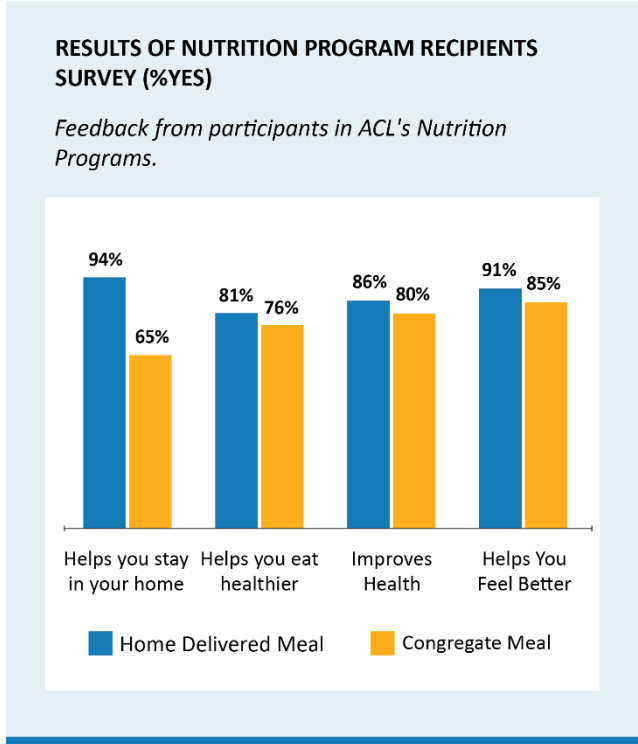
Increased longevity has led to the rapid growth of the older population in the United States. Modern health care improvements allow older adults to stay active and healthy, and live independently. The U.S. population over age 60 is projected to increase by 31 percent between 2017 and 2030, from 70.8 million to 92.7 million.

The Budget includes a new general provision to maximize funding flexibility for 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. The Budget funds essential community-based services

and supports that help older Americans stay healthy, independent, and living in their communities.

Nutrition Services Programs

The Budget requests \$907 million for Nutrition Services. ACL’s Congregate and Home-Delivered Nutrition Programs provide 221 million healthy meals to approximately 2.3 million older adults every year. ACL grantees provide meals in congregate facilities such as senior centers, and deliver to seniors who are homebound due to illness, disability, or geographic isolation.



Home and Community-Based Supports

The Budget includes \$410 million for Home and Community-Based Supportive Services and Preventive Health Services. These two programs provide formula grants to states to help older adults, with and without disabilities, to live independently and avoid costlier care settings.

Through its Home and Community-Based Supportive Services program, ACL's budget supports 50.9 million hours of personal care, homemaker, and chore services as well as 10.2 million hours of adult day care.

The Budget consolidates the Falls Prevention Program and the Chronic Disease Self-Management Program into the Preventive Health Services Program. The Preventive Health Services Program prevents chronic disease and disability through formula grants to states and territories for evidence-based interventions. With this consolidation, states will have more flexibility to direct funding based on local needs.

Elder Rights and Support

Elder abuse and neglect affects at least 1 in 10 older Americans each year. The Budget provides \$39 million to support the protection of vulnerable older adults, including \$10 million for the Adult Protective Services Program. In collaboration with State Adult Protective Services agencies, ACL supports a national reporting system for Adult Protective Services programs and will provide targeted technical assistance grants to address opioid misuse in older adults.

Other Aging Programs

The Budget provides \$46 million for two other health and independence services programs: Native American Nutrition and Supportive Services, and Aging Network Support Activities. The latter maintains funding for the Holocaust Survivor Assistance Fund.

CAREGIVER AND FAMILY SUPPORT SERVICES

The Family Caregiver Support Program enables family and informal caregivers to care for seniors and individuals with disabilities in their homes and communities, avoiding or delaying the need for costly nursing home care. The Budget provides \$162 million for three programs designed to support family and informal caregivers.

The Family Caregiver Support Services Program, the Native American Caregiver Support Services Program,

and the Lifespan Respite Care Program work with states, community-based, and tribal programs to provide coordinated support services including counseling, respite care, training, and supplementary services (such as access to medical equipment and transportation).

In FY 2020, ACL's caregiver support programs will serve approximately 800,000 family caregivers. In addition to these efforts, ACL will implement the Recognize, Assist, Include, Support, and Engage Family Caregivers Act and the Supporting Grandparents Raising Grandchildren Act to support family caregivers and their diverse needs.

Alzheimer's Disease

The FY 2020 Budget provides \$19 million for Alzheimer's Disease activities. 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 related dementia, and nearly 14 million Americans are expected to be diagnosed with such diseases by 2050.

HELPING INDIVIDUALS WITH DISABILITIES PARTICIPATE IN THEIR COMMUNITIES AND ACHIEVE THEIR GOALS

ACL is dedicated to ensuring that individuals with disabilities and their families can live, work, play, and learn as contributing members of their communities. ACL works with states, territories, communities, and nonprofit organizations to improve access to community-based care.

State Health Insurance Program

The State Health Insurance Program assists Medicare-eligible individuals, their families, and caregivers to make informed health insurance decisions to optimize their access to care and benefits. The Budget provides \$49 million in both discretionary and mandatory funding, for grants to states for local activities and community-based services.

Additionally, the Budget extends \$38 million in mandatory funding for Aging and Disability Resource Centers, Area Agencies on Aging, the National Center for Benefits Outreach and Enrollment, and the State Health Insurance Assistance Program through FY 2021, which target low-income and rural populations.

State Councils on Developmental Disabilities

The Budget provides \$56 million for State Councils on Developmental Disabilities, a nationwide network of state-based organizations that identify and address the most pressing needs of people with developmental disabilities in their state or territory. Councils on Developmental Disabilities focus on developmental disabilities that are lifelong, significant, and require ongoing support from existing and innovative services to improve the quality of life for these individuals. These services help individuals achieve independence, productivity, integration, self-determination, and inclusion in the community.

Independent Living

ACL's Independent Living programs coordinate services to individuals with disabilities, maximize their productivity and integration into communities, and foster working relationships among Centers for Independent Living. ACL's Centers for Independent Living help nearly 250,000 people with disabilities achieve greater independence and self-sufficiency each year. Independent Living services include peer counseling, information and referral, individual and systems advocacy, and independent living skills training.

The Budget provides \$109 million for over 350 Centers for Independent Living, and includes funding to support program evaluation and performance measurement activities to improve efficient evidence-based decision-making.

National Institute on Disability, Independent Living, and Rehabilitation Research

The Budget provides \$90 million for the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) within ACL to

support and leverage NIDILRR's applied research with ACL's other programs. NIDILRR is committed to ensuring that its research and development promote the independent living, health, and function, employment, and community living outcomes of individuals with disabilities.

Other Disability Programs

The Budget provides \$43 million for additional disability programs, research, and services. This includes \$33 million for University Centers for Excellence in Developmental Disabilities and \$1 million for Projects of National Significance.

The Budget also provides \$9 million for the Traumatic Brain Injury Program to support grants for rehabilitation, counseling, and vocational services for individuals with traumatic brain injury.

RESPONSIBLE STEWARDSHIP AND DELIVERY OF SERVICES

The Budget discontinues funding for program activities carried out with other funding sources and available through other ACL programs, including the Limb Loss and Paralysis Resource Centers. Resources for individuals living with paralysis are 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 \$39 million for program management and support activities. This funding helps ACL carry out its mission by ensuring adequate support for oversight and program integrity activities.



General Departmental Management

	dollars in millions			2020 +/- 2019
	2018	2019	2020	
Discretionary Budget Authority /1	470	481	340	-141
Public Health Service Evaluation Funds	65	65	69	+4
Health Care Fraud and Abuse Control Program /2	7	10	10	+3
Proposed User Fee Collections – Department Appeals Board	-	-	2	+2
Total, Program Level /3	542	556	421	-132
Full-Time Equivalents /3	1,030	1,029	1,130	+101

1/ The 2018 level reflects the 2018 Enacted level, post 2018 Secretary’s Transfer for Unaccompanied Alien Children.

2/ The Health Care Fraud and Abuse Control Program allocation in FY 2019 is \$7 million.

3/ This table does not include funding of Full-Time Equivalents for the Pregnancy Assistance Fund, nor does it include funding for the Physician-Focused Payment Model Technical Advisory Committee created by the Medicare Access and CHIP Reauthorization Act of 2015.

The General Departmental Management budget line supports the Secretary’s role as chief policy officer and general manager of the Department.

LEADING THE NATION’S PUBLIC HEALTH ENTERPRISE

The Secretary oversees HHS programs, policies and operations to ensure effective stewardship of Department resources toward helping Americans live healthier lives. The Budget supports the Secretary's role in administering and overseeing the organization, programs, and activities of the largest cabinet Department through 11 Staff Divisions within the Office of the Secretary. The fiscal year (FY) 2020 President’s Budget requests a program level of \$421 million for General Departmental Management.

The Budget ensures health policy and program coordination across the Department as well as supporting Administration priorities such as the initiative *Ending the HIV Epidemic: A Plan for America*. Further, the Budget addresses critical operations including addressing Medicare claim appeals which have a direct impact on Medicare beneficiaries and providers.

PUBLIC HEALTH POLICY AND PROGRAM COORDINATION

The Office of the Assistant Secretary for Health (OASH) serves as the senior advisor to the Secretary for public

health, science and medicine and coordinates public health policy and programs across the Staff and Operating Divisions of HHS. Additionally, the ASH oversees the Office of the Surgeon General and the United States Public Health Service Commissioned Corps (Corps).

OASH coordinates through 11 core program offices including the Office of Minority Health and the Office on Women’s Health offices to lead policy coordination across the Department, government-wide, and with nongovernmental partners. This coordination enables the Department to address a diverse range of public health challenges, including OASH’s lead role in defining best practices and opportunities for improvement in pain management to lessen dependence on opioids. OASH focuses on supplying information and tools that empower individuals, communities, and health systems to emphasize health promotion and disease prevention.

MINORITY HIV/AIDS FUND

Advances in prevention and treatment for HIV/AIDS make the prospect for ending the HIV epidemic in America possible. HHS has long-standing HIV/AIDS programs that have played a major role in addressing the impact of the epidemic. The Budget includes

\$54 million for the Minority HIV/AIDS Fund. These funds provide the Department with the flexibility to target funding for hard-to-serve communities and individuals enabling HHS to implement programs that support the goals of the early phase of this initiative.

OFFICE OF MINORITY HEALTH

The Budget includes \$52 million for the Office of Minority Health. 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 reduce health and health care disparities and advance health equity in America.

OFFICE ON WOMEN'S HEALTH

The Budget includes \$27 million for the Office on Women's Health. 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 to support the advancement of women's health programs with other government organizations and with consumer and health professional groups.

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 manages the daily operations of the Corps, which consists of approximately 6,500 uniformed public health professionals who underpin the nation's response network for public health emergencies. Corps officers, including physicians, nurses, dentists, pharmacists, social workers and engineers have supported the U.S. government response to natural disasters and other public health emergencies such as hurricanes and the Ebola outbreak.

The ASH initiated an extensive plan to modernize the Corps structure, organization, and force strength to meet the current and future needs of the nation. This modernization plan will: strategically decrease positions filled by Corps officers in non-mission-priority areas and functions; recruit new officers to serve specific underserved and vulnerable population missions; establish a highly trained, deployable, and

fully capable Ready Reserve Corps; and deliver annual training to the Regular Corps to meet current and emerging mission requirements.

The FY 2020 Budget provides \$3 million within the Immediate Office of the ASH to implement the planning phase for the Ready Reserve.

ADDRESSING MEDICARE CLAIM AND OTHER APPEALS

The Budget includes \$20 million for the Department Appeals Board (DAB), an increase of \$9 million above FY 2019. DAB provides impartial, independent review of certain disputed decisions, as detailed below. In the event of a disputed Medicare claim, the DAB serves as the final level of review before a claim can be appealed to federal court.

The Budget increase for FY 2020 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.

DAB also hears cases initiated by outside parties who disagree with a determination made by an HHS agency or its contractor. Outside parties include states, universities, grantees, nursing homes, clinical laboratories, doctors, medical equipment suppliers, and Medicare beneficiaries. DAB decisions on certain cost allocation issues in grant programs have government-wide impact because HHS decisions in this area legally bind other Federal agencies.

OTHER GENERAL DEPARTMENTAL MANAGEMENT

The Budget includes \$263 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 11 staff divisions and includes funding to continue ongoing programmatic activities, including strengthening program integrity by reducing fraud, waste, and abuse.

Office of the Secretary

Office of Medicare Hearings and Appeals



	dollars in millions			2020 +/- 2019
	2018	2019	2020	
Office of Medicare Hearings and Appeals				
Medicare Appeals Adjudication	182	182	182	--
Proposed User Fee Collections	--	--	4	+4
Program Level	182	182	186	+4
Subtotal	182	182	186	+4
Full-Time Equivalent	664	950	1,375	+425

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 Administrative Law Judges exercising decisional independence under the Administrative Procedures Act with the support of professional, legal, and administrative staff.

The Office of Medicare Hearings and Appeals (OMHA) administers the nationwide hearing process for appeals arising from Medicare coverage and payment claims for items and services furnished to beneficiaries.

The Fiscal Year (FY) 2020 Budget requests \$186 million for OMHA, an increase of \$4 million over the funding provided in FY 2019. The FY 2020 Budget increase consists of \$4 million in proposed user fee collections that would allow OMHA to recoup a small part of the administrative costs resulting from unsuccessful appeals.

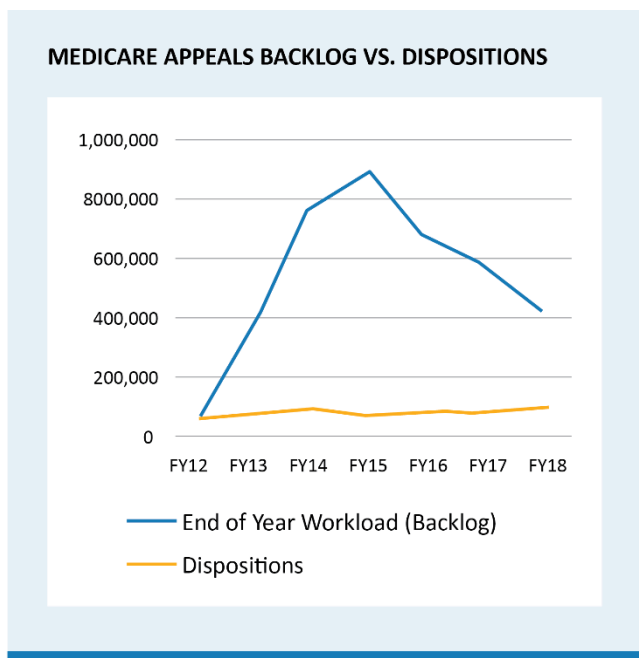
THE MEDICARE APPEALS BACKLOG

Since FY 2011, the growth in Medicare claims, partially driven by an aging population and HHS’s Medicare program integrity efforts, has led to a significant increase in Medicare appeal claims. The claim increase has resulted in more appeals than OMHA could process within the 90-day case adjudication time frame required by law. Despite OMHA’s efforts to resolve this issue, appeal receipts continue to exceed annual adjudication capacity, resulting in a backlog of appeals pending adjudication.

To address this challenge, the Department took a number of administrative actions to reduce the pending appeals workload, including alternative dispute resolution and settlement actions. Thanks to these efforts, the backlog of cases was reduced by

55 percent to approximately 400,000 appeals (from a high of nearly 900,000 in FY 2015).

In FY 2019, Congress funded OMHA at a level which enabled the agency to increase adjudication capacity and properly address receipt levels. This funding allowed OMHA to hire more Administrative Law Judges (ALJs) and adjudicatory staff to handle the incoming workload and reduce the backlog of appeals.



This additional adjudicatory capacity and staffing include the opening of four new field offices in

Albuquerque, New Mexico; Atlanta, Georgia; New Orleans, Louisiana; and Phoenix, Arizona.

The Department projects that the backlog of appeals will be resolved by FY 2022.

OMHA remains committed to continuous improvement in the Medicare appeals process by implementing initiatives to enhance the quality and timeliness of its services within its statutory authorities and funding levels. Through increased process efficiency and targeted addition of support staff, OMHA has streamlined its business processes and has implemented a number of new initiatives to the maximum extent possible without sacrificing program integrity.

Office of the Secretary, Office of the National Coordinator for Health Information Technology



	dollars in millions			2020 +/-
	2018 /1	2019	2020	2019
Office of the National Coordinator for Health Information Technology				
Total Discretionary Budget Authority	60	60	43	-17
Full-Time Equivalents	176	164	164	--

1/ Reflects FY 2018 enacted, post required and permissive transfers.

The mission of the National Coordinator for Health Information Technology is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

The Office of the National Coordinator for Health Information Technology (ONC) leads the nation’s effort to advance health information technology (IT). Improved exchange of health information promotes the quality, safety and efficiency of health care for the American public. ONC supports the Administration’s efforts to achieve interoperability, promote common data standards, encourage innovation and competition in the health IT industry, and improve patient and provider experiences with health IT.

In a large and complex health care delivery system, achieving an interoperable health IT system is critical. A safe, secure, and efficient health IT infrastructure improves health care delivery, reduces health care costs, and supports better health for all Americans. The Fiscal Year (FY) 2020 Budget prioritizes policy and rulemaking activities, standards development and implementation, and electronic health record (EHR) certification efforts to fulfill ONC’s commitment to an interoperable health IT system. In FY 2020, ONC will accelerate development of data standards and the implementation of a trusted exchange framework and common agreement across health information networks, to accelerate the achievement of this goal.

The FY 2020 Budget includes a total of \$43 million for ONC to support mission critical work that advances the interoperability and usability of health IT. Additionally, ONC will promote health IT approaches to combat the opioid epidemic through targeted collaborations with HHS partners.

POLICY DEVELOPMENT AND COORDINATION

The Budget reflects ONC’s continued commitment to achieving a nationwide interoperable health IT system through coordination of health IT stakeholders. ONC works closely with public and private sector stakeholders, including providers, patients, payers, researchers, and policymakers, to advance a safe and secure health IT infrastructure. Through rulemaking and supporting activities authorized in the 21st Century Cures Act (Cures Act), ONC will continue to promote patient access to their health information and to reduce provider burden. In addition, ONC will coordinate federal health IT policy, lead Health IT Advisory Committee operations, and maintain the statutorily required website, HealthIT.gov.

Health IT Advisory Committee

The Budget supports a single Health IT Advisory Committee (HITAC), established by the Cures Act, that provides recommendations to the National Coordinator related to the implementation of a health IT infrastructure that advances the electronic access, exchange, and use of health information. The HITAC provides critical input from its 30 members, who represent a broad and balanced spectrum of the health care system. By the end of FY 2018, the HITAC and its task forces met 35 times to develop recommendations to address priority areas identified in the Cures Act. The HITAC has contributed to several ONC efforts, including the development of the Trusted Exchange Framework and Common Agreement, U.S. Core Data for Interoperability, and the Strategy for Reducing

Regulatory and Administrative Burden associated with the use of health IT and EHRs.

Promoting Trusted Exchange of Health Information

The Trusted Exchange Framework will establish a set of common principles, terms, and conditions that facilitate trust between health information networks. In FY 2020, ONC will implement this framework and work with private sector stakeholders to promote access, exchange, and use of relevant health information across networks. Through this exchange, patients and providers can access health information more easily and efficiently. This will enhance care coordination and delivery, and allow patients to participate in their care and manage their health information.

EFFECTS OF GAPS IN HEALTH INFORMATION

1 in 3 individuals who have seen a health care provider in the last year experienced at least one of the following gaps in information exchange.



Had to bring an X-Ray, MRI, or other type of test result with them to the appointment.



Had to wait for test results longer than they thought reasonable.



Had to redo a test or procedure because the earlier test results were not available.



Had to provide their medical history again because their chart could not be found.



Had to tell a health care provider about their medical history because they had not gotten their records from another health care provider.

Source: https://www.healthit.gov/sites/default/files/briefs/oncdata-brief30_accesstrends_.pdf

Reducing Provider Burden

In the Cures Act, Congress directed ONC to work with healthcare stakeholders and CMS to reduce clinician burden from health IT.

For example, ONC and CMS heard from stakeholders—including physicians, nurse practitioners, physician assistants, and other clinicians who bill Medicare—that the evaluation and management documentation requirements are administratively burdensome and often medically unnecessary. In July 2018 CMS proposed the Physician Fee Schedule rule and announced plans to improve flexibility and reduce documentation requirements for office and outpatient evaluation and management billing. The final rule, published on November 1, 2018, significantly changed several documentation policies to reduce burden for clinicians who treat Medicare beneficiaries. These reforms could lead to more efficient and effective use of EHRs in clinicians' offices, and support patient-centered care. In FY 2020, ONC will continue to work with CMS and healthcare stakeholders to identify and implement efforts to reduce provider burden from health IT.

Addressing the Opioid Epidemic

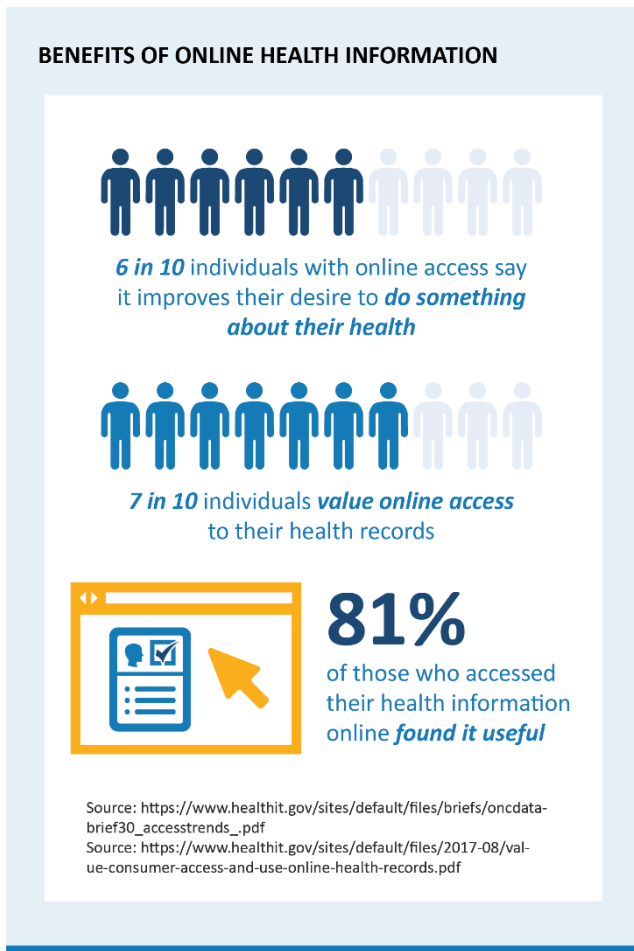
ONC galvanizes health IT stakeholders, including healthcare practitioners, administrators, and physician practice owners, to leverage health IT to mitigate the opioid epidemic. In FY 2020, ONC will work closely with HHS partners to improve opioid prescribing practices, inform clinical practice, protect patients at risk, and reduce illegal use of prescription medications through health IT. This work will also advance the accessibility and interoperability of Prescription Drug Monitoring Programs.

STANDARDS, INTEROPERABILITY AND CERTIFICATION

ONC leads coordination, technical, and programmatic activities to develop and implement data standards to promote equity, scalability, integrity, and sustainability of information sharing. In FY 2020, ONC will advance nationwide health IT interoperability through implementation of the Cures Act. Interoperability will lead to improved patient care, inform consumers, and provide transparency into the cost and quality of care.

In FY 2020, ONC's standards work will focus on application programming interface standards, demonstration projects and pilots, implementation testing, and collaboration with industry stakeholders. These efforts will modernize health care computing through standardized application programming interfaces to improve clinical workflow, enable robust competition for useful and interoperable health IT products, and enhance patient access to their health

data which has shown positive benefits as illustrated below.



Health IT Certification Program

The FY 2020 Budget prioritizes ONC’s mandate to operate the Health IT Certification Program, including the Certified Health IT Product List. The program maintains nearly 60 certification criteria used to standardize information across 21 federal efforts. By the end of 2018, the Certified Health IT Product List included health IT products from more than 600 health IT developers, and was used to register the EHR products of 550,000 care providers and hospitals participating in Medicare and Medicaid.

Combatting Information Blocking

In FY 2020, ONC’s budget will prioritize interoperability and usability of electronic health information. The Cures Act directs ONC to continue its work to combat information blocking and build health IT exchanges. ONC will aggressively implement Certification Program rules that prohibit information blocking, create and promote channels for reporting information blocking, and enforce relevant provisions required of the Cures Act. The Certification Program will continue its oversight responsibilities and improve the surveillance of certified products for adherence to technical, security, and regulatory requirements for interoperability, and assess the potential for information blocking.

Promoting Operational Efficiencies

In FY 2020, ONC will continue to reduce operational and administrative costs in information technology, space, staff training, and agency travel. ONC will continue to seek additional administrative and operational efficiencies.



	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Discretionary Budget Authority				
	39	39	30	-9
Civil Monetary Settlement Funds				
Settlement Funds	8	13	23	+10
Subtotal, Discretionary Budget Authority	39	39	30	-9
Total, Program Level	47	52	53	+1
Full-Time Equivalents /1	138	155	159	+4

1/ Includes Full-Time Equivalents supported at the Program Level.

The Office for Civil Rights is the Department's chief law enforcer and regulator of civil rights, conscience, religious freedom, and health information privacy and security.

The Fiscal Year (FY) 2020 Budget requests \$30 million for the Office for Civil Rights (OCR), \$9 million below the FY 2019 Enacted Level. OCR will use civil monetary settlement funds to support Health Insurance Portability and Accountability Act (HIPAA) enforcement activities, necessitating a smaller discretionary appropriation request. The Budget supports OCR's role as the primary defender of the public's right to:

- Nondiscriminatory access to, and receipt of, HHS-funded health and human services.
- Conscience and religious freedom protections.
- Access to, and 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.

Case receipts across the range of complaints have continually risen the past few fiscal years and are expected to once again increase in FY 2020. In FY 2018, OCR received 33,194 complaints, an increase of 10 percent from FY 2017, resolving 28,466 cases, a 16 percent increase.

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.

OCR will continue to address a broad range of critical civil rights issues that address compliance issues and are of paramount importance to the American people. Examples of these activities include:

- OCR's national multimedia public education campaign (launched in 2018) to safeguard the civil rights of persons seeking treatment for opioid use disorder and ensure all persons have equal access to treatment.
- In January 2018, as part of its disability non-discrimination work, OCR partnered with the Office of the Inspector General and the Administration for Community Living to jointly publish a report to help improve the health and safety of, and respect for the civil rights of, individuals living in group homes. OCR continues to participate in a series of Department-coordinated outreach events to discuss the recommendations with stakeholders and to educate the general public.

HEALTH INFORMATION PRIVACY AND SECURITY

General Authorities

OCR administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules (HIPAA Rules). OCR seeks to ensure covered entities understand and comply with their obligations under the HIPAA Rules, and to increase individuals' awareness of their HIPAA rights and protections. OCR accomplishes this objective by issuing regulations and guidance, conducting outreach, and providing technical assistance to the regulated community, in addition to pursuing investigations, settlement agreements, and civil monetary penalties.

OCR works to find and resolve substantial noncompliance with the HIPAA Rules. FY 2018 was a record year for OCR in enforcement: its collections, settlements, and judgments totaled over \$25 million. High profile cases send important messages to industry stakeholders about the importance of protecting health information; however, they represent only a small portion of OCR's enforcement work. OCR investigates every breach affecting the health information of 500 or more individuals, and closes over 95 percent of its cases after investigation – often through the provision of technical assistance to ensure compliance with HIPAA regulations.

OCR continues to issue guidance to providers and consumers to facilitate access to needed health information and prevent inappropriate disclosures. For example:

- OCR published HIPAA guidance in FY 2018 empowering doctors to share information with loved ones to help persons with opioid use disorder. Throughout the year, OCR conducted outreach with key stakeholder groups to raise awareness of this new and important guidance.

- In June 2018, OCR issued additional guidance required by the 21st Century Cures Act explaining certain requirements for authorization to use or disclose protected health information for future research. The guidance also clarified aspects of the individual's right to revoke an authorization for research uses and disclosures of their personal health information.

CONSCIENCE AND RELIGIOUS FREEDOM

In FY 2018, OCR issued a notice of proposed rulemaking to promote effective and comprehensive compliance with and enforcement of 25 federal health care conscience and associated anti-discrimination laws. In addition, OCR established a Conscience and Religious Freedom Division to ensure protection of the conscience and religious freedom rights of individuals and entities working in health care and human services. The Conscience and Religious Freedom Division provides a central point at 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. The Division is actively engaged in outreach, enforcement, and policymaking.

OCR conducts nationwide investigations and enforcement activities under HHS's conscience and religious freedom authorities. Unlike the Civil Rights and Health Information Privacy Divisions, the Conscience and Religious Freedom Division is responsible for managing the totality of a conscience or religious freedom complaint, including all case processing and investigation.

Office of the Secretary
Office of Inspector General



	<i>dollars in millions</i>			2020 +/-
	2018	2019	2020	2019
Health Care Fraud and Abuse Control (HCFAC) Program Discretionary	84	87	98	+11
HCFAC Mandatory	190	196	213	+17
HCFAC Collections	12	11	12	+1
Subtotal, HCFAC Oversight	287	294	323	+29
Public Health and Human Services Oversight Discretionary Budget /1	82	87	80	-7
Total, Program Level	369	381	403	+22
Full-Time Equivalents	1601	1650	1670	+20

1/ FY 2018 includes \$1.5 million for the FDA transfer (PL 115-245). Funding level does not include supplemental hurricane appropriations (\$2 million). FY 2019 Enacted includes the current annualized FY 2019 CR level of \$1.5 million for the FDA transfer (PL 115-245) and \$5 million required transfer from NIH in the Labor, Health and Human Services, and Education and Related Agencies appropriations bill.

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 Department of Health and Human Services, Office of Inspector General (OIG) is the largest inspector general's office in the federal government, with approximately 1,600 employees dedicated to combating fraud, waste and abuse and improving the efficiency of HHS programs. A majority of OIG's resources goes toward the oversight of Medicare and Medicaid—programs that represent a significant part of the federal budget and affect our country's most vulnerable citizens. OIG's oversight extends to programs under other HHS agencies such as the Centers for Disease Control and Prevention, National Institutes of Health, and the Food and Drug Administration.

The Fiscal Year (FY) 2020 Budget requests \$403 million for OIG, an increase of \$22 million above FY 2019 primarily for Medicare and Medicaid oversight. These funds will enable OIG to target oversight efforts and ensure efficient and effective use of resources within the Department's programs through the development of new data models and tools to support data-driven audits, evaluations, and inspections.

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 discretionary budget funds 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 issues and new cyber-security threats facing the Department.

The FY 2020 Budget requests \$80 million for Public Health and Human Services Oversight to strengthen the integrity of HHS programs through the following investments:

- **Indian Health Service:** OIG will continue providing oversight to promote quality of care, safety, and program integrity in the Indian Health Service.
- **Grants Oversight:** OIG will continue its focus on oversight of high-risk grant programs, including grants for services to children and grants for opioid abuse prevention and treatment programs provided under the 21st Century Cures Act. OIG will continue to provide training and education to prevent grant fraud, waste, and abuse. OIG will leverage successful approaches from Medicare and Medicaid oversight to help ensure high-risk grant

and contract funds are administered and used properly.

- **Privacy and Security:** OIG will enable HHS to enhance its cybersecurity and the security of public health data held in non-HHS systems through increased audits and penetration testing that identify risks and vulnerabilities. OIG will also support more investigations of cyber threats and criminals stealing valuable health care data to commit fraud.
- **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 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. 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 HCFAC Program to combat fraud, waste, and abuse in health care. The HCFAC Program provides funds to OIG dedicated to activities relating to Medicare and Medicaid fraud and abuse. Overall, HCFAC funding constitutes the major portion of OIG's annual operating budget.

The FY 2020 Budget for OIG includes \$323 million for Medicare and Medicaid oversight, an increase of \$29 million over FY 2019. The additional resources will support the development of new data models and tools to support data-driven audits, evaluations, and inspections. These models and tools will help OIG detect and target new and emerging fraud schemes, trends, and migration of known fraud schemes. Resources will be used to conduct reviews expected to

result in new recommendations for targeted program safeguards and improvements to prevent fraud, waste, and abuse and patient neglect; create efficiencies; and promote patient-centered outcomes, while also eliminating unnecessary burden on legitimate providers. With these resources, OIG will focus oversight on new technologies, including telehealth and digital technologies, that are increasingly being used by Medicare and Medicaid beneficiaries in their homes.

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 has identified serious health and human services program vulnerabilities in both the fiscal integrity of payments made for services delivered and the quality of care received in noninstitutional care settings. Funding will support expansion of prevention, detection, and enforcement efforts that help ensure the integrity, quality, and safety of the services rendered in homes and other noninstitutional care settings.

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 Medicaid Fraud Control Units on joint criminal investigations to tackle fraud, including in home- and community-based services, including 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.

OIG's "boots on the ground" initiative is designed to take enforcement actions against fraud perpetrators, including building OIG's capacity to respond to referrals generated by its own analyses.

OIG seeks to enhance program integrity in geographic hot spots through outreach, education, audits, evaluations, inspections, investigations, and administrative enforcement.

Medicare Managed Care

Approximately 30 percent of Medicare beneficiaries are enrolled in Medicare Advantage. OIG will continue to develop and implement a sustained, focused, and strategic initiative to combat fraud and abuse in Medicare Advantage. OIG will use audits, evaluations, investigations, and enforcement actions to prevent, detect, and remediate fraud, waste, and abuse in Medicare Advantage. These efforts will employ advanced data modeling and specialized clinical expertise, including medical record review.



Public Health and Social Services Emergency Fund

	dollars in millions			2020 +/- 2019
	2018 /1	2019	2020	
Assistant Secretary for Preparedness and Response (ASPR)				
Preparedness and Emergency Operations	25	25	25	--
National Disaster Medical System	57	57	77	+20
Hospital Preparedness Program	265	265	258	-7
Medical Reserve Corps	6	6	4	-2
Biomedical Advanced Research and Development Authority	537	562	562	--
Project BioShield	710	735	735	--
Strategic National Stockpile /2	604	610	620	+10
Policy and Planning	15	15	20	+5
Operations	31	31	31	--
Subtotal, ASPR	2,249	2,305	2,331	+26
Other Office of the Secretary				
Office of National Security (ONS) /3	8	7	7	--
Cybersecurity /3	50	59	68	+9
Subtotal, Other Office of the Secretary	58	66	76	+9
Pandemic Influenza				
No-Year Funding	215	225	225	--
Annual Funding	35	35	35	--
Subtotal, Pandemic Influenza	250	260	260	--
Total Discretionary Budget Authority				
	2,557	2,631	2,667	+35
Full-Time Equivalents	732	1,007	1,017	+10

1/ Reflects the FY 2018 enacted, post required and permissive transfers and rescissions. Funding level does not include supplemental hurricane appropriations (\$80 million).

2/ HHS administratively transferred the SNS from CDC to ASPR in FY 2019. Funding in FY 2018 is comparably adjusted and includes a Secretarial transfer of \$6.1 million to CDC for transition costs. Funding in FY 2019 does not reflect an additional Secretarial transfer of \$6.1 million to CDC.

3/ FY 2018 total reflects a realignment of \$1.04 million from Cybersecurity to ONS to support the cyber threat activities carried out by ONS.

The Public Health and Social Services Emergency Fund's mission is to directly support the nation's ability to prepare for, respond to, and recover from, the health consequences of naturally occurring and man-made threats.

Within the Office of the Secretary, the Public Health and Social Services Emergency Fund (PHSSEF) supports efforts across the U.S. Department of Health and Human Services (HHS) to safeguard the public and prepare the nation for a wide range of health security threats. The Fiscal Year (FY) 2020 Budget includes \$2.7 billion, an increase of \$35 million above FY 2019. Resources support the Department's biodefense capacity, information security needs, and disaster

response capability. The additional funds support medical countermeasure stockpiling, pediatric care during emergencies, and cybersecurity enhancements.

BIOTERRORISM AND EMERGENCY PREPAREDNESS

PHSSEF agencies support bioterrorism and emergency preparedness activities that prepare the nation to respond to, and recover from, natural and man-made

public health threats. HHS leads the federal response to public health emergencies and incidents covered by the National Response Framework. These responsibilities include coordinating public health and medical services, and supporting the delivery of mass care, emergency assistance, housing, and human services when state and local response and recovery needs exceed their capability. The PHSSEF supports many of the Department's key crosscutting preparedness and response efforts, including:

- Responding to emergency situations,
- Developing, procuring, and stockpiling medical countermeasures,
- Enhancing state and local health care readiness in coordination with the Centers for Disease Control and Prevention (CDC), and
- Supporting emergency response planning and policy coordination efforts across HHS.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The mission of the Assistant Secretary for Preparedness and Response (ASPR) is to save lives and protect Americans from 21st century health security threats. In partnership with other HHS Operating and Staff Divisions, ASPR prepares the nation to withstand public health and medical emergencies by promoting resilient communities, deploying emergency resources and medical personnel, and managing logistical support for disaster areas. ASPR collaborates with academia, non-government organizations, and private sector companies, including the pharmaceutical industry, to develop and manufacture vaccines, drugs, devices, and technologies to combat chemical, biological, radiological, and nuclear threat agents.

The FY 2020 Budget includes \$2.6 billion for ASPR, including Pandemic Influenza, an increase of \$26 million above FY 2019. This total reflects the FY 2019 transfer of the Strategic National Stockpile (SNS) from the CDC to ASPR. The Budget prioritizes enhanced pediatric care during emergencies, biodefense strategy coordination, and the advanced development of medical countermeasures through procurement, storage, and deployment. These investments ensure ASPR can fulfill its unique federal role to protect all Americans from the impact of natural disasters, terrorist threats, and emerging infectious diseases on their health.

Biomedical Advanced Research and Development Authority (BARDA)

The Budget includes \$562 million for BARDA to support the advanced development of medical countermeasures, including vaccines, therapeutics, diagnostics, and devices against chemical, biological, radiological and nuclear threats. BARDA works with public and private partners to transition candidate medical products from early development into the advanced and late stages of development and approval, licensure, or clearance by the Food and Drug Administration (FDA). BARDA provides clinical and non-clinical support services and advances innovative technologies and approaches to product development and manufacturing, including repurposing commercial products for bioterror needs and supporting the development of new multipurpose products for treating multiple illnesses.

MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

BARDA has proven successes of building a robust research and development pipeline for medical countermeasures, supporting 43 Food and Drug Administration (FDA) product approvals since 2006.

In 2018, nine medical countermeasures supported by BARDA achieved FDA approval including:



Antibiotics for complicated infections



Smallpox antiviral drug



Treatment for radiation exposure

In 2018, BARDA also supported critical manufacturing efficiency improvements to increase pandemic influenza vaccine production capacity.

The FY 2020 Budget will support advanced development of the highest priority medical countermeasures, including Ebola vaccines and therapeutics, broad-spectrum antimicrobials, treatments for illnesses caused by radiation and

thermal burns, and antidotes and diagnostics for chemical and biological agents. BARDA will also continue efforts under the Division of Research, Innovation, and Ventures (DRIVE) to expand public-private investment in innovative health security technologies and products. DRIVE accelerates health care innovation by supporting a nationwide network of accelerators along with venture capital practices to assist startups and businesses with developing transformative medical countermeasures. DRIVE is currently focused on enhancing medical countermeasure innovations in wearable diagnostics, distributed manufacturing technologies, and combatting sepsis.

Project BioShield

The Budget provides \$735 million for Project BioShield to support late-stage development and procurement of medical countermeasures for the Strategic National Stockpile. Following successful advanced development of medical countermeasures, BARDA supports late-stage development and potential procurement of promising products through Project BioShield. The products need to be of sufficient maturity for potential use during a public health emergency. Project BioShield's goal is to support late-stage development of products towards FDA approval. The FY 2020 Budget will support development and procurement of products, including:

- Ebola vaccines and therapeutics,
- a next generation anthrax vaccine,
- new antibacterial drugs,
- a therapeutic to minimize injury resulting from exposure to chemical agents, and
- new countermeasures to detect and treat acute exposure to ionizing radiation.

Progress achieved through Project BioShield continues to improve the nation's readiness to respond to the medical consequences of public health threats to homeland security. BARDA's commitment to advanced development and enhanced partnerships with industry under Project BioShield has led to the late-stage development and procurement of 27 medical countermeasures, of which 15 were delivered to the SNS and 10 achieved FDA approval since 2004. Products developed and procured through Project BioShield protect against adverse health effects of anthrax, botulism, smallpox, viral hemorrhagic fever, and chemical, radiological, and nuclear agents. BARDA anticipates three new products transitioning to Project

BioShield in FY 2020, as well as additional FDA product approvals.

BARDA's antimicrobial program leverages public-private partnerships to advance innovation in antibacterial drug, vaccine, and diagnostic development, supporting the government-wide National Action Plan for Combating Antibiotic Resistant Bacteria. Under BARDA's antimicrobial program, three products have been approved by the FDA that are able to treat hospital and community acquired bacterial infections and infections resulting from biothreat agents. BARDA also collaborates with the National Institutes of Health, academia, and private partners through the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X), which accelerates the efforts of numerous companies developing novel classes of antibiotics and new approaches to treating drug resistant bacterial infections. The Budget provides funding to continue to support BARDA's antimicrobial drug pipeline, new diagnostic technologies, and CARB-X investments.

Strategic National Stockpile

The Strategic National Stockpile (SNS) is the nation's largest federally owned repository of life-saving pharmaceuticals, medical equipment and supplies, and Federal Medical Stations that can be rapidly deployed to support federal, state, and local emergency responses. The SNS is the only federal resource readily available to respond when state and local medical supplies are depleted, or when unique medical supplies are required but not commercially available. The Budget provides \$620 million for the SNS, which is \$10 million above FY 2019. The transfer of the SNS to ASPR has consolidated strategic decision-making for product development and procurement and streamlined leadership to enable nimble responses to public health emergencies. The Budget supports procurement of products transitioned from Project BioShield, inventory replenishments, and continued training for responders nationwide to sustain state and local capabilities to receive and use stockpiled products when deployed. The increased funding level supports procurements of a newly developed thermal burn bandage and smallpox antiviral drug.

Hospital Preparedness Program

The Hospital Preparedness Program (HPP) is the only source of federal funding devoted to readying the United States' complex health care system to save lives and protect Americans. ASPR supports hospitals and

health care coalitions through HPP to expand critical care during large-scale emergencies. HPP improves response systems, conducts realistic exercises, builds collaborative partnerships, and facilitates valuable information sharing. The Budget provides \$258 million for ASPR's HPP, funding cooperative agreements with 62 awardees, including all 50 states, eight U.S. territories and freely associated states, and four localities, to continue support for hospital preparedness awards at the FY 2019 level. HPP will prioritize efficiency and effectiveness by continuing to incorporate risk into the funding formula.

National Disaster Medical System

The FY 2020 Budget provides \$77 million, an increase of \$20 million above FY 2019, to support the National Disaster Medical System (NDMS), a federally coordinated system of intermittent federal employees who deploy in the event of a natural or manmade disaster to provide critical medical services, protect public health, and help communities recover faster. The \$20 million increase will continue support for the pediatric disaster care pilot initiative which aims to improve pediatric care during emergencies. NDMS includes clinical and emergency medical providers that deploy to provide 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).

Medical Reserve Corps

The Medical Reserve Corps is a national network of over 200,000 volunteers organized into 1,000 community-based units across the U.S. The Budget provides \$4 million for ASPR's management of the Medical Reserve Corps. 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.

Office of Strategy, Planning, Policy, and Requirements

ASPR is tasked with implementing the government-wide, HHS-led National Biodefense Strategy. The President launched the National Biodefense Strategy in 2018 to protect America from modern biological threats. The strategy establishes the U.S. government's vision for biodefense, and also helps prioritize and coordinate federal biodefense activities.

Led by the Secretary, the Strategy's implementation requires complex coordination, leadership commitment, and an effective governance structure. The Secretary directed ASPR to lead the day-to-day coordination team to advance a whole-of-nation approach to biodefense. The Budget includes an additional \$5 million above FY 2019 to operationalize the Strategy across 17 covered agencies.

NATIONAL BIODEFENSE STRATEGY GOALS

- GOAL 1**
Enable risk awareness to inform decision-making across the biodefense enterprise
- GOAL 2**
Ensure biodefense enterprise capabilities to prevent bioincidents
- GOAL 3**
Ensure biodefense enterprise preparedness to reduce the impacts of bioincidents
- GOAL 4**
Rapidly respond to limit the impacts of bioincidents
- GOAL 5**
Facilitate recovery to restore the community, the economy, and the environment after a bioincident

PANDEMIC INFLUENZA

The Budget invests in pandemic influenza readiness by supporting domestic influenza vaccine manufacturing infrastructure; vaccine stockpiling; advanced development of novel influenza vaccines, therapeutics, diagnostics and respiratory protective devices; and international pandemic preparedness efforts. These activities maintain and improve the significant pre-pandemic preparedness and response capabilities

developed over the last decade, including technologies to improve and transform the nation’s approach to pandemic readiness. The FY 2020 Budget provides a total of \$260 million for pandemic influenza preparedness activities carried out by ASPR and the Office of Global Affairs.

The FY 2020 Budget will maintain current manufacturing capacity and accelerate the transition to, and further increase domestic production capacity of, modern cell or recombinant based influenza vaccines. The Budget also supports development of broadly effective influenza therapeutics or antivirals and rapid diagnostic tests to promote early detection of influenza viruses. ASPR invests in the advanced development of influenza countermeasure candidates through successful public-private partnerships with pharmaceutical companies that have the necessary infrastructure and manufacturing capacity to develop transformative influenza products.

DEPARTMENT-WIDE INFORMATION SECURITY

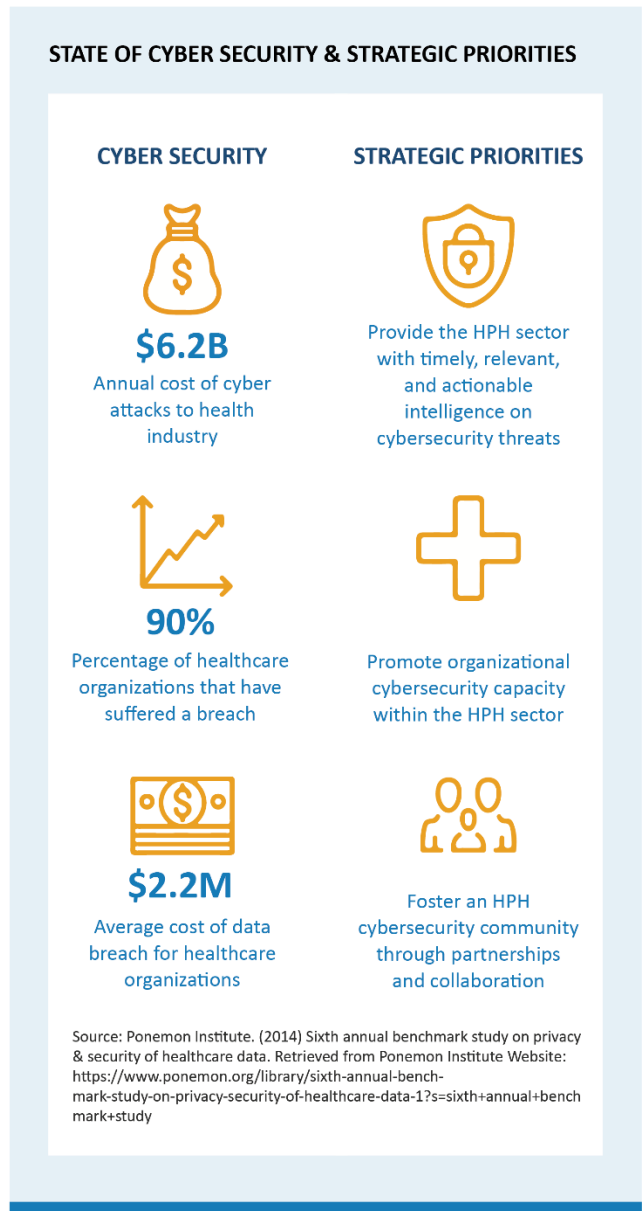
Office of National Security

The FY 2020 Budget includes \$7 million for the Office of National Security (ONS). ONS identifies, prioritizes, assesses, remediates, and protects critical infrastructure information for the health care and public health sectors. ONS integrates and synthesizes intelligence and all-source information on public health, terrorism, national security, weapons of mass destruction, and homeland security, and protects sensitive information for the Department. This funding will allow ONS to continue to serve clients across HHS, other U.S. government agencies, and 18 agencies within the intelligence community. ONS’s activities provide policymakers with early indicators and warnings of potential national security threats.

Cybersecurity

The Cybersecurity program ensures the Department’s critical information is secure. The FY 2020 Budget provides \$68 million for the Cybersecurity program, an increase of \$9 million above FY 2019. This funding supports solutions to identify, evaluate, acquire, coordinate, and deploy cybersecurity information and tools across the Department as well as the Health and Public Health sector. This increase will enable the Department to take action against cyber threats; limit the impact of those events; and engage with stakeholders, both internal and external to HHS, to provide cybersecurity solutions, workforce, and tools

integration to enhance threat identification and management.



Abbreviations and Acronyms

A

ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organization
ACT NOW	Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome
AFM	Acute Flaccid Myelitis
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
ALJ	Administrative Law Judge
APM	Alternative Payment Model
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
ASP	average sales price

B

BA	budget authority
BARDA	Biomedical Advanced Research and Development Authority
BPCI	Bundled Payments for Care Improvement

C

CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CBRN	chemical, biological, radiological, and nuclear
CCBHC	Certified Community Behavioral Health Clinic
CCDBG	Child Care and Development Block Grant
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPI-U	Consumer Price Index for all Urban Consumers
CR	Continuing Resolution
CY	Calendar Year

D

DAB	Departmental Appeals Board
DAWN	Drug Abuse Warning Network
DEA	Drug Enforcement Agency
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOJ	Department of Justice
DRIVE	Division of Research, Innovation, and Ventures
DSH	Medicaid Disproportionate Share Hospital

E

E/M	evaluation and management
EHR	electronic health record
ESRD	End-Stage Renal Disease
ET3	Emergency Triage, Treat, and Transport

F

FDA	Food and Drug Administration
FSMA	Food Safety Modernization Act
FY	Fiscal Year
FUL	Federal Upper Limit

G

GDM	General Departmental Management
GME	Graduate Medical Education

H

HCFA	Health Care Fraud and Abuse Control
HEAL	Helping to End Addiction Long-term
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITAC	Health Information Technology Advisory Committee
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
HMRF	Healthy Marriage Promotion and Responsible Fatherhood
HPOG	Health Profession Opportunity Grants
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
HSA	Health Savings Accounts

I

ICU	intensive care unit
IDeA	Institutional Development Award
IHS	Indian Health Service
InCK	Integrated Care for Kids Model
IPPS	Inpatient Prospective Payment System
IT	Information Technology

L

LTCH	Long Term Care Hospital
LIS	Low-income subsidy

M

MA VBID	Medicare Advantage Value Based Insurance Design
MAGI	Modified Adjusted Gross Income
MEPS	Medical Expenditure Panel Survey
MIPS	Merit-based Incentive Payment System
MOM	Maternal Opioid Misuse
MSA	Medicare Savings Accounts

N

NCI	National Cancer Institute
NDMS	National Disaster Medical System
NDNH	National Directory of New Hires
NEMT	Non-Emergency Medical Transportation
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
NIRSQ	National Institute for Research on Safety and Quality
NVDRS	National Violent Death Reporting System

O

OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
ONS	Office of National Security
OPPS	Medicare Outpatient Prospective Payment System

P

PACE	Program of All-inclusive Care for the Elderly
PHS	Public Health Service
PHSSEF	Public Health and Social Services Emergency Fund
PrEP	pre-exposure prophylaxis

R

RADV	Risk Adjustment Data Validation
RCORP	Rural Communities Opioids Response Program
RFI	Request for Information
RWHAP	Ryan White HIV/AIDS Program

S

SAMHSA	Substance Abuse and Mental Health Services Administration
SEP	Special Enrollment Period
SNS	Strategic National Stockpile
SSBG	Social Services Block Grant
STI	Sexually-Transmitted Infections

T

TANF	Temporary Assistance for Needy Families
TrOOP	true out-of-pocket costs
TB	tuberculosis

W

WAC	wholesale acquisition cost
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