
Fiscal Year 2016

# Budget in Brief

Strengthening Health and Opportunity for All Americans

U.S. Department of Health & Human Services

HHS.GOV













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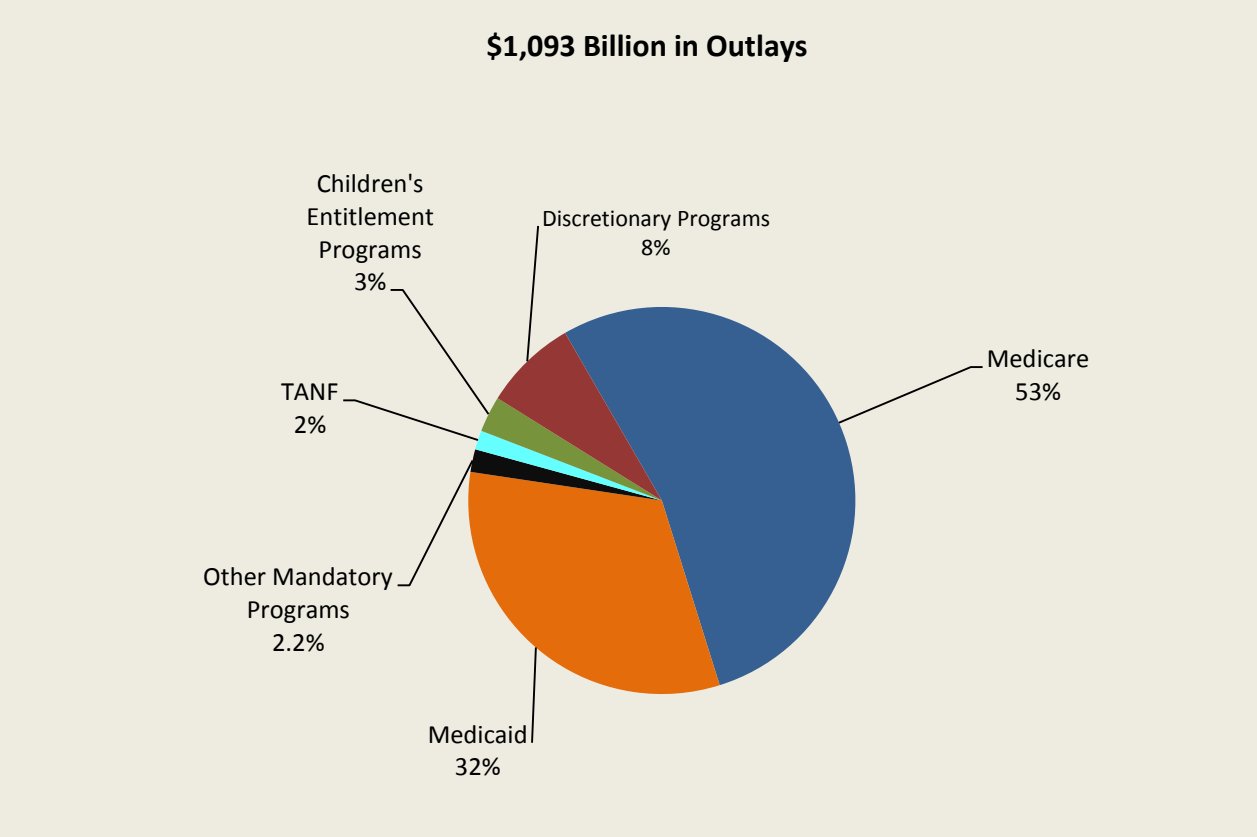
# ADVANCING THE HEALTH, SAFETY, AND WELL BEING OF THE NATION

## FY 2016 President's Budget for HHS

| *dollars in millions* | 2014 | 2015 | 2016 /1 |
|---|---|---|---|
| | | | |
| **Budget Authority** | **961,166** | **1,048,237** | **1,092,992** |
| **Total Outlays** | **936,223** | **1,013,051** | **1,093,041** |
| | | | |
| Full-time Equivalents (FTE) | 74,947 | 77,865 | 80,418 |
| 1/ FY 2016 estimates do not include the reductions to mandatory spending that will be applied in FY 2016 as required under the Budget Control Act. | | | |




**General Notes**

Detail in this document may not add to the totals due to rounding. Budget data in this book are presented "comparably" to the FY 2016 Budget since the location of programs may have changed in prior years or be proposed for change in FY 2016. This approach allows increases and decreases in this book to reflect true funding changes.

The FY 2015 and FY 2016 mandatory figures incorporate mandatory proposals reflected in the Budget.

# WELL-BEING OF THE NATION

*The Department of Health and Human Services enhances the health and well-being of 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 Budget for the Department of Health and Human Services (HHS) invests in scientific research, health care, disease prevention, early education, social services, and children's wellbeing, to support healthier families, stronger communities, economic opportunity, and a thriving America.

The President's fiscal year (FY) 2016 Budget for HHS includes investments needed to support the health and well-being of the nation, and legislative proposals that taken together would save on net an estimated $249.9 billion over 10 years. An additional $38.4 billion in savings over 10 years to Marketplace subsidies will be realized in the Department of Treasury programs and accounts. The Budget proposes $83.8 billion in discretionary budget authority, an increase of $4.8 billion from FY 2015. With this funding HHS will continue to create opportunities for children and families by ensuring the building blocks for success at every stage of life, promote science and innovation through critical investments, protect the nation's public health and national security, and focus on the responsible stewardship of taxpayer dollars.

## ACCESS TO QUALITY AFFORDABLE HEALTH CARE

The Affordable Care Act is working to expand health insurance coverage to millions of Americans, including many gaining coverage and access to health care for the first time. The Budget builds on the successes of the Affordable Care Act by extending funding for the Children's Health Insurance Program, improving and expanding coverage provided to American Indians and Alaska Natives through the Indian Health Service, expanding capacity in the nation's health centers, making strategic investments in the health care workforce to increase access for rural and underserved populations, and targeting Medicare and Medicaid payments to better support primary and preventive care. The Budget continues to make investments in federal public health and safety net programs to help individuals without coverage get the medical services they need while strengthening local economies.

***Expanding Access to Health Insurance Coverage.*** The Affordable Care Act is making quality, affordable health coverage available to millions of Americans who would otherwise be uninsured through expansion of Medicaid, the Marketplaces, and other private insurance reforms. As a result, the number of uninsured Americans was reduced by about 10 million people in the first year of full Affordable Care Act implementation. As of January 2015, 28 states and the District of Columbia have elected to expand Medicaid to low income adults with household income up to 133 percent of the federal poverty level. The Affordable Care Act is also increasing competition and choice among insurance plans. There are over 25 percent more issuers participating in the Marketplace in 2015 compared to 2014, and about 91 percent of consumers are now able to choose from three or more issuers for their coverage. Additionally, in the first month of open enrollment, 87 percent of consumers got financial assistance to help lower the cost of premiums.

***Extending the Children's Health Insurance Program.*** The Budget includes an additional four years of funding for the Children's Health Insurance Program (CHIP) through FY 2019 to align with the maintenance of effort requirement and ensure comprehensive and affordable coverage for children covered by CHIP. This extension will provide stability to state budgets and continuity of coverage to families who rely on CHIP. This proposal is paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives.

***Securing IHS Contract Support Costs.*** The Budget fully funds Contract Support Costs in FY 2016 and proposes to modify the program in FY 2017. In FY 2016, Contract Support Costs will be funded at $718 million, an increase of $55 million over FY 2015. These funds are paid to tribes that administer their own health care programs to cover reasonable costs that the Department did not incur when providing for the direct operation of the program. In FY 2017, the Contract Support Costs program will be reclassified as mandatory providing a long-term approach to fully fund

Contract Support Costs and ensuring that tribes receive the support they need to provide health care to their members.

***Investing in Health Centers.*** Health centers are an essential primary care provider for America's most vulnerable populations. The Budget includes $4.2 billion for health centers, including $2.7 billion in mandatory resources, to serve approximately 28.6 million patients in FY 2016 at more than 9,000 sites in medically underserved communities throughout the country. These resources will support the establishment of 75 new health center sites in areas of the country where they do not currently exist, advance health centers' efforts provide quality primary health care services, and support on-going efforts to help uninsured patients navigate their insurance options, enroll in affordable coverage, and understand their benefits.

***Bolstering the Nation's Health Workforce.*** The Budget makes strategic investments in our nation's health care workforce to ensure rural communities and other underserved populations have access to doctors and other providers. The Budget includes a $14.2 billion investment beginning in FY 2016 to bolster the nation's health workforce and to improve the delivery of health care across the country.

***Extending the National Health Service Corps.*** National Health Service Corps clinicians serve in medical facilities in high-need areas of the country, including rural areas and federally funded health centers, where access to care is limited and where shortages of health care professionals often persist. The Budget includes $2.6 billion in mandatory resources for the National Health Service Corps for FY 2016 through FY 2020, which is in addition to $287 million in discretionary funding requested for the program. The proposed investment by the Health Resources and Services Administration (HRSA) is projected to support a historically high field strength of over 15,000 providers and to serve the primary care needs of nearly 16 million patients.

***Reforming Graduate Medical Education.*** The focus of the Targeted Support for Graduate Medical Education program will be to support primary and preventive care, in order to advance the Administration's goals of higher-value health care that reduces long-term costs. Between FY 2016 and FY 2025, the Budget includes $5.3 billion in total mandatory funding for the Targeted Support program, to be distributed through a competitive grant program to teaching hospitals, children's hospitals, and community-based consortia of teaching hospitals or other health care entities. This investment will support more than 13,000 residents over 10 years.

***Promoting Medicaid and Medicare Primary Care.*** To continue encouraging provider participation in Medicaid, the Budget invests $6.3 billion to extend the enhanced Medicaid reimbursement rate for primary care services through December 31, 2016, expands the program to include additional providers, and targets the funding by excluding emergency department care. The Budget also supports making the temporary 10 percent Medicare primary care incentive payment program permanent in a budget neutral manner to further expand primary care services.

## HEALTH CARE DELIVERY SYSTEM REFORM FOR QUALITY AND ECONOMY

HHS has made tangible progress in helping to lower costs and improve quality and safety across the health care system. Growth rates for total health care expenditures and Medicare are historically low. At the same time, in part due to the Affordable Care Act, substantial reductions to readmissions and harm to patients have also been realized.

***Improving the Way Care is Provided.*** To drive progress on the way care is provided, the Administration is focused on improving the coordination and integration of health care, engaging patients more fully in decision-making, and improving the health of patients – with an emphasis on prevention and wellness. HHS believes that incentivizing the provision of preventive and primary care services will improve the health and well-being of patients and reduce costs over the long run through avoided hospitalizations and additional office visits.

Furthermore, incentivizing and supporting clinicians and providers to deliver care to beneficiaries in the lowest cost and most clinically appropriate setting is a major opportunity for increased efficiency in our healthcare system.

***Improving the Way Information is Distributed.*** The Administration is improving the way information is distributed by working to create transparency of cost and quality information and to bring electronic health information to the point of care. These efforts will enable patients and providers to make the right decisions at the right time to improve health and care. The Centers for Medicare & Medicaid Services (CMS) is making major strides to expand and improve its provider compare websites, which empower consumers with information to make more informed health care decisions, encourage providers to strive for higher levels of quality, and drive overall health system improvement. In September, CMS released the first set of data under Open Payments, a national disclosure program created by the Affordable Care Act that promotes transparency and accountability by making information about financial arrangements between drug and device manufacturers and physicians and teaching hospitals available to the public.

Improved communication can help providers make more informed care decisions and coordinate the care they provide. The adoption and meaningful use of electronic health records was the first step towards achieving interoperability of health systems to improve communication and enhance care coordination for patients. The FY 2016 Budget includes $92 million for activities in support of interoperability and Meaningful Use. The Office of the National Coordinator for Health Information Technology (ONC) will expand the certification program in order to meet the requirements of meaningful use of health IT across the care continuum and including public health. The Budget supports ONC's efforts to implement the 2015-2020 Federal Health IT Strategic Plan and the National Roadmap to Interoperability. As of November 2014, 428,317 eligible professionals, hospitals, critical access hospitals, and Medicare Advantage organizations have attested as meaningful users of health information technology, accounting for $26.4 billion in incentive payments through the Medicare and Medicaid electronic health records (EHR) incentive program. HHS is on track to meet the performance goal of 450,000 providers receiving incentive payments for demonstrating meaningful use of health IT in 2015.

***Improving the Way Providers are Paid.*** To improve the way providers are paid, the Administration is testing and implementing new payment models that reward value and care coordination – rather than volume and care duplication. The Budget includes proposals targeted at changing provider incentives and payment mechanisms. One of these proposals represents an improvement in physician payment that replaces the recurring threat of payment reductions known as the Sustainable Growth Rate. The Budget would eliminate this payment system and establish annual physician payment updates while creating incentives for physicians and other practitioners to participate in alternative payment models focused on quality and efficiency. It would also streamline value-based incentives for the physicians who remain outside of such models.

***Studying Health Insurance.*** As part of the Administration's commitment to incorporating evidence and evaluation into policy solutions, the Budget includes $30 million for a new project to examine how changes in health insurance benefit packages impact health care utilization, costs, and outcomes. This project will use the gold standard randomized controlled trial study design to update the Health Insurance Experiment, a groundbreaking trial begun in 1971 that has benefited policymakers for more than forty years. A new effort is needed to rigorously examine how modern health insurance plans can be redesigned to maximize health status and quality, and minimize unnecessary costs. The requested funds will enable HHS to plan and initiate the study using state-of-the-art evaluation methods to answer critical research questions that cannot be directly addressed through other means. The study will inform the development of health care

models that work better for families and providers.

## KEEPING AMERICA HEALTHY

***Investing in a Domestic and International Public Health Preparedness Infrastructure.*** Epidemic threats to national security arise at unpredictable intervals and from unexpected sources. Because these threats do not recognize national borders, the health of people overseas directly affects America's safety and prosperity, with far-reaching implications for economic security, trade, the stability of foreign governments, and the well-being of U.S. citizens abroad and at home. The Budget includes $975 million for CDC and Assistant Secretary for Preparedness and Response (ASPR) for domestic and international public health preparedness infrastructure, an increase of $22 million above FY 2015, including $12 million for Global Health Security Agenda Implementation, to build the capacity for a country to detect and respond to a potential disease outbreak or public health emergency and prevent the spread of disease across borders.

The Budget also includes $110 million to respond to unanticipated public health emergencies through support for domestic international activities, such as state and local response and emergency staffing, hospital and containment facilities, infection control, laboratory equipment and supplies, data gathering and analysis, countermeasures, and other potential needs in such an incidence. Within the total, there are resources for staff coordination and training, command and control, and other related logistical needs.

***Addressing Prescription Drug and Opioid Misuse.*** The misuse of prescription drugs impacts the lives of millions of Americans across the country. At the same time, it costs the American economy tens of billions of dollars in lost productivity, increased health care, and criminal justice expenses. As part of a new, aggressive, multi-pronged initiative, the Budget includes more than $99 million in new funding this year in targeted efforts to reduce the prevalence and impact of opioid use disorders. These investments, prioritized by the best evidence available and the greatest opportunity for measurable impact, are in addition to a package of policy changes and executive actions that will further drive reforms.

***Fighting Prescription Drug and Opioid Misuse, Abuse, and Overdose Death Prevention.*** The Budget includes $99 million in new investments across HHS to fight misuse and abuse of prescription opioids and heroin, which together take the lives of 20,000 Americans per year. This investment includes a $54 million increase for the Centers for Disease Control and Prevention (CDC). These funds would support grants to all 50 states for improvements to prescription drug monitoring programs, such as interstate interoperability and improved proactive reporting. Grants will also support national-level activities, including patient safety improvements and enhancements in data quality and monitoring with an emphasis on real-time mortality data. CDC will also apply its scientific expertise to identify risk factors for initiating heroin use to best prioritize prevention efforts throughout the Department and develop and track pain management and opioid prescribing quality measures. These funds will also support an evaluation of demonstration programs proposed for FY 2016 administered by the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Budget includes a $35 million increase for SAMHSA to increase access to opioid addiction treatment services, to implement a community-based demonstration to equip first responders with the overdose reversal drug naloxone and education on its use, and to help state substance abuse authorities develop comprehensive prevention approaches through collaboration with state partners and integration of health information technology systems with strategic plans. The Budget includes a $5 million increase for ONC to improve the integration of Prescription Drug Monitoring Programs with health information technology. In addition, a $5 million increase is included within AHRQ to provide a robust review of evidence and evaluation support regarding Medication Assisted Treatment in primary care settings.

***Tracking High Prescribers of Prescription Drugs.*** The Budget proposes to require states to track high prescribers and utilizers of prescription drugs in Medicaid. By requiring states to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program, this proposal would improve program integrity, save $710 million over 10 years, and bolster other efforts to reduce abuse of prescription drugs.

***Addressing Over Prescription of Psychotropic Medications for Children in Foster Care.*** The Budget includes $500 million for a new Medicaid demonstration in partnership with the Administration for Children and Families (ACF) to provide performance-based incentive payments to states through Medicaid, coupled with $250 million in mandatory child welfare funding to build provider and systems capacity through a specialized workforce with specific training, screening and assessment tools, coordination between systems, and fidelity monitoring of the evidence-based interventions. This transformational approach will encourage the use of evidence-based screening, assessment, and treatment of trauma and mental health disorders among children and youth in foster care to reduce the over-prescription of psychotropic medications and improve social and emotional outcomes for some of America's most vulnerable children.

***Reducing Abuse of Part-D Drugs.*** The Budget proposes to establish a program in Medicare Part D to prevent prescription drug abuse by requiring that high-risk beneficiaries only obtain controlled substances from specified providers and pharmacies.

***Bringing Mental Health Out of the Shadows.*** Mental and medical condition comorbidity results in decreased length and quality of life, and increased functional impairment and cost. Patients diagnosed with a serious mental illness die 25 years earlier than other Americans, and they are also among the least likely to seek treatment. The Budget includes an increase of $35 million, a total of $151 million, within SAMHSA for the President's *Now is the Time* initiative to make sure students and young adults get treatment for mental health issues. Reaching 750,000 young people per year and training thousands of additional behavioral health professionals and paraprofessionals, this investment represents a substantial step toward bringing mental health out of the shadows. Additional funds will be used to increase workforce capacity across the nation by expanding an existing partnership with HRSA that addresses the number of licensed behavioral health professionals available and by creating a Peer Professionals program to get training for individuals who have lived through their own battle with behavioral health issues to help reach those in need of treatment. In addition, this increase will help change the attitudes of Americans about mental and substance use disorders and their willingness to seek help through a social media campaign and other outreach efforts.

The Budget also proposes the elimination of Medicare's 190-day lifetime limit on inpatient psychiatric facility services, removing one of the last obstacles to behavioral health parity in the Medicare benefit.

***Promoting Upward Mobility.*** Improving coordination and effectiveness of anti-poverty programs is essential to moving families out of poverty and into the middle class. As part of the Administration's commitment to achieving economic mobility, the Budget provides $1.5 billion over 5 years in additional competitive funding that will allow up to ten states, localities, or consortia of states and localities, to use funding from up to four block grants to implement evidence-based and promising strategies for helping individuals succeed in the labor market and improving economic mobility, children's' outcomes, and the ability of communities to expand opportunity. The Upward Mobility Projects would build on successful safety net programs, like the Supplemental Nutrition Assistance Program, housing assistance, and tax credits, that help families make ends meet and promote children's health and educational outcomes.

***Addressing Viral Hepatitis.*** Viral hepatitis is the leading cause of liver cancer and the most common reason for liver transplantation in the United States. An estimated 4.4 million Americans are living with chronic hepatitis; most do not know they are infected. In addition to causing substantial morbidity and mortality, viral hepatitis infection has adverse economic consequences. The Budget includes $63 million for CDC's Viral Hepatitis program, an increase of $32 million over FY 2015 to focus on controlling the emerging epidemic of hepatitis C virus infection in young people, working to eliminate mother-to-child transmission of hepatitis B virus infection, and decreasing premature death resulting from chronic viral hepatitis infection. These priorities are aligned with the HHS Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis.

***Improving Tribal Health.*** The Budget reflects the President's reaffirmed commitment to ensure tribal members are able to lead healthy and productive lives. The FY 2016 Budget funds IHS at $6.4 billion, an increase of $486 million over FY 2015. The Budget prioritizes providing quality health care services to Indian Country through both the IHS and tribal health care systems. The Budget includes funding for rising health care costs due to medical inflation, population growth, and pay costs for health care providers, ensuring increased levels of health care are provided to American Indians and Alaska Natives. Also, the Budget expands the Purchased/Referred Care program, provides funding for a new program to help IHS and tribal facilities maximize reimbursements from third-party payers, and funds a crucial health information technology project. As in past years, funding is provided for staffing and operating costs for new and replacement health care facilities that expand both IHS and tribal capacity to provide health care services. The Budget also provides funding for collaboration with SAMHSA to fund programs targeted at Native American Youth through the government-wide Generation Indigenous initiative. This funding will allow IHS to expand the successful Methamphetamine and Suicide Prevention initiative to hire providers to work directly with Native Youth.

***Improving Health through Improved Care Coordination.*** People with multiple chronic conditions represent a growing segment of the population and currently comprise over one-quarter of the U.S. population and two-thirds of Medicare beneficiaries. These individuals are at high risk for adverse health outcomes, use more health care services, and have higher rates of disability, poor quality of life and premature death. The FY 2016 Budget includes $12 million for a new initiative by AHRQ to improve the care and quality of life of patients with multiple chronic conditions. This initiative addresses the challenges of a growing high-cost, high-need patient population by developing and evaluating evidence-based tools to improve care coordination.

## ADVANCING SCIENCE AND RESEARCH

Innovative scientific research and technological breakthroughs are vital for the nation to succeed and thrive in the 21st century. The nation depends on science, technology, and innovation to protect the safety and health of the American people and promote sustainable economic growth and job creation. It is also critical to ensure that the nation's food supply is safe and secure by enhancing domestic and international capacity and establishing standards based on scientific and public health expertise to address today's complex food safety challenges. The FY 2016 Budget continues strong investments in these areas to ensure that the nation remains at the forefront of new discovery and improves public health.

***Supporting Biomedical Research for Real World Applications.*** As a result of long-term national investments, scientific and technological breakthroughs generated by research supported by the National Institutes of Health (NIH) are behind much of the gains in health and longevity that the nation has enjoyed. For example, deaths from heart disease have been reduced by more than 70 percent from 1950 to 2008, and cancer death rates have been dropping about one percent annually for the past 15 years. The FY 2016 Budget includes $31.3 billion for NIH, an

increase of $1 billion over FY 2015, to continue such progress and maintain the nation's leadership in the life sciences. NIH's main areas of emphasis for FY 2016 include advancing basic biomedical and behavioral research, translating basic discoveries into applications that improve the health of patients and communities, harnessing data and technology to further benefit health, and preparing a diverse and talented biomedical research workforce. In FY 2016, NIH estimates it will support a total of 35,447 research project grants, including over 10,000 new and competing awards.

***Addressing Alzheimer's Disease.*** Alzheimer's disease already afflicts over 5 million Americans and costs the nation approximately $200 billion per year in health costs – and those numbers are projected to rise steadily as the population ages. Recent advances in our understanding of the genetics and biology of Alzheimer's have identified new potential targets for innovative therapies to slow and ultimately prevent this devastating disease. NIH estimates it will spend $638 million on Alzheimer's research in FY 2016, an increase of $51 million over FY 2015 to implement the research components of the *National Plan to Address Alzheimer's Disease*, a roadmap to assist in meeting the goal to prevent and effectively treat Alzheimer's by 2025. Recent research has led to more than 25 drugs in clinical trials for Alzheimer's disease, with many more in the pipeline for human testing.

***Combating Bacteria Resistant to Common Antibiotics***. As more strains of bacteria become resistant to an ever-larger number of antibiotics, our treatment choices become increasingly limited, expensive, and in some cases, nonexistent. If this problem continues to expand, a wide range of routine medical procedures could pose a significantly higher risk to patients of developing a potentially untreatable, antibiotic-resistant infection. Annually, at least 2 million illnesses and 23,000 deaths are cause by antibiotic-resistant bacteria. The Administration has prioritized scientific and public health efforts to detect, prevent, and control illness and death related to antibiotic-resistant infections, consistent with the recently released *National Strategy for Combating Antibiotic-Resistant Bacteria*. The FY 2016 Budget includes a total of $993 million, an increase of $491 million across HHS to accelerate progress in these areas. This funding will specifically support research and development and clinical trials of new drug candidates and diagnostic products to ensure the continued availability of effective therapeutics for the treatment of bacterial infections; surveillance activities to detect the emergence of new antibiotic-resistant threats; and prevention efforts to promote best practices on antibiotic use in health care settings.

***Securing the Nation's Food Supply.*** The burden of foodborne illness is considerable. Every year, 1 out of 6 people in the United States suffers from foodborne illness, more than 100,000 are hospitalized, and thousands die. The economic loss to industry, farmers, and the public from foodborne diseases is estimated to be over $75 billion a year. HHS has helped advance a more modern food safety system that is shifting from reacting to foodborne illness outbreaks, to one that is poised to prevent outbreaks and enhance response activities in coordination with other federal, state, local, and foreign partners. The FY 2016 Budget includes $1.6 billion within the Food and Drug Administration (FDA) and CDC, an increase of $303 million over FY 2015, to support a broad range of food safety activities. These investments will further the Department's implementation of the Food Safety and Modernization Act by improving surveillance systems; enhancing response and detection; and establishing the framework for an integrated federal, state, and local system; and improving import safety to prevent foodborne illnesses from domestic and international foods and feed.

In addition, the President is seeking broad reorganization authority in the FY 2016 Budget. With this authority, the Administration is proposing to consolidate the Department of Agriculture's Food Safety Inspection Service and the food safety components of the Food and Drug Administration to create a single new agency within HHS. The new agency would be charged with pursuing a modern, science-based food safety regulatory regime drawing on best

practices of both agencies, with strong enforcement and recall mechanisms, expertise in risk assessment, and enforcement and research efforts across all food types based on scientifically supportable assessments of threats to public health. The Budget schedules for these agencies and programs continue to reflect them in their current alignment.

***Advancing Countermeasure Development.*** As new infectious diseases and public health threats emerge, HHS continues to invest in efforts to bolster the nation's preparedness against chemical, biological, nuclear, and radiological threats. The FY 2016 Budget includes $646 million, an increase of $391 million, for Project BioShield to support procurements and replenishments of new and existing countermeasures and to advance final stage development of new products. To complement these efforts, the Budget also includes $571 million, an increase of $37 million above FY 2015, within CDC to support the Strategic National Stockpile. Strategic procurement, storage, and maintenance of medical countermeasures are necessary to protect lives during a public health emergency. The requested funding level for the Stockpile will enable CDC to replace some expiring countermeasures and maintain the current preparedness levels.

***Advancing Precision Medicine.*** The FY 2016 Budget includes $215 million for a new cross-Department initiative to focus on developing treatments, diagnostics, and prevention strategies tailored to the individual genetic characteristics of each patient, also known as precision medicine. This effort includes $200 million for NIH to launch a national research cohort of a million or more Americans who volunteer to share their genetic information, expand current cancer genomics research, and initiate new studies on how a tumor's DNA can inform prognosis and treatment choices. FDA will spend $10 million to modernize the regulatory framework to aid the development and use of molecular diagnostics in precision medicine, and ONC will use $5 million in FY 2016 to help develop technology and define standards and certification criteria to enable the exchange of genomic data. The Office for Civil Rights will also work with the participating agencies to ensure that adequate privacy protections are in place to support implementation of this initiative.

## SERVING AMERICANS AT KEY STAGES OF LIFE

HHS seeks to serve Americans at key stages of life, when many may be at their most vulnerable. Investments that promote the safety, well-being, resilience, and healthy development of our nation's children and youth will ultimately pay dividends, as the children of today grow into the employees, parents, and leaders of tomorrow. The Budget also makes investments to help older Americans live as independently as possible while maintaining their freedom and dignity.

***Early Learning.*** In the FY 2016, the President calls on Congress to create a continuum of early learning opportunities from birth through age 5 by providing high-quality preschool for every child, guaranteeing quality child care for working families, growing the supply of early learning opportunities for young children, and expanding investments in voluntary, evidence-based home visiting programs.

***Child Care Development Fund.*** The President's budget makes a historic investment in early childhood education by providing an additional $82 billion over ten years in mandatory funding for the Child Care and Development Fund to ensure that all low-income working families with children ages three or younger have access to quality, affordable child care. This investment will increase the total number of children served to more than 2.6 million, reaching over 1.1 million additional children, and ensuring that the youngest children from the most vulnerable communities are in high quality settings where they are safe and ready to learn. The Budget also provides a $266 million increase in discretionary funding in 2016 to help states implement the policies required by the new bipartisan child care law and improve the safety and quality of care while giving parents the information they need to make good choices about their child care providers. The Budget also includes $100 million for competitive grants to test and evaluate innovative child care models that better meet the

needs of working families, including those who work non-traditional hours.

***Investing in Head Start.*** The Budget includes an additional $1.5 billion above FY 2015 to improve the quality of Head Start services and expand access to Early Head Start, including through Early Head Start – Child Care Partnerships. A total of $1.1 billion will ensure that every Head Start program provides services for a full-day and a full-school year, which research shows promotes better outcomes for young children. An additional $150 million will expand access to high-quality early learning programs for infants and toddlers through Early Head Start and Early Head Start – Child Care Partnerships, and $284 million will help programs keep pace with rising costs without diminishing the quality of services.

***Expanding Home Visiting.*** Home Visiting programs have been shown to improve maternal and child health outcomes in the early years, leaving long-lasing, positive impacts on parenting skills, children's development, and school readiness. The Budget seeks to extend and expand voluntary, evidence-based home visiting services through the Maternal, Infant, and Early Childhood Home Visiting program by providing $500 million in FY 2016, and $15 billion in mandatory funding from FY 2016 to FY 2025.

***Retaining Care for Children.*** The Budget would lift the exclusion of federal funds for comprehensive health care services for Medicaid-enrolled children receiving inpatient psychiatric treatment to ensure provision of essential health services to vulnerable populations.

***Promoting Family-Based Care and Reducing the Use of Congregate Care for Children in Foster Care.*** The Budget includes a proposal to provide additional support and funding to the child welfare system to promote family-based care, and to provide oversight of congregate care. The proposal includes training and resources for foster care parents to provide specialized care to children with complex mental health and behavioral health needs and a new provision to ensure that congregate care is only used when necessary.

***Enhancing Prevention and Permanency Services in the Child Welfare System.*** The Budget proposes to allow additional federal funding for prevention and post-permanency interventions in the child welfare system. A majority of those services must be evidence-based or evidence-informed. Providing such services is often key to preventing the removal of a child from his or her family and being placed into foster care, re-entering into foster care after reunification, or disrupting adoptions. This proposal represents a strategic shift of federal investment to the front-end of the service delivery system to prevent removals and foster care placement from the outset.

***Supporting Older Adults.*** In FY 2016, HHS also seeks to make key investments to address the needs of older Americans, many of whom require some level of assistance to continue living independently or semi-independently within their communities. The Budget also enacts common-sense reforms that help to protect older Americans from identity theft.

***Supporting Family Caregivers.*** The FY 2016 Budget provides $15 million for a new Family Support Initiative focused on ensuring the optimal deployment of public and private resources at the state and community level to support family members caring for older adults and/or people with disabilities across the lifespan. Research suggests that informal family care for the elderly is valued at over $500 billion annually, an amount that exceeded total Medicaid expenditures in 2013. Additionally, over 75 percent of people with developmental disabilities rely primarily on family caregivers. The Family Support Initiative will complement the $151 million in funding included in the FY 2016 Budget for Family Caregiver Support Services and spur innovation to support and sustain the largest provider of our nation's long-term care: families.

In addition, the Budget includes $5 million for Lifespan Respite Care, $3 million more than FY 2015, to provide resources that will allow caregivers to continue care for their loved ones for longer, and thereby allow more care recipients

to remain at home and independent for longer periods of time.

***Providing Nutrition Assistance for Older Americans.*** Nutrition Services are a vital support for older Americans nationwide, many of whom are low-income, as meals provided through home delivery or in senior centers allow many older Americans to remain independent and living at home for as long as possible, delaying or preventing the need for more costly institutional services. The FY 2016 Budget includes over $875 in funding for the Administration for Community Living (ACL) Nutrition Services programs, $60 million more than was provided for these programs in FY 2015. Leveraged further by state and local funding, $40 million of this increase will allow states to continue to provide 208 million meals to over 2 million older Americans nationwide, helping to halt the decline in service levels for the first time since 2010. In addition to these core investments in Nutrition Services, the FY 2016 Budget invests the remaining $20 million in evidence-based innovations to help ensure that future funding for Nutrition Services programs is spent as efficiently as possible to maximize the impact of these funds.

***Protecting Seniors from Identity Theft.*** Protecting seniors from identity theft is a top priority for the Administration. This Budget requests $50 million to support the removal of Social Security Numbers from Medicare cards, so that millions of beneficiaries will no longer have to fear that their personal identification numbers could be used against them due to a lost, stolen or misused Medicare card.

***Improving Access to Medicaid Home and Community-Based Services.***
The Budget provides states the option to expand eligibility for the Community First Choice and 1915(i) home and community-based state plan options. The Budget also provides states the option to offer full Medicaid eligibility to medically needy individuals who access home and community-based services under the 1915(i) state plan option.

***Advancing Comprehensive Medicaid Long-Term Care.*** The Budget proposes an eight-year pilot program to create a Medicaid comprehensive long-term care state plan option for up to five states. Participating states would be authorized to provide long-term care services across the continuum of care under one authority, creating equal access to home and community-based care and nursing facility care. The Secretary would have the discretion to make these pilots permanent at the end of the eight years. This proposal works to end the institutional bias in long-term care and simplify state administration.

## CREATING A STRONGER DEPARTMENT

The Budget better positions the Department to fulfill its core mission to protect the health of Americans and provide essential human services. Investments in programs and the infrastructures that support them will improve transparency and efficiency across HHS. These improvements will allow HHS to not only meet the challenges of today, but also those of tomorrow.

***Investing in Cybersecurity.*** As cyber threats continue to multiply and become more complex, it is critical for the U.S. government to ensure that its information systems are protected from any potential attacks. In FY 2016, HHS proposes $73 million, $28 million above FY 2015, to manage and provide oversight to the Department's Cybersecurity Program. This investment is designed to reinforce and protect the Department's information technology systems against the growing threats within the cyber community. This funding also supports the Department's ability to quickly respond to evolving security threats and to better support ongoing infrastructure upgrades. The Budget includes funding to support the continued expansion of the Cybersecurity Operations program, enabling the Department to better ascertain the overall security risk to its systems and ensure compliance with requirements of the Federal Information Security Management Act.

***Improving Data Access and Innovation.*** The FY 2016 Budget includes funding to support HHS in its continuous improvement of the efficiency

and effectiveness of its operations and the transparency of federal spending.

The Budget includes $10 million to support the implementation of the Digital Accountability and Transparency Act and to formulate new data standards for grants. HHS will assess the impact of those standards on HHS' financial policies, processes and systems to ultimately improve data quality, reduce compliance costs and reporting burden for grant recipients, and improve overall business practices.

The Budget includes $10 million to create a Digital Service Team within HHS. The Digital Services Team will drive efficiency and effectiveness of the agency's highest-impact digital services.

The Budget includes $3 million for the HHS IDEA Lab, which will channel talents of the current workforce in an effort to modernize and increase government efficiency. The IDEA Lab will improve HHS services, business practices, and facilitate the mission of the Department.

***Reforming Medicare Appeals.*** To improve the efficiency of the Medicare appeals system and reduce the backlog of appeals awaiting adjudication at the Office of Medicare Hearings and Appeals (OMHA), HHS has developed a comprehensive strategy that involves additional funding, administrative actions, and legislative proposals. The Budget invests new resources at all levels of appeal to increase adjudication capacity and implements new strategies to alleviate the current backlog. The Budget includes $36 million for CMS to engage in discussion with providers to resolve disputes and additional funding for greater participation in Administrative Law Judge Hearings at OMHA. Additionally, the Budget includes $270 million for OMHA, of which $140 million is in budget authority and $130 million is from legislative proposals. OMHA received over 600,000 claims in FY 2013 and close to 1,000,000 claims in FY 2014. The Budget will expand adjudicatory capacity in new field offices in order to address the backlog in the number of appeals and maintain the quality and accuracy of its decisions. The Budget also includes a package of legislative proposals that provide new authority and additional funding to address the backlog.

***Strengthening Program Integrity.*** The FY 2016 Budget continues to make cutting health care fraud, waste, and abuse a top Administration priority. It includes new investments in program integrity totaling $201 million in FY 2016 and $4.6 billion over ten years. These investments include continuing to fund the full Health Care Fraud and Abuse Control discretionary cap adjustment, increasing mandatory Medicaid Integrity Program funding, and providing more funding to recovery auditors to undertake more corrective actions that will help reduce improper payments. In total program integrity investments in the Budget will yield an estimated $21.7 billion in savings to Medicare and Medicaid over ten years. In addition, the Budget supports efforts to monitor and prevent fraud, waste and abuse in the private health insurance market including the Health Insurance Marketplace.

***Building Indian Health Service Facilities.*** The FY 2016 Budget requests an increase of $179 million for Indian Health Service facilities to support construction across Indian Country. The Maintenance & Improvement program, which provides repairs and improvements to currently utilized IHS and tribal facilities, and the Sanitation Facilities Construction program, which builds much needed facilities to deliver potable water and provide waste disposal to American Indian and Alaska Native people, are increased by over $35 million each. The Budget proposes a substantial increase of $100 million for the Health Care Facilities Construction program to decrease the current Health Care Facilities Construction Priorities list backlog. These investments will have a lasting impact on Native communities, ensuring a healthier population.

***Protecting Unaccompanied Children.*** ACF is responsible for ensuring that unaccompanied children who are apprehended by immigration authorities are provided shelter until they can be placed with sponsors, usually parents or other relatives, who assume responsibility for their care while their immigration cases are processed. This past summer, the Administration responded to a

significant increase in the number of unaccompanied children who were apprehended on the southwest border, with an aggressive, coordinated federal response focused on providing humanitarian care for the children as well as on stronger deterrence, enforcement, foreign cooperation, and capacity for federal agencies to ensure that our border remains secure. In part as a result of those actions, the number of unaccompanied children apprehended at the border in FY 2015 is below FY 2014 and the number of children referred to ACF is projected to stabilize. To ensure ACF can take custody of all referred children in FY 2016, the Budget includes $948 million in base funding and creates a contingency fund that would trigger additional funds if caseloads exceed levels that could be supported with base funding and any prior-year carryover.

# HHS Budget by Operating Division

| *dollars in millions/1* | 2014 | 2015 | 2016/4 |
|---|---|---|---|
| **Food and Drug Administration** | | | |
| **Budget Authority** | 2,685 | 2,622 | 2,747 |
| **Outlays** | 1,967 | 2,943 | 2,775 |
| | | | |
| **Health Resources and Services Administration** | | | |
| **Budget Authority** | 9,078 | 10,555 | 10,602 |
| **Outlays** | 9,003 | 9,345 | 10,458 |
| | | | |
| **Indian Health Service** | | | |
| **Budget Authority** | 4,590 | 4,800 | 5,261 |
| **Outlays** | 4,510 | 5,010 | 5,237 |
| | | | |
| **Centers for Disease Control and Prevention** | | | |
| **Budget Authority** | 7,002 | 9,257 | 7,459 |
| **Outlays** | 6,313 | 7,792 | 8,093 |
| | | | |
| **National Institutes of Health** | | | |
| **Budget Authority** | 30,077 | 29,850 | 30,480 |
| **Outlays** | 29,348 | 29,565 | 29,933 |
| | | | |
| **Substance Abuse and Mental Health Services Administration** | | | |
| **Budget Authority** | 3,487 | 3,486 | 3,454 |
| **Outlays** | 3,193 | 3,920 | 3,465 |
| | | | |
| **Agency for Healthcare Research and Quality** | | | |
| **Budget Authority** | 7 | 364 | 276 |
| **Program Level** | 436 | 465 | 479 |
| **Outlays** | 42 | 106 | 128 |
| | | | |
| **Centers for Medicare & Medicaid Services /2** | | | |
| **Budget Authority** | 848,531 | 931,544 | 968,388 |
| **Outlays** | 826,759 | 897,791 | 970,460 |
| | | | |
| **Administration for Children and Families /3** | | | |
| **Budget Authority** | 51,659 | 51,590 | 59,679 |
| **Outlays** | 49,421 | 50,987 | 57,273 |
| | | | |
| **Administration for Community Living** | | | |
| **Budget Authority** | 1,640 | 1,646 | 2,071 |
| **Outlays** | 1,462 | 1,671 | 1,879 |
| | | | |
| **Office of the National Coordinator** | | | |
| **Budget Authority** | 16 | 60 | — |
| **Outlays** | 294 | 99 | 49 |

# HHS Budget by Operating Division

| *dollars in millions* | 2014 | 2015 | 2016/4 |
|---|---|---|---|
| **Medicare Hearings and Appeals** | | | |
| **Budget Authority** | 82 | 87 | 140 |
| **Outlays** | 82 | 87 | 140 |
| | | | |
| **Office for Civil Rights** | | | |
| **Budget Authority** | 39 | 39 | 43 |
| **Outlays** | 35 | 40 | 45 |
| | | | |
| **Departmental Management** | | | |
| **Budget Authority** | 480 | 473 | 518 |
| **Outlays** | 1,292 | 1,535 | 870 |
| | | | |
| **Public Health and Social Services Emergency Fund** | | | |
| **Budget Authority** | 1,251 | 1,966 | 1,910 |
| **Outlays** | 1,970 | 1,981 | 2,306 |
| | | | |
| **Office of Inspector General** | | | |
| **Budget Authority** | 70 | 73 | 84 |
| **Outlays** | 96 | 59 | 81 |
| | | | |
| **Program Support Center (Retirement Pay, Medical Benefits, Misc. Trust Funds)** | | | |
| **Budget Authority** | 645 | 653 | 708 |
| **Outlays** | 641 | 930 | 677 |
| | | | |
| **Offsetting Collections** | | | |
| **Budget Authority** | 6 | -746 | -751 |
| **Outlays** | 6 | -746 | -751 |
| | | | |
| **Other Collections** | | | |
| **Budget Authority** | -179 | -81 | -77 |
| **Outlays** | -179 | -81 | -77 |
| | | | |
| **Total, Health and Human Services** | | | |
| **Budget Authority** | **961,166** | **1,048,237** | **1,092,992** |
| **Outlays** | **936,223** | **1,013,051** | **1,093,041** |
| | | | |
| **Full-time Equivalents** | 74,947 | 77,865 | 80,418 |
| | | | |
| 1/ The budget authority levels presented here are based on the Appendix, and potentially differs from levels displayed in the individual Operating and Staffing Division chapters. | | | |
| 2/ Budget Authority includes Non-CMS Budget Authority for Hospital Insurance and Supplementary Medical Insurance for the Social Security Administration and MEDPAC. | | | |
| 3/ Includes rescission of $25 million in prior year Refugee Funds. | | | |
| 4/ FY 2016 estimates do not include the reductions to mandatory spending that will be applied in FY 2016 as required under the Budget Control Act. | | | |

# COMPOSITION OF THE HHS BUDGET
## Discretionary Programs

| *dollars in millions* | 2014 | 2015 | 2016/4 | 2016 +/-2015 |
|---|---|---|---|---|
| **Discretionary Programs (Budget Authority):** | | | | |
| | | | | |
| **Food and Drug Administration** | 2,561 | 2,596 | 2,744 | +148 |
| ***Program Level*** | *4,387* | *4,505* | *4,930* | *+425* |
| | | | | |
| **Health Resources and Services Administration** | 6,046 | 6,112 | 6,225 | +113 |
| ***Program Level*** | *8,902* | *10,330* | *10,375* | *+45* |
| | | | | |
| **Indian Health Service** | 4,435 | 4,642 | 5,103 | +461 |
| ***Program Level*** | *5,649* | *5,906* | *6,392* | *+486* |
| | | | | |
| **Centers for Disease Control and Prevention /1** | 5,863 | 6,073 | 6,170 | +98 |
| ***Program Level*** | *6,957* | *7,045* | *7,142* | *+98* |
| | | | | |
| **National Institutes of Health** | 29,923 | 29,446 | 30,314 | +868 |
| ***Program Level*** | *30,070* | *30,311* | *31,311* | *+1,000* |
| | | | | |
| **Substance Abuse and Mental Health Services Administration** | 3,426 | 3,474 | 3,396 | -78 |
| ***Program Level*** | *3,622* | *3,621* | *3,666* | *+45* |
| | | | | |
| **Agency for Healthcare Research and Quality** | — | 364 | 276 | -88 |
| ***Program Level*** | *436* | *465* | *479* | *+14* |
| | | | | |
| **Centers for Medicare & Medicaid Service** | 4,092 | 3,975 | 4,245 | +270 |
| ***Program Level*** | *5,759* | *11,231* | *14,281* | *+3,050* |
| | | | | |
| **Administration for Children and Families** | 17,678 | 17,791 | 19,825 | +2,034 |
| ***Program Level*** | *17,684* | *17,791* | *19,825* | *+2,034* |
| | | | | |
| **Administration for Community Living** | 1,907 | 1,919 | 2,096 | +177 |
| ***Program Level*** | *1,961* | *1,956* | *2,123* | *+168* |
| | | | | |
| **Office of the Secretary:** | | | | |
| | | | | |
| **General Departmental Management** | 457 | 448 | 493 | +44 |
| ***Program Level*** | *562* | *546* | *594* | *+48* |
| | | | | |
| **Office of Medicare Hearing and Appeals** | 82 | 87 | 140 | +53 |
| ***Program Level*** | 82 | 87 | 270 | +183 |

# COMPOSITION OF THE HHS BUDGET
## Discretionary Programs

| *dollars in millions* | 2014 | 2015 | 2016/4 | 2016 +/-2015 |
|---|---|---|---|---|
| **Office of the National Coordinator** | 16 | 60 | — | -60 |
| ***Program Level*** | *60* | *60* | *92* | *+31* |
| | | | | |
| **Office of Inspector General** | 71 | 73 | 83 | +11 |
| ***Program Level*** | *295* | *337* | *417* | *+80* |
| | | | | |
| **Office for Civil Rights** | 39 | 39 | 43 | +4 |
| | | | | |
| **Public Health and Social Services Emergency Fund /1** | 1,251 | 1,233 | 1,910 | +677 |
| ***Program Level*** | *1,251* | *1,233* | *1,940* | *+707* |
| | | | | |
| **Discretionary HCFAC** | 294 | 672 | 706 | +34 |
| | | | | |
| **Accrual for Commissioned Corps Health Benefits** | 27 | 28 | 28 | -0.2 |
| | | | | |
| **Total, Discretionary Budget Authority** | **78,165** | **79,032** | **83,795** | **+4,763** |
| | | | | |
| ***Title VI Ebola Funding /2*** | *—* | *+2,767* | *—* | *-2,767* |
| | | | | |
| ***Less One-Time Rescissions /3*** | *-6,317* | *-6,294* | *-5,433* | *+861* |
| | | | | |
| **Revised, Discretionary Budget Authority** | **71,848** | **75,505** | **78,362** | **+2,857** |
| | | | | |

1/ FY 2015 funding totals include additional funding provided by the FY 2015 Continuing Resolution (P.L. 113- 164) of $58 million to PHSSEF for Ebola Medical Countermeasures and $30 million to CDC for Ebola Outbreak Response.

2/ Reflects funding provided by the FY 2015 Omnibus; Consolidated and Further Continuing Appropriations Act (P.L. 113-235).

3/ The FY 2014 rescission is $6.3 billion from the CHIPRA performance bonuses. The FY 2015 rescission was $6.3 billion, which includes $4.5 billion from section 108 of CHIPRA and $1.8 billion from CHIPRA performance bonuses. The FY 2016 Budget proposes to rescind $5.4 billion: $2.1 billion from the CHIP Child Enrollment Contingency Fund and $3.3 billion from section 108 of CHIPRA.

4/ FY 2016 estimates do not include the reductions to mandatory spending that will be applied in FY 2016 as required under the Budget Control Act.

# COMPOSITION OF THE HHS BUDGET
## Mandatory Programs

| | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Mandatory Programs (Outlays):** | | | | |
| Medicare | 505,307 | 529,991 | 582,972 | +52,981 |
| Medicaid | 301,472 | 333,080 | 351,993 | +17,913 |
| Temporary Assistance for Needy Families /1 | 16,887 | 17,245 | 17,500 | +255 |
| Foster Care and Adoption Assistance | 6,868 | 7,079 | 7,593 | +514 |
| Children's Health Insurance Program /2 | 9,317 | 10,608 | 14,570 | +3,962 |
| Child Support Enforcement | 4,112 | 4,294 | 4,328 | +34 |
| Child Care | 2,838 | 2,957 | 5,919 | +2,962 |
| Social Services Block Grant | 1,748 | 1,954 | 2,065 | +111 |
| Other Mandatory Programs | 9,723 | 23,849 | 22,923 | -926 |
| Offsetting Collections | 6 | -746 | -751 | -5 |
| **Subtotal, Mandatory Outlays** | **858,278** | **930,311** | **1,008,112** | **+77,801** |
| **Total, HHS Outlays** | **936,223** | **1,013,051** | **1,093,041** | **+79,990** |

1/ Includes outlays for the TANF Contingency Fund and the Recovery Act's TANF Emergency Contingency Fund.

2/ Includes outlays for the Child Enrollment Contingency Fund.

# Food and Drug Administration

## Budget Overview

| *dollars in millions* | 2014/1 | 2015/2 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **FDA Programs** | | | | |
| Foods | 900 | 914 | 1,165 | +253 |
| Human Drugs | 1,289 | 1,339 | 1,372 | +33 |
| Biologics | 338 | 344 | 351 | +6 |
| Animal Drugs and Feeds | 173 | 175 | 197 | +22 |
| Medical Devices | 428 | 440 | 456 | +16 |
| National Center for Toxicological Research | 62 | 63 | 59 | -4 |
| Tobacco Products | 501 | 532 | 564 | +33 |
| Headquarters and Office of the Commissioner/3 | 275 | 277 | 300 | +22 |
| White Oak Consolidation | 62 | 47 | 52 | +5 |
| GSA Rental Payment | 220 | 228 | 242 | +14 |
| Other Rent and Rent Related Activities | 116 | 116 | 137 | +20 |
| Subtotal, Salaries and Expenses | 4,366 | 4,476 | 4,895 | +420 |
| Export Certification Fund | 5 | 5 | 9 | +4 |
| Color Certification Fund | 7 | 8 | 9 | +0.8 |
| Priority Review Vouchers | -- | 8 | 8 | -- |
| Buildings and Facilities | 9 | 9 | 9 | -- |
| **Total, Program Level** | **4,387** | **4,505** | **4,930** | **+425** |
| **Current Law User Fees /4/5** | | | | |
| Prescription Drug (PDUFA) | 760 | 798 | 826 | +28 |
| Medical Device (MDUFA) | 115 | 128 | 134 | +6 |
| Animal Drug (ADUFA) | 24 | 22 | 22 | +0.3 |
| Animal Generic Drug (AGDUFA) | 7 | 7 | 7 | +0.5 |
| Food Reinspection | 15 | 6 | 6 | -- |
| Food Recall | 13 | 1 | 1 | -- |
| Family Smoking Prevention and Tobacco Control Act | 534 | 566 | 599 | +33 |
| Generic Drug (GDUFA) | 306 | 312 | 320 | +8 |
| Biosimilars (BSUFA) | 21 | 21 | 22 | +0.5 |
| Mammography Quality Standards Act (MQSA) | 19 | 20 | 20 | +0.4 |

| *Proposed Law User Fees* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Current Law User Fees (cont'd)** | | | | |
| Export Certification Fund | 5 | 5 | 5 | -- |
| Color Certification Fund | 7 | 8 | 9 | +0.8 |
| Third Party Auditor Fee | -- | -- | 1.4 | +1.4 |
| Voluntary Qualified Importer Program | -- | 5 | 5 | -- |
| Outsourcing Facility Fee | -- | 1 | 1 | -- |
| Priority Review Vouchers | -- | 8 | 8 | +8 |
| **Subtotal, Current Law User Fees** | **1,826** | **1,909** | **1,988** | **+79** |
| **Proposed Law User Fees** | | | | |
| Export Certification /6 | -- | -- | 4 | +4 |
| Food Facility Registration and Inspection | -- | -- | 60 | +60 |
| Food Import | -- | -- | 103 | +103 |
| Food Substance Contact Notification | -- | -- | 5 | +5 |
| Cosmetics | -- | -- | 20 | +20 |
| International Courier | -- | -- | 6 | +6 |
| **Subtotal, Proposed Law User Fees** | -- | -- | **199** | **+199** |
| **Less Total, User Fee** | **1,826** | **1,909** | **2,187** | **+277** |
| **FDA Totals** | | | | |
| **Total, Discretionary Budget Authority** | **2,561** | **2,596** | **2,744** | **+148** |
| Full-time Equivalents | 14,682 | 15,935 | 16,757 | +822 |

1/ In addition to these resources, section 747 of the Consolidated Appropriations Act, 2014 makes approximately $79 million in user fees sequestered in FY 2013 available for obligation in FY 2014.

2/ The FY 2015 Appropriations also provided $25 million in one-time emergency resources to support Ebola response and preparedness activities.

3/ The FY 2015 Appropriations directed FDA to transfer a total of $1.5 million to the HHS Office of Inspector General for oversight activities.

4/ The Drug Quality and Security Act (P.L. 113-54) authorized three new FDA user fees: the outsourcing facility fees; the prescription drug wholesale distributer licensing and inspection fees; and, the third-party logistics provider licensing and inspection fees. It is expected that collections for wholesale distributer and third-party logistics provider fees in FY 2015 and FY 2016 will be minimal.

5/ The FY 2015 authorized user fee resources do not reflect the Federal Register notices published in July and August 2014.

6/ The FY 2016 President's Budget proposes to increase the statutory user fee limit for this program.

*The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. FDA also advances the public health by helping to speed innovations that make medicines more effective, safer, and more affordable, and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. Further, FDA regulates the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA plays a significant role in the nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.*

The FY 2016 Budget includes $4.9 billion in total resources for the Food and Drug Administration (FDA), an increase of $425 million, or 9 percent, above FY 2015. Of this increase, $148 million is in budget authority and $277 million in user fees to support FY 2016 activities that advance FDA's mission and address emerging and salient public health challenges. In FY 2016, FDA will continue to modernize the food safety system, enhance the safety and quality of human drugs and other medical products, continue to reduce tobacco use, support preparedness with medical countermeasures, address globalization, and conduct innovative research to support mission critical programs.

## Modernizing the Food Safety System

Foodborne illness and contamination outbreaks have a significant public health and economic impact. An estimated 48 million foodborne illnesses occur each year, which cost over $75 billion per year in total lost productivity, illness-related mortality, and medical costs. FDA oversees the safety of approximately 80 percent of the food supply which includes a growing proportion of imported products. Since the enactment of the Food Safety Modernization Act (FSMA) in 2011, FDA has made great strides to fulfill the Administration's goal to have a more coordinated, robust, and prevention-based system. FDA has worked with federal, state, local, and foreign partners to transform the food safety system from one that is reactive to one that is poised to prevent unintentional and intentional foodborne outbreaks and focuses on the highest risk circumstances. In 2015 and 2016, FDA will publish final versions of seven substantial regulations required by FSMA that will establish the framework for a preventive and integrated approach to ensuring the safety of the nation's food supply.

The Budget includes $1.5 billion across FDA for food safety, an increase of $301 million above FY 2015. This total includes $1.3 billion in budget authority and $206 million in user fees. In FY 2016 FDA will focus on the seven regulations which set preventive controls for food and feed; standards for the sanitary transport of food; produce standards for packing, harvesting, and growing fruits and vegetables; standards for imported foods equivalent to standards of safety in the United States; standards for animal food; and, steps to block intentional attempts of contamination. These activities will improve the public health by lowering the incidence of illness due to food hazards and will avoid interruptions to the food supply. In FY 2016 FDA will focus on the following objectives in support of FSMA implementation:

- Implement new food and feed standards;
- Modernize inspections and enhance training to ensure consistency;
- Support an integrated prevention-focused food and feed system;
- Enhance risk-based analytic tools to prioritize activities and optimize resources;
- Improve import oversight through Foreign Supplier Verification Program implementation
- Improve import safety including streamlining port-of-entry activities; and,
- Increase foreign presence and partnerships.

To support these critical activities in FY 2016, the Budget includes $190 million from new proposed user fees including the food import fee and the food facility registration and inspection fee. These proposed additional revenues are essential to support key implementation actions envisioned by FSMA. The FDA Budget also includes $5 million for a food contact notification user fee to reduce microbial food contamination through premarket notification. The Budget also includes currently authorized fees such as the voluntary qualified importer program, export certification, and the food re-inspection and recall fees to support agency-wide food safety activities. In addition, FDA expects to collect resources in support of the Third Party Auditor program authorized in FSMA. These fee revenues enable FDA to expedite processes such as the timely assessment of color additives used in

### Transforming the Food Safety System in a Global Market

FDA estimates that 18 percent of all food products are imported into the United States. The proportion of specific products is even more striking – an estimated 80 percent of seafood and between 20 and 50 percent of produce is imported from other countries. The growing proportion of imported products emphasizes a need to focus activities and resources to address the evolving global food supply system.

The Food Safety Modernization Act directed FDA to establish a program to accredit entities to conduct food safety audits and to issue certifications for foreign food facilities to ensure compliance with U.S. safety standards. This program will optimize federal resources by allowing FDA to leverage third-party auditors to enhance the assurance of the safety of imported food and animal feed products and will facilitate the efficient movement of regulated products in international trade. In FY 2016, FDA will begin collecting user fees in support of this program. The final regulation is scheduled to be finalized in 2015.

This program complements other global food safety efforts proposed in the Budget such as the foreign supplier verification program. This program, also required by FSMA, would ensure that foreign suppliers establish programs to ensure that foreign importers verify that products meet certain standards and are not adulterated. The FY 2016 Budget supports implementation of these programs to complement other foreign food safety activities.

foods, drugs, and cosmetics, and the approval of certifications to facilitate international trade.

In addition to implementing FSMA, FDA will continue to support a broad range of food and feed safety activities that are important to the public, such as ensuring Americans have the information they need to make the best nutritional decisions. In 2015, FDA issued a final regulation requiring the display of nutritional information on the menus of certain food establishments and vending machines. FDA will provide guidance to the food industry to facilitate implementation and compliance.

### Enhancing Medical Product Safety

An estimated 40 percent of finished drugs and 80 percent of active ingredients are imported into the United States from other countries. In a growing global market with increasing technical complexities, FDA continues to lead in the review of medical products. Three quarters of all significant pharmaceutical advances that were approved anywhere in the world in 2013 were approved first by FDA. FDA ensures the safety, quality and effectiveness of a broad scope of medical products used by Americans, including biologics, vaccines, blood products, and gene therapies, prescription and over-the-counter drugs, radiation emitting products, and medical devices such as pacemakers. In addition, FDA helps accelerate the availability of medical products including lower cost generic products, and eliminating drug shortages.

The FY 2016 Budget includes a total Program Level of $2.7 billion, $85 million above FY 2015, across the agency to advance FDA's highest priority medical product activities. Of the total, $1.3 billion is in budget authority and $1.4 billion is in user fees to support domestic and foreign inspections, product surveillance, product reviews, and applied research within the biologics, human drugs, and device programs. This effort will include ensuring that products regulated by FDA are marketed consistent with the newest requirements and standards and that the American public has access to the safest products available based on recent clinical data.

The Budget includes resources for emerging and ongoing public health issues and for investing in establishing a safer drug supply system. A total of $18 million, an increase of $1 million above FY 2015, is included to continue expanded and improved oversight of human drug compounding. The compounding process allows for the customizing of drugs to address a patient's specific needs. This funding will build on FY 2015 activities to continue support for a more comprehensive program to ensure compounded products are safe. Specifically, FDA will support inspection and enforcement activities to ensure compliance with new requirements in the Drug Quality and Security Act; develop additional regulations and provide guidance to enhance oversight; increase and strengthen coordination with states, and to train state inspectors.

#### Preventing Shortages of Life-Saving Medications

Interruptions in the drug supply are a significant public health threat with potentially severe consequences including death. In recognition of this challenge, the President issued an Executive Order in 2011 that provided FDA with additional tools to respond to shortages. The FDA Safety and Innovation Act greatly enhanced FDA's ability to take action by making previously voluntary actions – such as notifying FDA of potential disruptions or delays in drug manufacturing – into mandatory requirements.

In July 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act, which directed the FDA to develop and submit to Congress a plan to enhance FDA's response to preventing and mitigating drug shortages. In October 2013, FDA issued the "Strategic Plan for Preventing and Mitigating Drug Shortages" that outlines FDA's strategy for collaborating with industry, health professionals, and patients in order to improve its response to early notifications of a potential shortage. The plan also includes long-term tactics to address the underlying causes of shortages by highlighting opportunities for drug manufacturers to promote and sustain quality manufacturing. In FY 2013, FDA prevented 170 drug shortages. Preventing drug shortages remains a top priority for FDA.

The Budget also invests $5 million to establish two key requirements of the FDA Safety and Innovation Act and the Drug Quality and Security Act. In FY 2016, FDA will enhance existing systems so that the agency can receive electronic biological product application submissions. FDA will also establish the technology infrastructure needed to support the unique facility identifier activities in the Act. This infrastructure will enhance the accuracy and coordination of FDA data to support analysis of the highest risk products, combat counterfeiting, and improve regulatory oversight. FDA is also working on long-term implementation of the track and trace provisions in the Drug Quality and Security Act. All of these investments will enhance the overall medical product supply.

FDA will also invest an additional $15 million for new antimicrobial resistance activities in support of the Administration's National Strategy on Combating Antimicrobial Resistant Bacteria. This effort will build on FDA's current work, and will support the following program areas:

- Develop additional guidance for industry to measure the impact of recent regulatory action;
- Streamline clinical trial protocols;
- Develop new research models for high priority pathogens; and,
- Enhance availability of new data.

Finally, the Budget includes $10 million to support a new FY 2016 Department cross-cutting Precision Medicine Initiative that will allow treatments to be personalized for patient needs. FDA will establish the appropriate regulatory pathway to integrate genetic information into device development.

### Advancing Medical Countermeasures

FDA supports the Department's overall preparedness and response goals and strategies for protecting the nation from chemical, biological, radiological, nuclear, and emerging infectious disease threats by facilitating development and availability of medical countermeasures – including drugs, vaccines, and diagnostic threats. The FY 2016 Budget continues to support FDA's work in this important area and specifically includes $25 million to continue the Medical Countermeasures Initiative. This program enables FDA to accelerate the development and availability of countermeasures by establishing clear regulatory pathways for medical countermeasures, advancing regulatory science to create the data necessary to support regulatory decision-making, and establishing effective regulatory policies and mechanisms to facilitate timely access to available medical countermeasures. FDA's Countermeasure Initiative has been integral to the agency's response to the Ebola virus epidemic in West Africa by helping to expedite the development and availability of investigational treatments, vaccines, and diagnostics for Ebola. FDA to provided scientific and regulatory advice to commercial developers and to U.S. government agencies that support medical product development to accelerate development programs, expedited the regulatory review of data as it was received from product developers, quickly responded to requests for access to investigational medical products for patients with Ebola, and authorized the use of investigational diagnostic tests for Ebola under FDA's Emergency Use Authorization authority.

### Reducing the Use and Harms of Tobacco

An estimated 42 million individuals, approximately 1 in 5 adults, in the United States currently smoke cigarettes. Tobacco remains the leading preventable cause of disease, disability, and death in the United States. The Family Smoking Prevention and Tobacco Control Act gave FDA the authority to regulate the manufacturing, distribution, and marketing of tobacco products. Almost six years after enactment, FDA, through the Center for Tobacco Products, has made progress to establish regulatory oversight of covered tobacco products and to support other broader public health initiatives impacted by tobacco use. The Center for Tobacco Products supports the goals of the Tobacco Control Act through three strategic priorities:

1. Prevent initiation, particularly among youth;
2. Decrease the harms of tobacco product use; and
3. Encourage cessation among tobacco users.

Over the course of nearly six years FDA has had numerous accomplishments to prevent tobacco use in youth; educate Americans on the harms of tobacco products; ensure compliance of the Tobacco Control Act; review new tobacco products and changes to existing products to reduce harm; and, support cutting edge research. As of January 2015, FDA conducted over 283,000 inspections of tobacco product retailers across the United States to ensure that industry is meeting new requirements. FDA publishes guidance to the tobacco industry to increase awareness of their new obligations and of FDA's responsibilities. Another notable accomplishment of the Center for Tobacco Products is its research. In collaboration with NIH, FDA established and supports fourteen Tobacco Centers of Regulatory Science, which help inform and allow access to FDA's regulatory activities in the rapidly evolving tobacco market. The Centers will provide evidence in seven research areas: diversity of tobacco products; reducing addiction; reducing toxicity and carcinogenicity; adverse health consequences; communications; marketing of tobacco products; and, economics and policies.

The FY 2016 Budget includes $564 million in user fees to support the FDA tobacco program in three priority program areas. In FY 2016, FDA will advance the Tobacco Control Act responsibilities which contribute to the Department's crosscutting efforts to reduce

tobacco use in the United States. FDA will focus resources on five program areas: 1) product standards to protect public health; 2) an integrated nicotine regulatory policy; 3) pre and post market product reviews; 4) compliance and enforcement through inspections, investigations, monitoring, and review of covered tobacco products; and, 5) public education efforts particularly among at risk populations.

In addition, FDA is proposing to expand its authority to additional tobacco products. This expansion will enable FDA to apply age restrictions and rigorous scientific review to more products in an effort to reduce tobacco-related disease and death. In FY 2016, FDA will implement the final version of this regulation.

### FDA Infrastructure and Facilities

The FY 2016 Budget funds high priority infrastructure activities that directly support FDA's mission critical work. FDA's work force has more than doubled since 2008. During this time, five new substantial authorities have been enacted, significantly expanding FDA's responsibilities, and, as a result, the workforce to carry out these activities. The Budget ensures that FDA facilities support growing responsibilities and accounts for higher infrastructure costs without reducing programmatic resources. The Budget includes a total of $439 million, $38 million above FY 2015, to support these activities. Since FY 2014, more than 2,000 federal staff have transitioned to the White Oak, Maryland Campus that houses the state-of-the-art Life Sciences Biodefense Complex. The Budget includes resources for FDA to work with partners to identify future needs within the White Oak campus as the workforce continues to grow.

In addition, the Budget provides $9 million, the same as FY 2015, to fund repair and maintenance of FDA-owned facilities. Resources will support repairs within the Jefferson Laboratories Complex in Arkansas, which houses activities conducted by the National Center for Toxicological Research, and infrastructure support for FDA field facilities supporting inspections and compliance activities.

### User Fees

The FDA budget totals assume resources from five new proposed user fees across FDA, an increase to one currently authorized fee, and scheduled increases in all currently authorized user fees. Over the last five years alone, at least seven new user fees have been authorized to support medical product and food safety activities within FDA. User fees have been and continue to be a vital component that enable FDA to carry out its mission by providing predictable resources and instituting ambitious performance metrics that have led to a streamlined regulatory process, more efficiencies, and increased speed at which products are available to the public.

The Budget includes the proposed fees described in the narratives above as well as two additional proposed user fees for FY 2016. This request includes the proposed cosmetic user fee totaling $20 million to support FDA's role in ensuring the safety of cosmetic products in the United States as the volume of both domestic and imported cosmetic products continues to grow and manufacturing technology and ingredients become more complex. In addition, the international courier user fee, which would provide $6 million to support the activities related to the increased volume of FDA-regulated commodities, predominantly medical products, imported through express courier hubs.

The Budget proposes to increase allowable fee amounts for the export certification fee to keep up with the growing costs of these certification activities. FDA is also currently establishing additional fees authorized in the Drug Quality and Security Act to support drug safety work, and continues to work toward meeting performance goals and commitments associated with all currently authorized user fees.

**Developing the Evidence Base to Address Tobacco Use among Youth**

FDA estimates that nearly 9 out of 10 adults that smoke daily began smoking by the age of 18, the minimum age to purchase tobacco products. Each day more than 3,200 youth under the age of 18 smoke their first cigarettes. In addition, addicted smokers will on average die 13 years earlier than their non-smoker counterparts. These statistics demonstrate the sobering facts on tobacco use and emphasize the need to focus on reducing and limiting initiation of tobacco use among young people. In addition to FDA's broader tobacco program, FDA has supported targeted activities to increase the evidence base on youth and tobacco. FDA and CDC support the only nationally representative survey of middle and high school students which is conducted annually and has provided key findings to focus FDA regulatory actions. FDA is also evaluating its "The Real Cost" media campaign launched in 2013 to prevent tobacco use within at risk youth populations. These types of activities help formulate the scientific basis that FDA uses to identify strategies and develop future regulatory action to protect the public health.

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Primary Health Care** | | | | |
| Health Centers | 3,542 | 4,901 | 4,092 | -809 |
| *Discretionary Budget Authority [non-add]* | *1,397* | *1,392* | 1,392 | -- |
| *Current Law Mandatory Funding [non-add]* | *2,145* | *3,509* | -- | -3,509 |
| *New Mandatory Proposal [non-add]* | -- | -- | 2,700 | +2,700 |
| Health Centers Tort Claims | 95 | 100 | 100 | -- |
| Free Clinics Medical Malpractice | 0.040 | 0.100 | 0.100 | -- |
| **Subtotal, Primary Care** | **3,636** | **5,001** | **4,191** | **-809** |
| **Health Workforce** | | | | |
| National Health Service Corps | 283 | 287 | 810 | +523 |
| *Discretionary Budget Authority [non-add]* | -- | -- | *287* | *+287* |
| *Current Law Mandatory Funding [non-add]* | *283* | *287* | -- | *-287* |
| *New Mandatory Proposal [non-add]* | -- | -- | *523* | *+523* |
| Training for Diversity | 81 | 82 | 85 | +3 |
| *New Diversity Program [non-add]* | -- | -- | *14* | *+14* |
| Training in Primary Care Medicine | 37 | 39 | 39 | -- |
| Oral Health Training | 32 | 34 | 34 | -- |
| Interdisciplinary Community-Based Linkages | 71 | 73 | 53 | -20 |
| *Area Health Education Centers [non-add]* | *30* | *30* | -- | *-30* |
| *Clinical Training in Interprofessional Practice [non-add]* | -- | -- | *10* | *+10* |
| Rural Physician Training Grants | -- | -- | 4 | +4 |
| Workforce Information and Analysis | 5 | 5 | 5 | -- |
| Public Health and Preventive Medicine Programs | 18 | 21 | 17 | -4 |
| Nursing Workforce Development | 223 | 232 | 232 | -- |
| Children's Hospital Graduate Medical Education | 264 | 265 | 100 | -165 |
| Targeted Support for Graduate Medical Education | -- | -- | 400 | +400 |
| National Practitioner Data Bank User Fees | 27 | 19 | 20 | +1 |
| **Subtotal, Health Workforce** | **1,043** | **1,058** | **1,799** | **+741** |
| **Maternal and Child Health** | | | | |
| Maternal and Child Health Block Grant | 632 | 637 | 637 | -- |
| Sickle Cell Demonstration Program | 4 | 4 | 4 | -- |
| Traumatic Brain Injury | 9 | 9 | 9 | -- |
| Autism and Other Developmental Disorders | 47 | 47 | 47 | -- |
| Heritable Disorders | 12 | 14 | 14 | -- |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Maternal and Child Health (cont'd)** | | | | |
| Healthy Start | 101 | 102 | 102 | -- |
| Universal Newborn Hearing Screening | 18 | 18 | 18 | -- |
| Emergency Medical Services for Children | 20 | 20 | 20 | -- |
| Family to Family Health Information Centers (Mandatory) | 5 | 2.5 | -- | -2.5 |
| Home Visiting | 371 | 400 | 500 | +100 |
| *Current Law Mandatory Funding [non-add]* | *371* | *400* | -- | *-400* |
| *New Mandatory Proposal [non-add]* | -- | -- | *500* | *+500* |
| **Subtotal, Maternal and Child Health** | **1,220** | **1,254** | **1,352** | **+97.5** |
| **Ryan White HIV/AIDS Program** | | | | |
| Emergency Relief - Part A | 649 | 656 | 656 | -- |
| Comprehensive Care - Part B | 1,314 | 1,315 | 1,315 | -- |
| *AIDS Drug Assistance Program [non-add]* | *900* | *900* | *900* | -- |
| Early Intervention - Part C | 206 | 201 | 280 | +79 |
| Children, Youth, Women, and Families - Part D | 72 | 75 | -- | -75 |
| Education and Training Centers - Part F | 33 | 34 | 34 | -- |
| Dental Services - Part F | 13 | 13 | 13 | -- |
| Special Projects of National Significance | 25 | 25 | 25 | -- |
| *PHS Evaluation Fund Appropriation* | *25* | -- | -- | -- |
| **Subtotal, HIV/AIDS** | **2,313** | **2,319** | **2,323** | **+4** |
| **Healthcare Systems** | | | | |
| Organ Transplantation | 23 | 24 | 24 | -- |
| Cord Blood Stem Cell Bank | 11 | 11 | 11 | -- |
| C.W. Bill Young Cell Transplantation Program | 22 | 22 | 22 | -- |
| Poison Control Centers | 19 | 19 | 19 | -- |
| 340B Drug Pricing Program | 10 | 10 | 25 | +14.5 |
| *User Fees [non-add]* | -- | -- | *7.5* | *+7.5* |
| Hansen's Disease Programs | 17 | 17 | 17 | -- |
| **Subtotal, Healthcare Systems** | **103** | **103** | **118** | **+14.5** |
| **Rural Health** | | | | |
| Rural and Community Access to Emergency Devices | 3 | 4.5 | -- | -4.5 |
| Rural Hospital Flexibility Grants | 41 | 42 | 26 | -15 |
| Other Rural Health | 92 | 101 | 101 | -- |
| **Subtotal, Rural Health** | **142** | **147** | **128** | **-20** |
| **Other Activities** | | | | |
| Family Planning | 286 | 286 | 300 | +14 |
| Program Management | 153 | 154 | 157 | +3 |
| Vaccine Injury Compensation Program Direct Operations | 6 | 7.5 | 7.5 | -- |
| **Subtotal, Other Activities** | **445** | **448** | **465** | **+17** |
| **HRSA Budget Totals – Less Funds from Other Sources** | | | | |
| **Total, Program Level** | **8,902** | **10,330** | **10,375** | **+45** |
| PHS Evaluation Fund Appropriation | -25 | -- | -- | -- |
| User Fees | -27 | -19 | -27 | -8 |
| Current Law Mandatory Funding | -2,804 | -4,199 | -- | +4,199 |
| New Mandatory Proposals | -- | -- | -4,123 | -4,123 |
| **Total, Discretionary Budget Authority** | **6,046** | **6,112** | **6,225** | **+113** |
| | | | | |
| Full-time Equivalents | 1,856 | 1,985 | 2,072 | +216 |

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

As the principal federal agency charged with increasing access to basic health care for those who are medically underserved, uninsured, or underinsured, the Health Resources and Services Administration (HRSA) is a vital component of the nation's safety net. The FY 2016 Budget provides $10.4 billion total, including $4.1 billion in mandatory funding, to invest in and expand programs that will ensure that the nation's most vulnerable populations, as well as the millions of newly insured individuals, have access to services and providers that meet their healthcare needs.

### Ensuring Affordable and Available Health Care

***Health Centers:*** Health centers provide quality, affordable health care and the peace of mind that comes with it to millions of individuals, regardless of their ability to pay, who they are, where they live, or their native language. The Budget provides $4.2 billion for the Health Centers Program in FY 2016, and requests $2.7 billion in mandatory resources in each of FYs 2016, 2017, and 2018, for a total of $8.1 billion in new mandatory funding. These resources, combined with FY 2015 funding reserved for use in FYs 2016-2018, will help sustain health center funding in future years and ensure that current health centers can continue to provide essential health care services to their patient populations.

In FY 2016, health centers will grow to serve a total of 28.6 million patients, an increase of 1.1 million, at 1,300 health centers that operate in over 9,000 locations across the country. This funding will maintain ongoing services for current grantees, including those funded in FY 2015, invest $50 million to establish 75 new health center locations across the country, and provide $40 million to recognize the highest clinically performing health centers nationwide as well as those that have made significant quality improvement gains.

Americans continue to gain access to health insurance through Health Insurance Marketplaces or through expanded access to Medicaid in many states. Health centers are well positioned to meet this demand for services as they can provide an accessible and dependable source of primary care in underserved communities. In Massachusetts, after the passage of health insurance reform, health centers saw a significant increase in newly-insured patients. From 2005 to 2013, the number of health center patients in the state increased by more than 50 percent, even while the percentage of uninsured patients decreased by nearly 20 percent. Health centers will also remain a vital source of primary care for patients who cannot gain access to coverage, as well as insured patients seeking a quality source of care for services not covered by insurance.

**Helping Americans Access Health Care**

In small towns and big cities, health centers serve as a trusted network, connecting patients with community resources. The Affordable Care Act made substantial investments in health centers so they can open their doors to record numbers of patients. Since the beginning of the Administration, health centers have added 5 million patients; they now serve nearly 22 million patients each year, and that number is expected to grow to 28.6 million in FY 2016. Further, over 7 million people received enrollment assistance at their local health center to help them access coverage through the Affordable Care Act.

***340B Drug Pricing Program:*** The Budget provides $17 million in budget authority for the 340B Drug Pricing Program, an increase of $7 million above FY 2015. In addition, it proposes a new user fee totaling $7.5 million as a long-term financing strategy to support the program's activities.

The 340B Program requires drug manufacturers to provide outpatient prescription drugs to eligible health care organizations at significantly reduced prices. By offering organizations access to low-cost medications, the 340B Program enables participating entities to stretch federal resources to treat more patients and provide more services to the most vulnerable patient populations. Eligible organizations include safety-net clinics and hospitals such as Federally Qualified Health Centers, children's hospitals, critical access hospitals, Ryan White HIV/AIDS clinics and State AIDS Drug Assistance programs, Indian Health Service tribal clinics, and certain other community-based providers.

In recent years, HRSA has significantly increased its commitment to program integrity and compliance. As additional covered entities and associated sites join the 340B Program, HRSA has nearly doubled its program audits, instituted annual recertification for all entities, and increased its proactive education and technical assistance. Nearly 13,000 organizations and over 15,000 associated sites across the country currently participate in the 340B Program. In FY 2013, organizations participating in the 340B Program saved an estimated $3.8 billion on covered outpatient drugs.

### Investing in a 21st Century Health Workforce

A well-trained and high-performing health workforce is vital to our nation's future. The Budget provides a total of $1.8 billion for HRSA workforce programs—including $923 million in mandatory funding—in order to ensure that all Americans have access to high-quality clinicians, particularly in areas across the country where shortages of health professionals exist. This effort includes strategic investments in graduate medical education, the National Health Service Corps, and workforce diversity. Additionally, the Budget invests in health workforce programs that target a number of specific disciplines and competencies, including oral health, mental and behavioral health, and geriatric medicine. By addressing the inadequate supply and distribution of certain health professionals, the diversity of the health workforce, and the need for training in interdisciplinary practices focused on more efficient models of care, the Budget works toward ensuring that all Americans have access to quality clinicians.

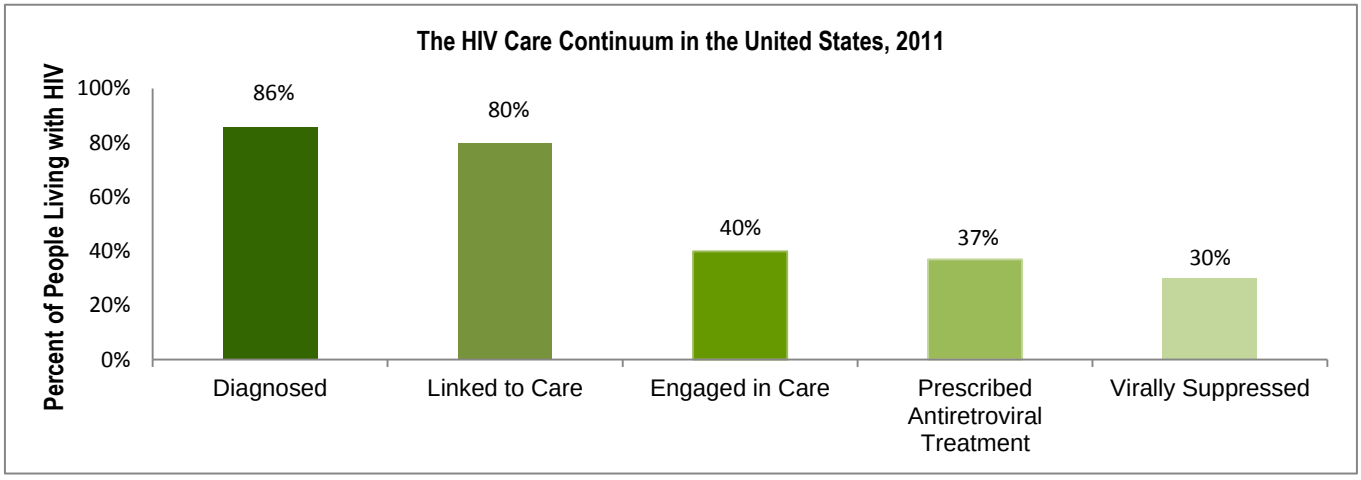
***Targeted Support for Graduate Medical Education:*** The Budget requests $400 million in mandatory funding for the Targeted Support for Graduate Medical Education program. This competitive grant program would continue the work of the Teaching Health Center Graduate Medical Education program and offer a variety of eligible entities—including teaching hospitals, children's hospitals, and community-based consortia of teaching hospitals and/or other health care entities—the opportunity to expand residency training, with a focus on primary and preventive care, which advances the goals of higher value health care that reduces long-term costs.

The Budget proposes to continue mandatory funding for the Targeted Support for Graduate Medical Education program annually in FYs 2016-2025, for a total investment of $5.3 billion over these 10 years. During this period, the program is expected to support more than 13,000 residents by providing them with a range of training experiences while addressing key health care workforce development goals, including the training of more physicians in primary care and other specialties where there are shortages, better aligning training with efficient and effective care delivery, and encouraging physicians to practice in rural and underserved areas.

***Children's Hospital Graduate Medical Education:*** The Budget includes $100 million for the Children's Hospital Graduate Medical Education program, which supports graduate training for physicians in freestanding children's teaching hospitals across the country. This level would cover the full direct costs associated with training all the residents currently in the program.

***National Health Service Corps:*** The National Health Service Corps is one of the most efficient and effective means to assist communities facing shortages of key health care professionals, including primary medical, oral, and mental and behavioral health clinicians. To achieve the goal of supporting communities with limited access to care, the Budget includes $810 million for the National Health Service Corps, including $523 million in mandatory funding. This funding will support scholarships and loan repayment for clinicians who commit to providing care in underserved communities across the country. In 2014, over 9,200 National Health Service Corps clinicians were practicing in underserved communities, approximately half of which were health centers and close to half of which were in rural America. The Budget would allow for significant growth in the National Health Service Corps, bringing it to a historic high of over 15,000 Corps members who serve nearly 16 million patients.

***Supporting Diversity within the Health Workforce:*** A number of HRSA programs seek to foster a more diverse health workforce by providing support for individuals from disadvantaged backgrounds, including underrepresented racial and ethnic minorities. The Budget provides $14 million to establish a new program to increase the diversity of the health professions workforce. Greater diversity among health professionals is associated with improve access to care to health care, as minority clinicians are more likely to go on to practice in underserved communities.




This new program is expected to leverage or establish partnerships, including public-private partnerships, in academic training and workforce development. Building on both the experience gained from the Health Careers Opportunity Program and evidence-based strategies, grantees will provide academic enrichment and other supports to disadvantaged students to help them complete their education and enter the workforce. The Budget also includes $45 million for the Scholarships for Disadvantaged Students program, $25 million for the Centers of Excellence program, and $15 million for the Nursing Workforce Diversity program. These programs seek to increase the number of disadvantaged and/or underrepresented minorities within the health workforce. The goal of increasing diversity is to meet the growing need for culturally-competent, quality health care for the nation's diverse population and to reduce health disparities and inequities.

### Continuing the Progress Needed to Achieve an AIDS-Free Generation

The FY 2016 Budget provides $2.3 billion for the Ryan White HIV/AIDS Program to support cities, states, and local community-based organizations that provide HIV-related services to more than half a million people each year who do not have sufficient health care coverage or financial resources for coping with HIV.

Funding in FY 2016 will continue to address gaps in the HIV Care Continuum, a model that shows the sequential stages of care from being diagnosed to receiving optimal treatment. Today, more than 1.2 million Americans are living with HIV infection; however, only 30 percent of these individuals are virally suppressed. The Ryan White HIV/AIDS Program supports many of the services that are essential for people to access and remain in care but are not covered by Medicaid or private insurance. By helping people stay in care and adhere to their treatments, the Ryan White HIV/AIDS Program plays a critical role in preventing the spread of the HIV epidemic, as people living with HIV who are on drug treatment and virally suppressed are much less likely to transmit the infection. Within the requested funding level, $900 million, the same level as FY 2015, is allocated for the AIDS Drug Assistance Program, which provides grants to states to pay for HIV/AIDS medications for uninsured and low-income clients who cannot afford the drugs due to inadequate insurance coverage. Since the beginning of this Administration, the number of clients served annually by state AIDS Drug Assistance Programs has increased by nearly 20 percent.

#### AIDS Drug Assistance Program Wait Lists

The most recent data demonstrates that those who remain in medical care through the Ryan White HIV/AIDS Program increased their viral suppression rates from 69.5 percent in 2010 to 75.1 percent in 2012, due in part to increased investments in the AIDS Drug Assistance Program. In FY 2012, the AIDS Drug Assistance Program, which provides grants to states to pay for HIV/AIDS medications for uninsured and low-income clients, served more than 244,000 individuals.

As a result of the economic downturn, a national HIV testing initiative that brought more people infected with HIV into care, changing federal guidelines for the treatment of HIV, and continued improvements in HIV care to prolong survival, led a number of states to implement waiting lists, beginning in 2008, to contain program costs at the expense of limiting patients' access to drugs. Due to funding increases and the Department's work to leverage funding flexibilities, waiting lists for HIV-related medications from the AIDS Drug Assistance Program decreased from a peak of 9,310 individuals in September 2011 to 0 in July 2014.

The Budget continues to propose consolidating funds in Ryan White Part C and Part D programs. The consolidated Part C program will emphasize care across all vulnerable populations, genders and ages, thus assuring services for women, infants, children, and youth throughout the program. By consolidating the two programs, resources can be better targeted to points along the care continuum and populations most in need among an increased number of grantees, while reducing duplication of effort and administrative burden.

### Keeping Families and Communities Healthy

***Maternal and Child Health:*** The FY 2016 Budget requests $1.4 billion, an increase of $98 million, to improve the physical and mental health, safety, and well-being of the nation's mothers, children, and their families. Of this amount, $500 million in mandatory funding is requested in FY 2016 and $15 billion through FY 2025 to extend and expand the Maternal, Infant, and Early Childhood Home Visiting program, which allows states to implement voluntary, evidence-based home visiting services to women during pregnancy and to parents with young children. These services enable nurses, social workers, and other professionals to meet with at-risk families and connect them to assistance to support children's health, development, and learning ability. Home visiting programs have been shown to prevent child abuse and neglect, promote child health and development, including school readiness, and improve parenting skills. The request also provides $637 million, the same as FY 2015, for the Maternal and Child Health Block Grant, to improve the health of mothers, adolescents and children through a broad array of public health and community-based programs.

***Rural Health:*** Over 46 million Americans live in rural areas. These individuals experience higher rates of chronic disease, disability, and mortality as well as inequities in access to health services, including preventive care, than their urban counterparts. The Budget provides $128 million for the Federal Office of Rural Health Policy within HRSA to work with rural hospitals and other rural health providers to ensure that Americans living in rural communities have access to high-quality care.

The Budget also provides $4 million to fund new Rural Health Physician grants to help rural-focused training programs recruit and graduate students most likely to practice medicine in underserved areas. In addition, the proposed expansion of the National Health Service Corps will also allow more providers to serve in high-need rural communities across the country.

***Family Planning:*** The Budget includes $300 million, an increase of $14 million above FY 2015, to expand family planning services to low-income individuals by improving access to family planning centers and preventive services. This funding will provide services to nearly 4.7 million low-income women and men at more than 4,150 clinics. Historically, 90 percent of family planning clients have family incomes at or below 200 percent of the federal poverty level.

In FY 2016, approximately 90 percent of family planning funding will be used for clinical services, such as screening for Chlamydia, other sexually transmitted diseases, and cervical cancer; providing a broad range of contraceptive methods; and administering community-based education and outreach. These services assist individuals and families with both preventing unintended pregnancy and assisting with achieving pregnancy leading to healthy birth outcomes.

### Supporting HRSA Programs

***Program Management:*** The Budget requests $157 million, an increase of $3 million, to support the infrastructure necessary to operate HRSA programs. Funding in FY 2016 will allow HRSA to enhance oversight of grant and contract recipients, improve program integrity and reduce improper payments, develop and maintain its information technology infrastructure, train and hire skilled staff, improve return on investment, and eliminate duplication.

# Indian Health Service

## Budget Overview

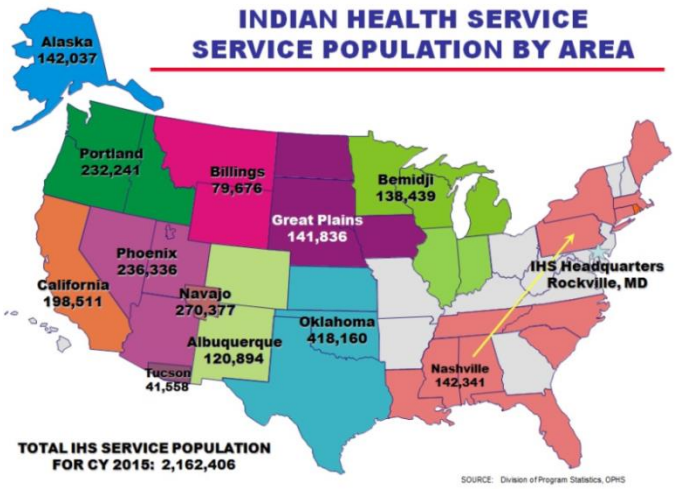
| *dollars in millions* | 2014/1 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Services** | | | | |
| Clinical Services: | 4,142 | 4,303 | 4,545 | +242 |
| *Purchased/Referred Care (non-add)* | *879* | *914* | *984* | *+70* |
| *Medicaid (non-add)* | *738* | *771* | *781* | *+10* |
| Preventive Health | 147 | 154 | 163 | +9 |
| Contract Support Costs | 612 | 663 | 718 | +55 |
| Tribal Management/Self-Governance | 6 | 8 | 8 | -- |
| Urban Health | 41 | 44 | 44 | -- |
| Indian Health Professions | 28 | 48 | 48 | -- |
| Direct Operations | 66 | 68 | 68 | -- |
| Diabetes Grants | 147 | 150 | 150 | -- |
| **Subtotal, Services** | **5,190** | **5,438** | **5,744** | **+306** |
| **Facilities** | | | | |
| Health Care Facilities Construction | 85 | 85 | 185 | +100 |
| Sanitation Facilities Construction | 79 | 79 | 115 | +36 |
| Facilities and Environmental Health Support | 211 | 220 | 227 | +7 |
| Maintenance and Improvement | 62 | 62 | 98 | +36 |
| Medical Equipment | 23 | 23 | 24 | +1 |
| **Subtotal, Facilities** | **460** | **468** | **648** | **+180** |
| **IHS Budget Totals – Less Funds From Other Sources** | | | | |
| **Total, Program Level** | **5,649** | **5,906** | **6,392** | **+486** |
| Health Insurance Collections | -1,060 | -1,106 | -1,131 | -25 |
| Rental of Staff Quarters | -8 | -8 | -9 | -1 |
| Diabetes Grants /2 | -147 | -150 | -150 | -- |
| **Total, Budget Authority** | **4,435** | **4,642** | **5,103** | **+461** |
| | | | | |
| Full-time Equivalents | 15,244 | 15,803 | 15,860 | +57 |

1/ This column reflects the FY 2014 reprogramming of funds within the Services appropriation for contract support costs.

2/ These mandatory funds were pre-appropriated in P.L. 112-240, the American Taxpayer Relief Act of 2012, and P.L. 113-93, the Protecting Access to Medicare Act of 2014, and are proposed for reauthorization in FY 2016.

*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 FY 2016 Budget requests $6.4 billion for the Indian Health Service (IHS), an increase of $486 million above FY 2015 and 49 percent above FY 2008. The President's visit to the Standing Rock Reservation in 2014 reaffirmed the Administration's commitment to address health disparities in Indian Country. The FY 2016 Budget requests increases for targeted areas where funding will have long-term impacts on the health and well-being of those served by IHS. Specifically, the Budget includes increased investments for the Purchased/Referred Care Program and other direct health care services to cover increases in costs due to medical inflation, population growth, and pay costs; proposes funding for staffing and operating costs for new and replacement tribal and IHS health care facilities; proposes substantial investments in IHS health care facilities; includes an increase for Health Information Technology to help modernize IHS systems; and includes funding to help improve collections from public and private insurance at IHS and tribally operated facilities, which are vital to a facility's success. The Budget supports tribes and tribal organizations that administer health programs by fully funding estimated Contract Support Costs, and proposes a long-term solution for the Contract Support Costs program that would begin in FY 2017.




## Fulfilling the Administration's Commitment to Indian Country through the Indian Health Service

The IHS strives to assure that comprehensive, culturally acceptable personal and public health services are available and accessible to almost 2.2 million eligible American Indians and Alaska Natives who are members of 566 federally recognized tribes across the United States.

Tribal partnerships ensure that appropriate, culturally competent care is a focus for programs that impact tribal communities directly. To achieve this goal, IHS both serves as a health care system and partners with tribes as authorized by the Indian Self-Determination and Education Assistance Act, to provide health care and facilities services. Under this system, IHS and its tribal partners provide primary health care, behavioral health care, and community health services.

Additionally, IHS provides public health services that extend beyond the provision of health care. In partnership with other federal agencies, IHS builds sanitation systems to provide safe water and waste disposal for Indian homes, supports tribal self-governance and consultation, and recruits health professionals to serve in areas with high provider need through its Scholarships and Loan Repayment programs.

### Prioritizing Access to Quality Health Care Services

IHS provides direct care services in over 650 hospitals, clinics, and health stations on or near Indian reservations. These facilities are managed by IHS, urban Indian health programs, and contracting and compacting tribes across the United States who provide services directly to tribal members, ensuring each tribe the opportunity to provide care in the best way possible for its members.

***Construction:*** Construction projects are integral to ensuring continued access to quality health care services for Native people. Since the beginning of the Administration, IHS has worked to decrease construction backlogs by funding additional facilities through both the American Recovery and Reinvestment Act, and the annual IHS Budget. The FY 2016 Budget includes an additional $171 million over FY 2015 for a number of construction projects within IHS. These funds will allow IHS to build new health care and sanitation facilities, and repair and improve currently-owned structures to ensure access for American Indians and Alaska Natives across Indian Country.

The largest portion of this funding, $185 million, will be used to complete construction of the Gila River

**Tribal Behavioral Health Initiative**

IHS and Substance Abuse and Mental Health Services Administration will make investments in behavioral health as part of the Administration's Generation Indigenous Initiative, created to remove the barriers to success for Native youth. As part of Generation Indigenous, IHS will dedicate resources to a new behavioral health effort that focuses on youth by expanding the successful Methamphetamine and Suicide Prevention Initiative. Through this $25 million expansion, IHS will provide funding to hire child and adolescent behavioral health providers to provide critical mental health services including prevention and early intervention of youth suicide and substance abuse.

Southeast Health Center in Chandler, Arizona, and to design and initiate construction on the Salt River Northeast Health Center in Scottsdale, Arizona, the Rapid City Health Center in Rapid City, South Dakota, and the Dilkon Alternative Rural Health Center in Dilkon, Arizona. Once completed, these facilities are projected to collectively serve a user population of 59,504 patients.

IHS will also continue to work on improving sanitation facilities for American Indians and Alaska Natives. Many homes on tribal lands lack water or adequate sewage facilities. Throughout the course of the Administration, approximately 180,000 homes will have received sanitation facilities services for the first time or upgrades to existing services. The $115 million requested for FY 2016, in addition to partnerships with the Environmental Protection Agency, will allow IHS to make continued progress toward reducing the remaining backlog over the coming year.

***Staffing New and Replacement Health Facilities:*** The Joint Venture Program links tribal and IHS funding to ensure construction and staffing of safe, state-of-the-art facilities for American Indians and Alaska Natives. Through this arrangement, IHS requests funds from Congress for staffing, equipping, and operating the facility while the participating tribe funds the costs of design and construction. These partnerships, where staffing costs have been funded by Congress in recent years, are key to increasing access to care and decreasing health disparities faced in Indian Country. The Budget includes an additional $18 million to support staffing and operating costs for three new or replacement health facilities to be completed by FY 2016, successfully funding the remaining facilities that were approved through the previous Joint Venture application process. When fully operational, these three facilities are projected to collectively serve a user population of over 16,844 patients. Additionally, IHS reopened another round application for the Joint Venture program based on significant tribal interest in this successful program.

### Prioritizing Health Care Services

The Budget includes an increase of $306 million to support and expand the provision of health care services and public health programs for American Indians and Alaska Natives. Increased funding, the Affordable Care Act, and the permanent reauthorization of the Indian Health Care Improvement Act strengthened the provision of health care services for American Indians and Alaska Natives. However, despite tremendous progress, disparities remain. For example, the rates of drug-induced deaths as well as suicide rates remain elevated across Indian Country. Continued funding increases for health care services, like the increase that is part of the government-wide Generation Indigenous effort, are essential to reducing these disparities and ensuring healthier tribal communities.

***Increases for Direct Healthcare Services:*** The Budget includes an increase of $147 million to cover increased costs associated with medical inflation, population growth, and pay cost increases for medical workers. Increases for direct healthcare services benefit all American Indians and Alaska Natives by ensuring continued health care service levels despite rising health care costs. The Budget also proposes reauthorization of the Special Diabetes Program for Indians, which provides grants to IHS, tribes, and urban Indian health programs to prevent and treat diabetes. The Diabetes Program has significant tribal support, and has been successful in achieving better health outcomes.

***Purchased/Referred Care:*** The Budget includes $984 million, an increase of $70 million or 8 percent over FY 2015, for the Purchased/Referred Care program. IHS provides care both directly and by contracting with hospitals and other health care providers to purchase care when IHS and tribally-contracted programs are unable to provide care through internal networks. The Purchased/Referred Care program is often cited as the top tribal priority because it ensures access to health care services for eligible American Indians and Alaska Natives.

By using a medical priority review system, facilities determine preference for purchasing care when funding is limited. A 70 percent increase since FY 2008 has ensured that many programs can now pay for

additional priorities beyond emergent services care. The requested FY 2016 funding increase ensures IHS can continue this expansion despite rising system-wide costs and a growing population.

***Health Insurance Reimbursements:*** In addition to funds included in this request, IHS estimates that in FY 2016, it will collect approximately $1.1 billion in health insurance reimbursements from Medicare, Medicaid, private insurers, and the Veterans Health Administration. Implementation of the Affordable Care Act expanded IHS's ability to collect additional third-party health insurance reimbursements. By law, IHS is the payor of last resort, so it is essential that efforts are made to ensure the correct entity funds care provided to IHS eligible American Indians and Alaska Natives. This request includes an additional $10 million to improve collections from public and private insurance at IHS and tribally operated facilities. Third-party collections are crucial to hiring additional medical staff, purchasing equipment, making necessary building improvements, and ensuring accreditation standards are met.

### Supporting Indian Self-Determination

Planning and delivery of health services at the local level often produces effective, quality health care because tribes and tribal organizations are the most knowledgeable about what services are needed in their communities. About 67 percent of the IHS budget is administered by tribes primarily through the authority provided to them under the Indian Self Determination and Education Assistance Act, which allows tribes to assume the administration of programs previously carried out by the federal government.

***Contract Support Costs:*** The Budget fully funds estimated Contract Support Costs need at $718 million, an increase of $55 million above FY 2015. These funds are paid directly to tribes to support infrastructure needed to administer health programs and cover necessary costs in the operation of those programs. The estimated increase includes funding for new and expanded contracts and compacts. The Budget also requests a reclassification of contract support costs to a mandatory appropriation beginning in FY 2017. If enacted by Congress, this change is a long-term solution that will continue the policy to fully fund contract support costs, make new investments to ensure program integrity, and protect the health care services budget.

**Long-Term Solution for Contract Support Costs**

Starting in FY 2017, contract support costs are proposed as a mandatory appropriation. This change would provide a long-term solution for funding of contract support costs, and would protect health care services provided to American Indians, Alaska Natives and Indian self-determination programs that improve the lives of America's first people.

***Tribal Consultation:*** Recognizing that tribes are in the best position to understand the unique needs of their diverse communities, the President and other senior leaders have met with tribal leaders and groups both on Reservations and at the White House. Additionally, 2014 saw unprecedented communication on self-determination issues between the federal government and tribal leaders, with IHS engaging in a robust plan, submitted to Congress, to ask for input from tribal leaders on possible long-term solutions for the Contract Support Costs program. IHS, in conjunction with other HHS agencies, intends to continue this communication via tribal consultation activities in FY 2016.

One of the largest consultations on the budget is the HHS annual, Department-wide Tribal Budget Consultation. At the beginning of each calendar year tribal leaders are provided an opportunity to communicate with all the operating and staff divisions of HHS. Tribal leaders are also able to exchange updated information, meet colleagues who face similar challenges, share their culture with other tribal members and HHS staff, and present recommendations for the IHS budget based on an annual tribal budget formulation process. Where possible, information shared with HHS is reflected in the FY 2016 Budget to ensure a continued legacy of improved health outcomes in Indian Country.

**Investment Funding for Health Care Facilities Construction Projects**

The FY 2016 Budget proposes an additional $172 million above FY 2015 for projects on the IHS Health Care Facilities Construction priority list, the Sanitation Facilities Construction priority list, and for much needed Maintenance and Improvement projects. The average age of IHS facilities is over 25 years, well above the industry standard for comparable private sector facilities of 9 to 10 years. To ensure facilities are safe for occupancy, IHS must spend additional funding on maintenance each year. These investments will decrease IHS's construction and maintenance backlogs across Indian Country and help ensure American Indians and Alaska Natives are receiving high-quality, state-of-the-art health care services.

# Centers for Disease Control and Prevention

## Budget Overview

| *dollars in millions* | 2014 | 2015/1 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Immunization and Respiratory Disease | 783 | 798 | 748 | -50 |
| *ACA Prevention Fund (non-add)* | *160* | *210* | *210* | -- |
| *Balances from P.L. 111-32 Pandemic Flu (non-add)* | -- | *15* | -- | *-15* |
| Vaccines For Children | 3,557 | 3,981 | 4,109 | +128 |
| HIV/AIDS, Viral Hepatitis, STIs and TB Prevention | 1,118 | 1,118 | 1,162 | +44 |
| Emerging and Zoonotic Infectious Diseases | 390 | 405 | 699 | +294 |
| *ACA Prevention Fund (non-add)* | *52* | *52* | *55* | *+3* |
| Chronic Disease Prevention and Health Promotion | 1,186 | 1,198 | 1,058 | -140 |
| *ACA Prevention Fund (non-add)* | *446* | *451* | *480* | *+29* |
| Birth Defects, Developmental Disabilities, Disability and Health /2 | 129 | 132 | 132 | -- |
| *ACA Prevention Fund (non-add)* | -- | -- | *68* | *+68* |
| Environmental Health | 179 | 179 | 179 | -1 |
| *ACA Prevention Fund (non-add)* | *13* | *13* | *37* | *+24* |
| Injury Prevention and Control | 150 | 170 | 257 | +87 |
| Public Health Scientific Services | 481 | 481 | 539 | +58 |
| *ACA Prevention Fund (non-add)* | -- | -- | *64* | *+64* |
| Occupational Safety & Health | 332 | 335 | 283 | -51 |
| World Trade Center Health Program /3 | 236 | 243 | 268 | +24 |
| Energy Employee Occupational Illness Compensation Program | 50 | 50 | 55 | +5 |
| Global Health /4 | 416 | 447 | 448 | +2 |
| Public Health Preparedness and Response | 1,368 | 1,353 | 1,382 | +29 |
| Buildings and Facilities | 24 | 10 | 10 | -- |
| CDC-Wide Activities and Program Support /5 | 275 | 274 | 114 | -160 |
| *ACA Prevention Fund (non-add)* | *160* | *160* | -- | *-160* |
| Agency for Toxic Substances and Disease Registry | 75 | 93 | 75 | -19 |
| *ATSDR ACA Mandatory Funds /6* | -- | *19* | -- | *-19* |
| User Fees | 2 | 2 | 2 | -- |
| **Subtotal, Program Level** | **10,750** | **11,269** | **11,519** | **+250** |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **CDC Budget Totals – Less Funds from Mandatory Sources** | | | | |
| Vaccines for Children | -3,557 | -3,981 | -4,109 | +128 |
| Energy Employee Occupational Injury Compensation Program | -50 | -50 | -55 | +5 |
| World Trade Center Health Program | -236 | -243 | -268 | +24 |
| ATSDR ACA Mandatory Funds | -- | -19 | -- | -19 |
| ACA Prevention Fund | -831 | -886 | -914 | +28 |
| User Fees | -2 | -2 | -2 | -- |
| **Total, Discretionary Program Level** | **6,074** | **6,088** | **6,170** | **+83** |
| **CDC Budget Totals – Less Funds From Other Sources** | | | | |
| PHS Evaluation Fund Appropriation | -211 | -- | -- | -- |
| Balances from P.L. 111-32 Pandemic Flu | -- | -15 | -- | -15 |
| **Total, Discretionary Budget Authority** | **5,863** | **6,073** | **6,170** | **+98** |
| | | | | |
| Full-time Equivalents | 11,125 | 11,134 | 11,177 | +43 |

1/ The FY 2015 appropriations also provided $1.8 billion in emergency resources to support Ebola response and preparedness activities.

2/ Comparably adjusted to reflect the FY 2015 transfer of the Limb Loss program to ACL.

3/ The FY 2016 President's Budget Appendix includes erroneous data for the World Trade Center Health Program for FY 2015 and FY 2016; the above estimates are accurate.

4/ Includes $30 million for Ebola response from PL 113-164.

5/ Comparably adjusted to reflect the creation of a separate Buildings and Facilities account in FY 2015.

6/ Funds are available through FY 2020.

*The Centers for Disease Control and Prevention works 24/7 to protect America from health, safety and security threats, both foreign and domestic. Whether diseases start at home or abroad, are chronic or acute, are curable or preventable, caused by human error or deliberate attack, CDC fights disease and protects Americans.*

The Centers for Disease Control and Prevention (CDC) work to keep Americans safe and healthy where they work, live, and play. CDC scientists and disease detectives work around the world to put proven prevention strategies to work, track diseases, stop outbreaks, and respond to emergencies of all kinds. CDC provides Americans the essential health information and tools they need to protect and advance their health. CDC is committed to reducing the health and economic consequences of the leading causes of death and disability and helping to ensure our nation's citizens are safer and healthier people. The FY 2016 Budget request for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) is $11.5 billion, a $250 million increase above FY 2015. This total includes $914 million from the Prevention and Public Health Fund (Prevention Fund).

In order to continue to advance CDC's core public health mission, the Budget includes funding increases to combat antibiotic resistant bacteria, prevent opioid abuse and overdose, reduce viral hepatitis-related illness and death, advance CDC laboratory safety and quality, improve environmental health, implement the Global Health Security Agenda, and sustain the inventory of the Strategic National Stockpile. In addition, the Budget includes targeted reductions to the discretionary immunization program, occupational safety and health activities, cancer screening programs, community grants, and eliminates the Preventive Health and Health Services Block Grant.

### HIV/AIDS, Viral Hepatitis, STI and TB Prevention

The Budget includes $1.2 billion for Domestic HIV/AIDS, Viral Hepatitis, Sexually Transmitted Infections, and Tuberculosis Prevention, an increase of $44 million over FY 2015. The Budget includes an increase of $31 million to bolster CDC's viral hepatitis prevention activities. CDC will focus on controlling the emerging epidemic of hepatitis C virus infection in young people, work to eliminate mother-to-child transmission of hepatitis B virus infection, and decrease premature death resulting from chronic viral hepatitis infection. These priorities are aligned with the *HHS Action Plan*

*for the Prevention, Care, and Treatment of Viral Hepatitis*.

The Budget includes an increase of $13 million for HIV/AIDS Prevention for adults and adolescents, and further aligns HIV/AIDS activities with the *National HIV/AIDS Strategy*. CDC will promote high-impact prevention, focusing resources on effective, scalable, and sustainable strategies along the HIV continuum of care for persons living with HIV and populations at highest risk for contracting HIV.

CDC is improving program collaboration and service integration across HIV, viral hepatitis, sexually transmitted infections, and tuberculosis prevention programs. These efforts strengthen collaborative work across disease areas, resulting in improved health outcomes, efficiency, and cost effectiveness. CDC publishes information on best practices and maintains support of integration by encouraging grantees to address related infections and to develop capacities that can be shared across programs.

CDC is leveraging the Affordable Care Act to improve the prevention and control of these diseases in the United States, and will continue to complement the Act's provisions by supporting critical public health services at the state and local levels. These services include surveillance, monitoring, partner services and contact investigations, laboratory services, provider training, operational research, and outreach to populations unlikely to access clinical care.

### Emerging and Zoonotic Infectious Disease

CDC is responsible for the prevention and control of a wide range of infectious diseases, including rare but deadly diseases, like anthrax and Ebola hemorrhagic fever, and more common illnesses, like foodborne diseases and healthcare-associated infections. CDC's expert staff manages a broad portfolio of science-based programs that also promote water safety, the health of migrating populations, and the identification and control of diseases transmitted by animals and insects. State and local health departments, other federal agencies, and foreign ministries of health around the world look to CDC to assist with wide-ranging problems—from the invasion of chikungunya virus into the Western hemisphere , to an outbreak of salmonella in 39 states linked to chicken in 2014. The Budget includes $699 million for Emerging and Zoonotic Infectious Disease activities, a $294 million increase over FY 2015.

The FY 2016 Budget will allow CDC to expand the nation's ability to fight antibiotic resistance, advance laboratory quality and safety, further reduce healthcare-associated infections, and continue to modernize public health microbiology and bioinformatics capabilities. The Budget includes an increase of $264 million above FY 2015 to implement the surveillance, prevention, and stewardship activities of the *National Strategy to Combat Antibiotic Resistant Bacteria.* CDC will invest in direct action to protect patients and communities with proven interventions to reduce the emergence and spread of antibiotic resistant pathogens and to improve appropriate antibiotic prescribing and use.

In addition, CDC will expand the National Healthcare Safety Network to more than 17,000 facilities, and will work with state and local health departments and other partners. Expanded activities will include working with partners to prevent infections, targeting health care facilities that need additional assistance using National Healthcare Safety Network data, and implementing prevention strategies.

#### Viral Hepatitis

An estimated 4.4 million Americans are living with chronic hepatitis; up to 60 percent do not know they are infected and even fewer are receiving appropriate care and treatment. Therapies are available that cure hepatitis C infection in more than 90 percent of persons who complete treatment.

To stop transmission and prevent viral hepatitis-related illness and death, CDC will use the proposed increase of $31 million in FY 2016 to:

- Expand hepatitis testing and linkage to care by health systems and providers
- Develop monitoring systems and prevention strategies to stop the emerging hepatitis C epidemic among young persons and others at risk
- Enhance vaccination-based strategies to eliminate mother-to-child transmission of hepatitis B
- Strengthen state and local capacity to detect new infections, coordinate prevention activities, provide feedback to providers for quality improvement, and track progress toward prevention goals

### Public Health Scientific Services

The Budget includes $539 million, a $58 million increase above FY 2015, for public health scientific support services. These funds support various

surveillance systems, using external sources of information, and sharing best practices in collecting, managing, and using information among CDC programs and the public health community. In FY 2016, CDC will support expanded laboratory safety training and oversight, which will include a laboratory safety training center to provide ongoing training for CDC's scientists.

CDC's National Center for Health Statistics is the nation's principal health statistics agency, producing high quality, nationally representative data used to identify emerging health issues and help guide actions and policies to improve health. In FY 2016, CDC will expand electronic death reporting to provide robust Prescription Drug Overdose data. The Budget also includes an increase of $8 million to expand capacity to bill for direct services and ensure that foundational capabilities are effectively maintained and delivered.

**Combatting Antibiotic Resistant Bacteria**

The Budget includes an increase of $264 million to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria. Implementation of the *National Strategy for Combatting Antibiotic-Resistant Bacteria* is critical to addressing antibiotic resistance domestically and abroad. Some antibiotic resistant infections are already untreatable. If CDC does not work to stop these threats now, even minor infections may become life threatening and threaten the ability to perform routine surgeries or treat diseases like diabetes and cancer.

Each year, CDC estimates that over 2 million illnesses and about 23,000 deaths are caused by antibiotic resistance. In addition, almost 250,000 people each year require hospital care for *Clostridium difficile* infections. In most of these infections, the use of antibiotics was a major contributing factor leading to the illness.

Most critically, this FY 2016 initiative will invest in direct action to protect patients and communities by implementing proven interventions that reduce emergence and spread of antibiotic-resistant pathogens and improve appropriate antibiotic use.

As part of the *National Strategy*, by 2020, the United States, together with partners, will reduce by 50 percent the incidence of overall *Clostridium difficile* infection and reduce by 60 percent Carbapenem-resistant Enterobacteriaceae infections acquired during hospitalization.

In FY 2016, the Budget includes an increase of $15 million to strengthen the nation's public health workforce through programs that recruit new talent through fellowships, increase access to high quality training, and work with academia to improve education about population health. CDC supports fellows that receive in-depth, on-the-job training in applied epidemiology, public health operations and management, informatics, prevention effectiveness, policy, and preventive medicine. In addition, CDC works with academic partners to promote the integration of population health concepts into the curricula of medical and nursing schools and to ensure that public health education is focused on ground-level public health priorities. CDC also supports the current workforce by offering public health training and continuing education.

**Advancing CDC Laboratory Safety**

CDC is committed to implementing changes identified in recent laboratory safety reviews that are needed to protect CDC staff and to safely execute critical diagnostic and research work that is essential to protecting Americans. After a deliberate review of recent laboratory safety incidents, CDC is assessing safety practices at all levels of the agency and is putting in place key actions to address the root causes of recent incidents, including:

- Creating and reinforcing effective and redundant systems and controls for protocols and procedures, including inactivation of biological materials and access to laboratories;
- Ensuring adherence to laboratory quality and safety protocols;
- Ensuring adequate ongoing training for CDC laboratory staff that will keep pace with advancing technologies and protocol demands;
- Developing enhanced laboratory safety training programs; and
- Reviewing and monitoring the implementation of training policies and procedures for new and existing staff.

### Immunization and Respiratory Diseases

CDC estimates that vaccination of children born between 1994 and 2013 will prevent 322 million illnesses, help avoid 732,000 deaths, and save nearly $295 billion in direct medical costs. CDC prevents disease, disability, and death of children, adolescents, and adults through immunization against and control of respiratory and related diseases. The Budget includes $748 million for Immunization and Respiratory Diseases, a decrease of $50 million below FY 2015, as health insurance expands coverage for immunizations. Through the discretionary immunization program and the Vaccines for Children mandatory program, CDC

improves access to immunization services for uninsured and underinsured populations and supports the scientific evidence base for vaccine policy and practices across the United States. CDC also provides critical epidemiology and laboratory capacity to detect, prevent, and respond to vaccine-preventable, respiratory, and related infectious disease threats, and provides preparedness planning for pandemic influenza. In FY 2016, the immunization program will provide funding to implement health information technologies so healthcare providers have the necessary immunization information to get patients the vaccines they need, when they need them. CDC will manage vaccine supply disruptions and shortages to ensure the best public health outcomes until vaccine supplies are restored.

CDC's influenza planning and response activities ensure a comprehensive response for seasonal influenza as well as the ability to respond to an influenza pandemic. On average, influenza causes more than 200,000 hospitalizations annually and leads to more than $10 billion annually in direct medical costs. CDC provides leadership and a cutting-edge scientific and programmatic foundation for the diagnosis, prevention, and control of influenza domestically and internationally. In FY 2016, CDC will support efforts to prevent influenza through vaccination. Annual vaccination campaigns help reach the Healthy People 2020 influenza vaccination goals, including those for minority and high-risk populations, and they also help build capacity for vaccination efforts in the event of an influenza pandemic.

### Chronic Disease Prevention and Health Promotion

Chronic diseases and conditions—such as heart disease, stroke, cancer, diabetes, obesity, and arthritis—are among the most common, costly, and preventable of health problems. CDC is at the forefront of the nation's efforts to prevent and control chronic diseases, and creates information and tools to support people and communities in preventing chronic diseases and promoting health for all. The Budget includes $1.1 billion for chronic disease prevention and health promotion activities, $140 million below FY 2015, and proposes targeted reductions while continuing priority activities.

A small number of risk factors contribute to the sizeable chronic disease burden in the United States, some of which include tobacco use, poor nutrition, and physical inactivity. CDC has taken steps to effectively address these risk factors at both the individual and population levels by funding state and local governments and local and tribal organizations to advance the nation's chronic disease prevention and health promotion efforts. CDC's work targets four cross-cutting strategies: epidemiology and surveillance to monitor trends and evaluate progress; environmental approaches that promote health and support healthy behaviors across settings; health system interventions to improve the effective use of clinical and other preventive services; and community resources linked to clinical services to improve management of chronic conditions. In FY 2016, CDC will continue this work through the State Public Health Actions to Prevent Chronic Disease grant program, the Comprehensive Approach to Good Health and Wellness in Indian Country program, and the Partnerships to Improve Community Health program. The Budget includes a reduction of $20 million for the Partnerships to Improve Community Health program for the final year of the three-year awards.

Cigarette smoking is the leading preventable cause of disease and death in the United States, killing about 480,000 Americans each year. Annual health care spending in the U.S. attributable to cigarette smoking totals as much as $170 billion a year, and 60 percent of that cost is paid for by the public through programs such as Medicare or Medicaid. CDC's 2012 *Tips from Former Smokers* education campaign is estimated to have motivated 1.6 million smokers to make a quit attempt and encouraged more than 100,000 smokers to quit as a result of the campaign. In FY 2016, CDC will continue to build public awareness and encourage smokers to quit through the *Tips* campaign.

The Budget proposes targeted reductions, including the elimination of the REACH program and the Preventive Health and Health Services Block Grant. The Budget proposes the elimination of prostate cancer activities. However CDC will continue to share resources and lessons learned to support appropriate public health strategies for prostate cancer. In addition, reductions are proposed for cancer screening programs because health insurance expands coverage for these same screening services. In FY 2016 and beyond, CDC's cancer screening programs will continue to work to increase cancer screening on a population level, while still providing direct services to people who are not covered by insurance.

### Birth Defects and Developmental Disabilities

The Budget includes $132 million for Birth Defects and Developmental Disabilities, the same as FY 2015. CDC's

programs enhance the potential for full, productive living for a large and diverse segment of the American public. CDC puts research findings and recommendations into public health action to foster a safer, healthier population. Through this essential work, CDC prevents these conditions where possible and enhances the health and quality of life for individuals who live with them.

One in 33 babies are born with a major birth defect—one every 4.5 minutes. CDC's Child Health and Development activities employ surveillance and science to understand the characteristics of birth defects and developmental disabilities, and then use these findings to inform actions to prevent them and enhance the health of people affected. CDC investigates the risk factors for autism through the Centers for Autism and Developmental Disabilities Research and Epidemiology, which conducts the Study to Explore Early Development, the largest study in the United States working to identify factors that may put children at risk for autism and other developmental disabilities.

CDC's Human Development and Disability program prevents disease and promotes equity in health and development for children and adults with disabilities. CDC collaborates with a variety of partners and through cooperative agreements to address public health challenges facing the one in five Americans who have a disability. In FY 2016, CDC will continue to collaborate with partners to support a variety of public health practice and resource centers focused on improving the health and quality of life for people with intellectual disability, attention deficit/hyperactivity disorder, and Tourette syndrome. These resource centers help individuals living with disabilities by providing health information, education, and consultation to healthcare professionals, people with disabilities, caregivers, media, researchers, policymakers, and the public.

CDC works to prevent and reduce complications experienced by people with certain blood disorders. Blood disorders - such as hemophilia, thalassemia, sickle cell disease, and Venous thromboembolism - affect millions of people each year in the United States, cutting across the boundaries of age, race, sex, and socioeconomic status. Men, women, and children of all backgrounds live with the complications associated with these conditions, many of which are painful and potentially life-threatening.

### Environmental Health

CDC protects America's health from environmental hazards that can be present in the air we breathe, the water we drink, and the world that sustains us. CDC achieves this goal by investigating the relationship between environmental factors and health, developing guidance, and building partnerships to support healthy decision making. The Budget includes $179 million for these activities, the same as FY 2015.

The Environmental Health Laboratory improves the detection, diagnosis, treatment, and prevention of diseases resulting from exposure to harmful environmental chemicals and diseases that need advanced laboratory measurement for accurate diagnosis. CDC uses biomonitoring—measurements in human blood and urine—to identify harmful exposures or nutritional deficiencies in the U.S. population. The Environmental Health Laboratory measures more than 300 chemicals and nutritional indicators in Americans. In FY 2016, CDC plans to release new biomonitoring results, adding to previously published data for 308 chemicals and 58 nutritional indicators. CDC also expects to collaborate on more than 65 studies to assess environmental exposures in vulnerable population groups or investigate the relationship between environmental exposures and adverse health effects.

Each day, people everywhere experience environmental exposures that can make them sick, cause death, and lead to very costly health conditions. CDC programs funded under Environmental Health Activities monitor environmentally related disease, respond to urgent public health threats, apply environmental health research, provide training and guidance for the nation's environmental health workforce, assist in emergency preparedness and response efforts, and support grants that improve state and local capacity. The FY 2016 Budget includes an increase of $10 million to build on CDC's Climate-Ready States and Cities Initiative, through the Building Resilience Against Climate Effects program.

In addition, CDC's Childhood Lead Poisoning Prevention program provides national expertise, guidance, and analyses of childhood lead poisoning in the United States. Lead poisoning poses a social and economic burden on families, communities, and the country. In FY 2016, CDC will fund state lead poisoning prevention programs, advise state and local agencies and stakeholders in lead poisoning prevention, provide epidemiological and laboratory expertise, and monitor trends in childhood blood lead levels for states that provide data.

### Injury Prevention and Control

CDC is the nation's leading authority on violence and injury prevention. CDC keeps Americans safe by researching the best ways to prevent violence and injuries, using science to create real-world solutions to keep people safe, healthy, and productive. The Budget includes $257 million for injury prevention and control activities, an increase of $87 million above FY 2015.

CDC's Intentional Injury Prevention program focuses on youth violence, child maltreatment, teen dating violence, sexual violence, intimate partner violence, suicide, bullying, and firearm-related injuries and deaths nationally. Violence affects people throughout their lifespan. In the United States in 2012, approximately 78 children per hour, more than one child every minute, were victims of child maltreatment and over 1,600 children died as a result of child maltreatment.

Unintentional injuries are the leading cause of death for individuals ages 1–44 in the United States and are projected to cost more than $81 billion annually in medical costs. CDC's Unintentional Injury program promotes safety by tracking unintentional injuries to identify opportunities for prevention and by developing and evaluating recommendations for effective programs and policies for injury areas, including traumatic brain injury and older adult falls. Interventions in these areas are implemented at the state level.

Prescription drug overdose represents a growing public health concern, as evidenced by the fact that more than 60 people die every day in the United States from prescription drug overdoses, most of which involve prescription opioid pain relievers. The Budget includes an increase of $48 million to expand CDC's prescription drug overdose prevention activities to all 50 states. In addition, CDC will devote $6 million to activities to identify illicit opioid use risk factors in order to best prioritize prevention efforts throughout the Department. These efforts will ensure that heroin is appropriately addressed within the context of other opioid and wider prescription drug overdose threats to public health.

To reduce traumatic brain injuries, including concussions, CDC conducts surveillance, develops and shares educational materials and clinical guidelines, and supports prevention interventions. To ensure the health and safety of young athletes, CDC developed the Heads Up: Concussion in Youth Sports initiative to offer information about concussions to coaches, parents, and athletes involved in youth sports. The Heads Up campaign provides important information on preventing, recognizing, and responding to a concussion. Consistent with Institute of Medicine recommendations, the Budget includes an increase of $5 million for CDC to establish and oversee a national surveillance system to accurately determine the incidence of sports-related concussions among youth ages 5-21.

### Occupational Safety and Health

CDC's Occupational Safety and Health efforts help protect the nation's 155 million workers, and provide the only dedicated federal investment for research needed to prevent injuries and illnesses that cost the United States $250 billion annually. Research efforts are aligned under the National Occupational Research Agenda, which uses partnerships to maximize the impact of occupational safety and health research. CDC's other occupational safety and health activities involve areas such as surveillance, health hazard evaluations, and basic laboratory research. The Budget includes $283 million, -$51 million below FY 2015 for these activities. The Budget proposes targeted reductions to programs such as the Agricultural, Forestry, and Fishing Program and Education and Research Centers. CDC will continue to provide scientific and programmatic expertise to the Centers.

In FY 2016, CDC will continue a project in Spokane, Washington designed to characterize the burden of disease and opportunities for health promotion among western miners. Researchers will conduct health surveillance, including assessments of respiratory and cardiovascular function, and develop strategies to formally integrate worker health promotion into an occupational health surveillance program. This work will have a significant and direct impact on improving the health of metal and nonmetal mineworkers, and provide critical data to inform research planning for the

development of exposure assessment methods and engineering controls in these mines.

In addition, in FY 2016, CDC will support Personal Protective Technology research, conformity assessment, and respirator certification activities. CDC will conduct intramural and extramural research to advance state-of-the-art technology to understand and improve protection, usability, comfort, fit, and user acceptance, with an emphasis on personal protective equipment for fire fighters and healthcare workers, as well as escape technology for miners. Funding will also support evaluation of product performance for personal protective equipment used by 20 million workers in all industry sectors to protect them from job hazards.

The Budget includes $267 million in mandatory funding for the World Trade Center Health Program to support health services for responders and survivors enrolled in the Program. The Program provides quality care to the responders and other individuals affected by the events of September 11, 2001. HHS estimates that there are sufficient resources to continue the Program through the end of FY 2016.

The Budget also includes $55 million in mandatory funding to continue CDC's role in the Energy Employees Occupational Illness Compensation Program.

### Public Health Preparedness and Response

CDC's Public Health Preparedness and Response activity works 24/7 to protect the safety, security, and health of the United States from public health threats, foreign and domestic, intentional and naturally occurring. CDC provides life-saving responses to chemical, biological, radiological, and nuclear threats, as well as other disasters, outbreaks, and epidemics. The Budget provides $1.4 billion for public health emergency preparedness activities in CDC, an increase of $29 million above FY 2015.

Of this total, $644 million is requested for Public Health and Emergency Preparedness grants, the same as FY 2015. Since 2002, this program has provided more than $9 billion to public health departments across the nation to upgrade their ability to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Preparedness activities funded by the program are targeted specifically for the development of emergency-ready public health departments that are flexible and adaptable.

The Budget includes $571 million for the Strategic National Stockpile, an increase of $37 million above FY 2015 to replace some expiring countermeasures and maintain the current preparedness levels. The Strategic National Stockpile manages and delivers life-saving medical countermeasures during a public health emergency. It is the largest federally owned repository of pharmaceuticals, critical medical supplies, Federal Medical Stations, and medical equipment available for rapid delivery to support federal, state, and local response to health security threats.

In addition, the Budget will support CDC's critical infrastructure and cross-cutting research to facilitate rapid response to public health emergencies. CDC directs public health response efforts; detects sources of disease outbreaks; develops tests to rapidly detect biological, chemical, and radiological agents; and regulates laboratories handling the most dangerous infectious agents and toxins. The Budget also includes an increase of $10 million for CDC's Select Agent Program to oversee and regulate the possession, use, and transfer of potentially dangerous biological agents and toxins in the United States and is instrumental in implementing the CDC Director's initiative to create a culture of safety in all laboratories handling dangerous pathogens and toxins. In FY 2016, the Select Agent Program will increase by 25 percent the number of annual inspections for high-risk facilities.

**Ebola Outbreak Response in West Africa**

The 2014 Ebola outbreak is the largest in history and the first Ebola epidemic the world has ever known — affecting multiple countries in and around West Africa. CDC is working with other U.S. government agencies, the World Health Organization (WHO), and other domestic and international partners, and has activated its Emergency Operations Center to help coordinate technical assistance and monitor activities with its partners. CDC is mobilizing an unprecedented emergency response to control the ongoing epidemic of Ebola in West Africa and, importantly, to restore and strengthen the capacities of health systems in priority countries so that current and future global health threats can be better addressed. CDC personnel are deployed to the region to assist with response efforts, including surveillance, contact tracing, data management, laboratory testing, and health education. In FY 2015, CDC received $1,771 million in one-time emergency funding for the U.S. Government response to contain, treat, and prevent the spread of Ebola.

### Global Health

As evidenced by the 2014 Ebola outbreak in West Africa, an outbreak anywhere is a threat everywhere. CDC supports efforts around the globe to detect epidemic threats earlier, respond more effectively, and prevent avoidable catastrophes. With scientists and health experts embedded in countries around the globe, CDC works with partners to adapt scientific evidence into policies and public health actions—strengthening public health capacity and improving health impact in partner countries. The Budget provides $448 million for CDC's global health activities, an increase of $32 million above FY 2015.

CDC's global immunization program is involved in one of the most effective of all global public health missions – vaccination against deadly diseases – which saves the lives of two to three million people every year. CDC works closely with a wide variety of partners to protect global citizens against contagious and life-threatening vaccine-preventable diseases, such as polio and measles. In FY 2016, the Budget includes an increase of $10 million for the polio immunization program to scale-up response to ongoing and new polio outbreaks, such as speeding up global transition from an oral polio vaccine to an inactivated polio vaccine. In addition, as part of the Stop Transmission of Polio Program, CDC will train over 250 public health professionals placed in countries with the highest risk for poliovirus transmission to support critical national immunization functions.

CDC supports prevention, control, elimination, diagnosis, and treatment of a wide range of parasitic diseases that threaten the health of individuals in the United States and globally. CDC uses knowledge and experience gained from helping to eliminate malaria from the United States to further develop and apply the science of successful elimination of parasitic diseases. In FY 2016, CDC experts will provide scientific evidence and evaluation to help implement the next five-year plan for the President's Malaria Initiative. Central to this effort is continuing development of the evidence on insecticide resistance, antimalarial resistance, bed net durability, and effectiveness of additional malaria control efforts, such as mass screening and treatment.

The Budget includes an increase of $12 million in resources for CDC's Global Health Security Agenda program. Building the capacity for a country to detect and respond to a potential disease outbreak or public health emergency before an event occurs helps contain dangerous pathogens as they emerge, thereby saving lives, protecting the global and U.S. economies, and preventing the spread of disease across borders. In addition, the Budget includes an increase of $10 million to expand work with partners to build strong, nimble, and sustained public health systems by focusing on the foundational capacities of applied epidemiology, surveillance, policy development, informatics and health information systems, evaluation, research, and laboratory systems. Through the Field Epidemiology Training Program, CDC establishes a network of disease detectives around the globe who are the first line of defense in detecting and responding to outbreaks in their respective countries as well as neighboring countries.

### Agency for Toxic Substances and Disease Registry (ATSDR)

ATSDR promotes healthy and safe environments and prevents harmful exposures through responsive public health actions. ATSDR is a non-regulatory, environmental public health agency that investigates public health concerns from possible harmful exposures in communities. Managed as part of CDC, the Budget includes $75 million for ATSDR, the same as FY 2015.

ATSDR provides funds to 25 state health departments and supports environmental health professionals in 10 regional offices and field offices in Alaska and Montana. ATSDR experts are ready for a 24/7 response to environmental health threats from natural disasters, chemical spills, and other emergency events. ATSDR also maintains formal, consultative relationships with American Indian and Alaska Native tribes. In FY 2016, ATSDR anticipates conducting more than 125 formal evaluations of health risks in communities across the nation.

Whether facing a longstanding, low-level harmful environmental exposure or an acute emergency, people need the best medical information about how to manage potential health effects. Medical professionals often lack training about the health issues associated with harmful environmental exposures. To fill this clinical care gap, in FY 2016, ATSDR will support two networks with expertise in medical toxicology and pediatric environmental health–the National Environmental Medicine Education and Consultation Project and Pediatric Environmental Specialty Units.

# National Institutes of Health

## Budget Overview

| *dollars in millions* | 2014 | 2015/1 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Institutes/Centers** | | | | |
| National Cancer Institute | 4,932 | 4,953 | 5,098 | +145 |
| National Heart, Lung and Blood Institute | 2,989 | 2,996 | 3,072 | +76 |
| National Institute of Dental and Craniofacial Research | 398 | 398 | 407 | +9 |
| National Inst. of Diabetes & Digestive & Kidney Diseases | 1,884 | 1,899 | 1,938 | +39 |
| National Institute of Neurological Disorders and Stroke | 1,589 | 1,605 | 1,660 | +56 |
| National Institute of Allergy and Infectious Diseases | 4,401 | 4,418 | 4,615 | +197 |
| National Institute of General Medical Sciences | 2,367 | 2,372 | 2,434 | +61 |
| Eunice K. Shriver Natl. Inst. of Child Health & Human Development | 1,283 | 1,287 | 1,318 | +31 |
| National Eye Institute | 676 | 677 | 695 | +18 |
| National Institute of Environmental Health Sciences: Labor/HHS Appropriation | 666 | 667 | 682 | +14 |
| National Institute of Environmental Health Sciences: Interior Appropriation | 77 | 77 | 77 | — |
| National Institute on Aging | 1,172 | 1,198 | 1,267 | +70 |
| Natl. Inst. of Arthritis & Musculoskeletal & Skin Diseases | 520 | 522 | 533 | +12 |
| Natl. Inst. on Deafness and Communication Disorders | 404 | 405 | 416 | +11 |
| National Institute of Mental Health | 1,420 | 1,434 | 1,489 | +56 |
| National Institute on Drug Abuse | 1,018 | 1,016 | 1,047 | +32 |
| National Institute on Alcohol Abuse and Alcoholism | 446 | 447 | 460 | +13 |
| National Institute of Nursing Research | 141 | 141 | 145 | +4 |
| National Human Genome Research Institute | 498 | 499 | 515 | +17 |
| Natl. Institute of Biomedical Imaging and Bioengineering | 327 | 327 | 337 | +10 |
| Natl. Institute on Minority Health and Health Disparities | 268 | 271 | 282 | +11 |
| Natl. Center for Complementary and Integrative Health | 124 | 124 | 128 | +3 |
| National Center for Advancing Translational Sciences | 634 | 633 | 660 | +27 |
| Fogarty International Center | 68 | 68 | 70 | +2 |
| National Library of Medicine | 337 | 337 | 394 | +57 |
| Office of the Director | 1,303 | 1,414 | 1,443 | +29 |
| Buildings and Facilities | 128 | 129 | 129 | — |
| **Total, Program Level** | **30,070** | **30,311** | **31,311** | **+1,000** |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Less Funds from Other Sources** | | | | |
| PHS Evaluation Fund Appropriation (NLM) | -8 | -715 | -847 | -132 |
| Type 1 Diabetes Research (NIDDK) /2 | -139 | -150 | -150 | — |
| **Total, Discretionary Budget Authority** | **29,923** | **29,446** | **30,314** | **+868** |
| **Appropriations** | | | | |
| Labor/HHS Appropriation | 29,845 | 29,369 | 30,237 | +868 |
| Interior Appropriation | 77 | 77 | 77 | — |
| | | | | |
| Full-time Equivalents | 18,048 | 18,150 | 18,150 | — |
| 1/ The FY 2015 appropriations also provided $238 million in emergency resources to support Ebola response and preparedness activities. | | | | |
| 2/ These mandatory funds were pre-appropriated in P.L. 112-240, the American Taxpayer Relief Act of 2012, and P.L. 113-93, the Protecting Access to Medicare Act of 2014, and are proposed for reauthorization in FY 2016. | | | | |

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

The FY 2016 Budget requests $31.3 billion for the National Institutes of Health (NIH), an increase of $1 billion, or 3.3 percent, over FY 2015. The FY 2016 request supports the Administration's priority to invest in innovative biomedical and behavioral research that advances medical science and improves health while stimulating economic growth. In FY 2016, NIH estimates it will support a total of 35,447 research project grants, including over 10,000 new and competing awards.

Begun as a one-room Laboratory of Hygiene in 1887, NIH serves as the nation's medical research agency. Today, it is the largest source of multidisciplinary funding for biomedical and behavioral research in the world. NIH's budget is composed of 27 appropriations for its Institutes and Centers, Office of the Director, and Buildings and Facilities. In FY 2016, about 83 percent of the funds appropriated to NIH will flow out to the extramural community, which supports work by more than 300,000 research personnel at over 2,500 organizations, including universities, medical schools, hospitals, and other research facilities. NIH has supported 145 Nobel Prize winners over the past 46 years. About 11 percent of the Budget will sustain an in-house, or intramural, program of basic and clinical research and training activities managed by world class physicians and scientists. This intramural research program gives the nation the unparalleled ability to respond immediately to national and global health challenges. It includes the NIH Clinical Center, the largest hospital in the world totally dedicated to clinical research. Another six percent will provide for agency leadership, research management and support, and facilities maintenance and improvements.

### Research Priorities in FY 2016

In fulfilling its mission, NIH strives to fund a strong, diverse portfolio of biomedical research, flexible enough to capitalize on scientific opportunities and to respond to urgent public health needs as they arise. In FY 2016, with the $31.3 billion requested, NIH will focus on the priorities of generating basic science findings, translating these basic discoveries into improvements in personal and public health, better use of data and technology, and recruiting a diverse, creative, and talented workforce upon which the robust research enterprise depends.

**NIH Disease Accomplishments**

As a result of long-term national investments, scientific and technological breakthroughs generated by NIH-supported research are behind much of the gains in health and longevity that the nation has enjoyed. For example:

NIH research has generated effective drugs for lowering cholesterol, controlling blood pressure, and dissolving artery-clogging blood clots, as well as new techniques for heart attack prevention, including helping people make lifestyle changes that promote cardiovascular health. As a result, the death rate today for coronary heart disease is 60 percent lower – and for stroke, more than 70 percent lower – than during the World War II era in which cardiovascular disease caused half of U.S. deaths and claimed the lives of many people in their 50s or 60s.

Over the past 15 years, cancer death rates in the U.S. have dropped about one percent annually, due in large measure to NIH's success in improving the basic understanding of the causes and mechanisms of cancer, improving early detection and diagnosis, developing effective treatments, and expanding knowledge of cancer prevention strategies.

NIH has led the global research effort against HIV/AIDS over the past 34 years, enabling the development of rapid HIV tests and the identification of a new class of HIV-fighting drugs that could be combined in life-saving ways in the clinic. As a result, HIV infection has changed from a virtual death sentence into a manageable chronic disease. Today, HIV-infected people in their 20s who receive combination therapy may expect to live to age 70 or beyond.

***Unraveling Life's Mysteries through Basic Research:*** Advances in basic research fields such as genomics, proteomics, stem cells, the microbiome, imaging, and other technologies have transformed our understanding of how life works. Approximately 54 percent of the NIH research budget is devoted to basic biomedical and behavioral research.

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative: In FY 2016, NIH plans to spend $135 million, an increase of $70 million over FY 2015, to expand the BRAIN Initiative, which is aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both real time and space. This picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve vast quantities of information, all at the speed of thought. Ultimately, the technologies developed under the BRAIN Initiative may help reveal the underlying pathology in a vast array of brain disorders and provide new avenues to treat, cure, and even prevent neurological and psychiatric conditions, such as Alzheimer's disease, autism, depression, schizophrenia, and addiction.

***Translating Discovery into Health:*** NIH is heavily invested in translating recent insights about the molecular basis of disease into effective interventions that improve the health of individuals and the public, from diagnostics and therapeutics to medical procedures, behavioral changes, and disease prevention strategies.

Antimicrobial Resistance: NIH proposes to spend $461 million in FY 2016, an increase of $100 million over FY 2015, in support of the Administration's National Strategy to Combat Antibiotic Resistant Bacteria. These funds will be used to spur the development of new, rapid diagnostics to help ensure that antibiotics are prescribed appropriately; develop a national database of genome sequence data of all reported human infections with antimicrobial-resistant microorganisms; launch a large-scale effort to characterize drug resistance, focusing on changes in host/pathogen molecular interactions that occur as bacteria develop resistance to treatments; and create a rapid-response clinical trial network to test new antibiotics on individuals infected with highly resistant strains. Jointly funded at $20 million with the Biomedical Advanced Research and Development Authority, NIH is working to design a public competition for the accelerated development of an affordable, accurate, and rapid diagnostic test to be used by healthcare providers to identify highly resistant bacterial infections at the point of patient care.

Alzheimer's Disease: To assist in meeting the goal to prevent and effectively treat Alzheimer's disease by 2025, NIH is continuing to implement the research components of the National Plan to Address Alzheimer's Disease. NIH estimates it will spend

$638 million on Alzheimer's research in FY 2016, an increase of $51 million over FY 2015. NIH continues to invest in a broad spectrum of basic and translational research activities to combat Alzheimer's disease. This includes basic neuroscience research, epidemiologic studies to identify risk and protective genes, and clinical studies to identify biomarkers for early disease diagnosis and for disease progression. In addition, more than 25 NIH-funded clinical trials are underway, and more than 40 grants are testing compounds as potential preventive and therapeutic interventions for Alzheimer's and cognitive decline.

Vaccine Development: The FY 2016 request includes an increase of $51 million for NIH to invest in developing new or improved vaccines, particularly for HIV/AIDS and influenza. Several promising new HIV vaccine candidates are undergoing clinical trials and NIH is seeking to boost the efficacy of other previously tested candidates. With the additional funding proposed for FY 2016, these efforts will be accelerated, as will research using cutting-edge knowledge of immunology, genomics and structural biology to develop a universal influenza vaccine which could confer decades-long protection from any influenza virus strain and potentially end the need for annual flu shots.

Accelerating Medicines Partnership: In FY 2016, NIH will spend $23 million, the same level as in FY 2015, to continue to implement the Accelerating Medicines Partnership, a bold new venture between NIH, ten biopharmaceutical companies, and several non-profit organizations to transform the current model for developing new diagnostics and therapeutics by jointly identifying and validating promising biological targets of disease. The initial focus of the Partnership is on three- to five-year pilot projects in three disease areas: Alzheimer's disease, type 2 diabetes, and the autoimmune disorders of rheumatoid arthritis and lupus.

***Harnessing Data and Technology to Improve Health:*** Biomedical science continues to generate immense and complex datasets that present challenges for data creation, storage, and analysis, but also extraordinary opportunities to answer questions about biology, behavior, and medicine that previously were unanswerable.

Big Data to Knowledge (BD2K): NIH established the BD2K program in 2012 to develop systems and expertise that enable optimal use of the vast potential of Big Data in biomedical science, such as high-resolution medical images, recorded physiological signals, and next generation gene sequencing of large numbers of individuals. NIH will devote $102 million In FY 2016, an increase of $20 million over FY 2015, to the BD2K program to facilitate sharing and protection of data among researchers across the nation through a Data Commons, develop faster and more accurate analytical methods and software, enhance training, and establish Centers of Excellence. Such efforts will help solve the most intractable Big Data problems to deepen our understanding of disease and speed translation of new treatments.

***Preparing a Diverse and Talented Biomedical Research Workforce:*** An important part of the biomedical research endeavor is a diverse, well trained, and highly creative workforce capable of developing new scientific insights and translating these insights into improved health outcomes. To encourage exceptionally promising new investigators and to speed the transition of talented trainees to independent researcher positions, in FY 2016, NIH will continue to emphasize several High-Risk, High Reward research programs, such as the Pioneer Research Awards, the NIH Director's Early Independence Awards, Transformative Research Awards, and New Innovator Awards, as well as the Pathway to Independence Awards. In addition to these High-Risk, High-Reward activities managed within or in collaboration with the Common Fund, a number of NIH Institutes and Centers are now introducing similar programs of their own, which are expected to expand in FY 2016.

**Targeted Therapies for Disorders of the Immune System in Children**

NIH has set a performance goal for the next several years to identify more molecular-targeted therapies for disorders of the immune system in children. To help achieve this, NIH is supporting the International Childhood Arthritis Genetics Consortium, which recently completed a genome-wide association study of 982 patients with systemic-onset juvenile idiopathic arthritis (also known as Still's disease) and over 7,000 healthy control patients, examining 1.4 million genetic markers. This study identified the first known genetic variant that is linked to this disease. This genetic variant indicated that a specific T cell activation pathway may be a therapeutic target, a significant step toward developing an effective treatment for this childhood immune system disorder.

**Precision Medicine Initiative**

As part of a new cross-Department initiative, NIH plans to spend $200 million in FY 2016 to focus on developing treatments tailored to the individual characteristics of each patient, also known as precision medicine. The convergence of incredible breakthroughs in genomic sequencing technologies, computing power, and data sciences, coupled with a rapidly growing understanding of the molecular basis of disease has paved the way for an era of precision medicine.

Cancer Genomics ($70 million): The battle against cancer has been leading the way in precision medicine for many years. To capitalize on these successes, the FY 2016 request proposes to expand current cancer genomics research to initiate new studies of how a tumor's DNA can be used to predict and treat tumor cells that develop resistance to a therapy, apply new non-invasive methods to track response to therapy, and explore the efficacy of new combinations of cancer drugs targeted to specific tumor mutations.

National Research Cohort ($130 million): To harness the full potential of precision medicine across many diseases, NIH will use the FY 2016 request to launch a national research cohort of one million or more individuals, primarily those who have already participated in clinical research studies, who volunteer to share their genetic information in the context of other health data over time. This information will be linked to their electronic health records while ensuring privacy protections are in place. A database of this scale will lay the foundation for a wealth of new research studies which promises to lead to new prevention strategies, and novel therapeutics and medical devices. It will also help improve how drugs are prescribed, allowing a more optimum choice of the right drug at the right dose for the right person.

NIH will also continue to implement a series of steps to enhance its effort to recruit and advance the careers of people traditionally underrepresented in the biomedical and behavioral research workforce. For example, NIH will continue to provide mentorship and resources to undergraduate students in relatively under-resourced institutions that are interested in pursuing a biomedical research career. Other efforts include building a nationwide consortium that will connect students, postdoctoral fellows, and faculty to experienced mentors, and improving upon data collection and evaluation efforts to determine the most effective approaches. In addition, to help prepare the research workforce to thrive in an increasingly multidisciplinary environment, NIH has established the Broadening Experiences in Scientific Training Awards to allow trainees to supplement their academic experience with training in industry, non-profits, government, policy, science communication, and other settings within the biomedical research enterprise.

In FY 2016, NIH estimates it will spend a total of $785 million to support training 15,735 of the next generation of research scientists through the Ruth L. Kirschstein National Research Service Awards program. The Budget proposes a two percent stipend increase for predoctoral and postdoctoral trainees in FY 2016.

***HIV/AIDS:*** NIH estimates it will devote $3.1 billion for research on HIV/AIDS in FY 2016, an increase of $100 million over FY 2015. With newly discovered ways of identifying and treating HIV infection and preventing HIV transmission, coupled with the promise of safe, effective, and affordable vaccines, the world can, for the first time, imagine achieving an AIDS-free generation.

***Pediatric Research:*** NIH will continue in FY 2016 the $13 million for pediatric research authorized under the Gabriella Miller Kids First Research Act of 2014. Across the entire agency, NIH estimates it will spend a total of more than $3.6 billion for pediatric research in FY 2016, an increase of $75 million over FY 2015.

***Research Project Grants:*** NIH estimates that it will devote $17.2 billion, or 55 percent of its total budget, to finance a total of 35,447 competitive, peer-reviewed, and largely investigator-initiated research project grants in FY 2016. Within this total, NIH anticipates supporting over 10,000 new and competing grants, an increase of over 1,200 grants above FY 2015 levels.

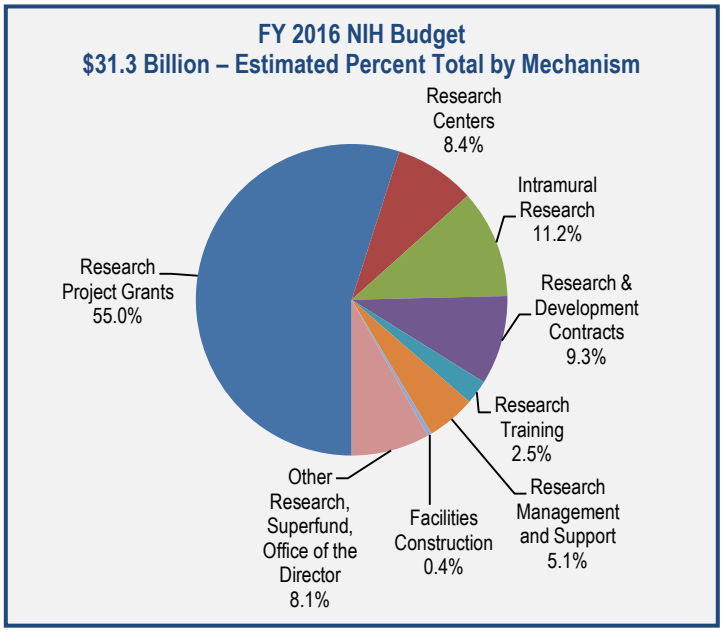
### Intramural Buildings and Facilities

A total of $145 million is requested for NIH intramural Buildings and Facilities in FY 2016, an increase of $8 million over FY 2015, to sustain and improve the physical infrastructure used to carry out quality biomedical research on the NIH campuses. Most of the funds will be used for facility repairs and improvements. The Buildings and Facilities mechanism total also includes $16 million, an increase of $8 million over FY 2015, requested within the National Cancer Institute budget for facilities repair and improvement projects at its Frederick, Maryland campus.

# Overview by Mechanism

| *Mechanism* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Mechanism | | | | |
| Research Project Grants (dollars) | 16,168 | 16,333 | 17,206 | +873 |
| *[ # of Non-Competing Grants]* | *[23,504]* | *[23,433]* | *[23,303]* | *[-130]* |
| *[ # of New/Competing Grants]* | *[9,168]* | *[9,076]* | *[10,303]* | *[+1,227]* |
| *[ # of Small Business Grants]* | *[1,660]* | *[1,697]* | *[1,841]* | *[+144]* |
| *[ Total # of Grants ]* | *[34,332]* | *[34,206]* | *[35,447]* | *[+1,241]* |
| Research Centers | 2,723 | 2,699 | 2,637 | -63 |
| Other Research | 1,847 | 1,844 | 1,882 | +38 |
| Research Training | 738 | 762 | 785 | +23 |
| Research and Development Contracts | 2,990 | 2,899 | 2,896 | -3 |
| Intramural Research | 3,384 | 3,426 | 3,521 | +95 |
| Research Management and Support | 1,528 | 1,561 | 1,580 | +20 |
| Office of the Director | 477 | 573 | 582 | +9 |
| *NIH Common Fund (non-add)* | *[531]* | *[546]* | *[566]* | *[+20]* |
| Buildings and Facilities | 136 | 137 | 145 | +8 |
| NIEHS Interior Appropriation (Superfund) | 77 | 77 | 77 | — |
| **Total, Program Level** | **30,070** | **30,311** | **31,311** | **+1,000** |
| **Less Funds Allocated from Other Sources** | | | | |
| PHS Evaluation Fund Appropriation(NLM) | -8 | -715 | -847 | -132 |
| Type 1 Diabetes Research (NIDDK) /1 | -139 | -150 | -150 | — |
| **Total, Budget Authority** | **29,923** | **29,446** | **30,314** | **+868** |
| Labor/HHS Appropriation | 29,845 | 29,369 | 30,237 | +868 |
| Interior Appropriation | 77 | 77 | 77 | — |

1/ These mandatory funds were pre-appropriated in P.L. 112-240, the American Taxpayer Relief Act of 2012, and P.L. 113-93, the Protecting Access to Medicare Act of 2014 and are proposed for reauthorization in FY 2016.



# Substance Abuse and Mental Health Services Administration


## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2016 |
|---|---|---|---|---|
| **Mental Health** | | | | |
| Community Mental Health Services Block Grant | 483 | 483 | 483 | -- |
| Programs of Regional and National Significance | 377 | 371 | 377 | +7 |
| Children's Mental Health Services | 117 | 117 | 117 | -- |
| Projects for Assistance in Transition from Homelessness | 65 | 65 | 65 | -- |
| Protection and Advocacy for Individuals with Mental Illness | 36 | 36 | 36 | -- |
| **Subtotal, Mental Health** | **1,078** | **1,071** | **1,078** | **+7** |
| **Substance Abuse Treatment** | | | | |
| Substance Abuse Prevention and Treatment Block Grant | 1,815 | 1,820 | 1,820 | -- |
| Programs of Regional and National Significance | 361 | 361 | 321 | -41 |
| **Subtotal, Substance Abuse Treatment** | **2,176** | **2,181** | **2,141** | **-41** |
| **Substance Abuse Prevention** | | | | |
| Programs of Regional and National Significance | 175 | 175 | 211 | +36 |
| **Subtotal, Substance Abuse Prevention** | **175** | **175** | **211** | **+36** |
| **Health Surveillance and Program Support** | | | | |
| Program Support | 72 | 72 | 80 | +8 |
| Agency-Wide Initiatives (Behavioral Health Workforce) | 46 | 47 | 78 | +31 |
| Health Surveillance | 47 | 47 | 49 | +2 |
| Public Awareness and Support | 13 | 13 | 16 | +2 |
| Performance and Quality Information Systems | 13 | 13 | 13 | -- |
| Data Request and Publications User Fees | 2 | 2 | 2 | -- |
| **Subtotal, Health Surveillance and Program Support** | **193** | **194** | **237** | **+43** |
| **SAMHSA Budget Totals, Program Level** | | | | |
| **Total, Program Level** | **3,622** | **3,621** | **3,666** | **+45** |
| *Prevention and Public Health Fund* | *-62* | *-12* | *-58* | *-46* |
| *PHS Evaluation Fund Appropriation* | *-133* | *-134* | *-211* | *-77* |
| *User Fees for Extraordinary Data Request and Publications* | *-2* | *-2* | *-2* | -- |
| **Total, Discretionary Budget Authority** | **3,426** | **3,474** | **3,396** | **-78** |
| | | | | |
| Full-time Equivalents | 615 | 665 | 665 | -- |

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

The FY 2016 Budget requests $3.7 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA), an increase of $45 million above FY 2015. The Budget continues investments to increase access to mental health services in order to protect the health of children and communities, prevent suicide and substance abuse, and promote mental health. The Budget also invests new resources to expand access to prevention and treatment of opioid prescription drug and abuse, with a special focus on heroin. In addition, the Budget includes new funding to integrate primary care and addiction services; to assist communities, and tribal organizations in particular, with addressing substance abuse, suicide prevention, and trauma; to establish effective crisis response systems; and to further respond to the critical need for additional behavioral health care providers.

The impact of untreated behavioral health conditions on individuals' lives and the costs of health care delivery in the United States are staggering. For example, Medicaid enrollees with common chronic conditions and co-occurring mental and substance use disorders have health care costs two to three times higher than Medicaid enrollees without these conditions. Incorporating mental and emotional health promotion into a public health approach as well as increasing treatment of mental and substance use disorders can reduce health care costs and improve overall health.

### Improving Mental Health throughout America

***Improving the Availability of Mental Health Services to Protect the Health of Children and Communities:*** While individuals with mental illness are more likely to be victims of violence than perpetrators, incidents of violence continue to highlight a crisis in America's mental health system. Today, less than half of children and adults with diagnosable mental health problems receive the treatment they need. The Budget expands key investments to improve access to care for those with mental health problems.

The President's *Now is the Time* initiative lays out changes toward a healthier and safer country. The Budget invests $151 million in SAMHSA to make sure students and young adults get treatment for mental health issues. These efforts will reach 750,000 young people every year through programs that promote mental health through identifying mental illness early and creating a clear pathway to treatment for those in need, including through additional outreach and training for those who work with youth.

In addition to the $116 million in *Now is the Time* activities supported in FY 2015, the Budget includes $35 million in new funding to:

- Expand the partnership with the Health Resources and Services Administration by $21 million to a total of $56 million to increase the number of licensed behavioral health professionals and paraprofessionals available to serve in communities across the nation;
- Provide $10 million for a Peer Professionals program to increase the number of trained peers, recovery coaches, mental health and addiction specialists, prevention specialists, and pre-Master's level addiction counselors in light of research showing people who regularly engage in peer-delivered interventions are more likely to abstain from substance abuse; and
- Provide $4 million to change the attitudes of Americans about mental and substance use disorders and their willingness to seek help.

***Improving State and Local Crisis Response:*** The Budget includes a new, targeted demonstration grant program, Crisis Support, to help states and communities build, fund, and sustain crisis systems capable of preventing and de-escalating behavioral health crises. This $10 million program will help build the evidence base by demonstrating models of effective, coordinated, and integrated crisis response systems and the accompanying array of crisis services and supports. Phase one of these grants will support planning activities to develop the necessary infrastructure for a comprehensive crisis response system. With effective prevention and planning efforts in place, this funding will also help curb demand for inpatient beds and focus attention on those with serious mental illness and substance use disorders.

***Preventing Suicide:*** The Budget provides $62 million to prevent suicide, $2 million above FY 2015. This increase will bolster funding to implement the National Strategy for Suicide Prevention, the nation's blueprint for reducing suicide over the next decade. This

important funding will help develop and test the interventions that may be most effective for suicide prevention, such as suicide awareness, changes in provider training requirements at the accreditation level, emergency room referral processes and clinical care standards to maximize post-discharge continuity of care, among other activities.

SAMHSA's suicide prevention programs provide funding to states and tribes to develop and implement youth suicide prevention and early intervention strategies in partnership with education and juvenile justice systems, youth support organizations, and other community organizations. In addition to basic prevention efforts, the Budget maintains the capacity of the National Suicide Prevention Lifeline, a hotline that routes calls across the country to a network of certified local crisis centers.

***Improving Tribal Capacity to Promote Mental Health and Prevent Suicide and Substance Abuse:*** During a visit to Indian Country on June 13, 2014, the President reaffirmed the Administration's partnership with tribal nations. Work remains to address behavioral health challenges faced by many tribes. SAMHSA and the Indian Health Service (IHS) will make new investments in behavioral health as part of the Administration's Generation Indigenous initiative, created to remove the barriers to success for Native youth. As a part of Generation Indigenous, the Budget expands a promising demonstration grant program from $5 million to $30 million for tribal entities to promote mental health and address substance abuse among American Indian and Alaska Native young people. In collaboration with IHS and in consultation with tribal leaders, this funding will help to address the disproportionate burden of mental illness, substance abuse, and suicide faced in many American Indian/Alaska Native communities by helping tribes implement evidence-based suicide prevention programs and integrate systems that address issues of child abuse and neglect, family violence, trauma, and substance abuse.

### Improving Nationwide Substance Abuse Prevention and Treatment Efforts

The Budget includes $1.8 billion for the Substance Abuse Prevention and Treatment Block Grant, and $483 million for the Community Mental Health Services Block Grant, the same levels as in FY 2015, to implement evidence-based strategies nationwide and to maintain the nation's public behavioral health infrastructure. Examples of services which can be provided by these flexible sources of funding include medical services, provider education, supported employment and housing, rehabilitation, crisis stabilization and case management services, and wrap around services for children and families such as education, counseling, on-site child care or transportation of children, and parenting classes.

These block grants, which represent 32 percent of total state substance abuse agency funding and 1 percent of all state and federal spending on mental health care in the United States, are anticipated to provide services to approximately 10 million individuals. As access to health coverage expands through the implementation of the Affordable Care Act, SAMHSA will work with states to leverage these resources to provide necessary care not paid for by insurance.

***Improving Health Care Quality by the Integration of Primary Care and Addiction Services:*** The Budget provides $20 million in new funding to bring primary care services to community substance abuse treatment provider sites. Individuals with substance abuse issues too rarely successfully complete referral to other care. By co-locating primary and specialty care medical services, this program increases the likelihood that patients will receive primary care services, which has been shown to lower health care costs. Drawing on lessons from the successful and ongoing Primary and Behavioral Health Care Integration program, this program will fund implementation, technical

**Secretary's Opioid Initiative**

The Budget includes $99 million in new funding in CDC, SAMHSA, ONC, and AHRQ to support targeted efforts to reduce the prevalence and impact of opioid use disorders. These investments, including $35 million in new funding in SAMHSA, represent one aspect of a new, aggressive, multi-pronged initiative including policy changes, executive actions, and new funding. This initiative prioritizes activities backed by the best evidence available and the greatest opportunity for measurable impact.

Among other activities, CDC will lead the development of improved opioid prescribing guidelines, NIH will prioritize additional research and clinician education, FDA will incentivize the development of new opioid overdose and opioid use disorder treatments through expedited administrative review, and the will propose to expand initiatives that address safe and appropriate prescribing.

**Behavioral Health Workforce**

The Budget includes a substantial expansion of a partnership with the Health Resources and Services Administration to increase the number of licensed behavioral health professionals and paraprofessionals available to serve in communities across the nation.

In FY 2014 and FY 2015, the partnership is projected to result in 3,500 additional behavioral health professionals and paraprofessionals annually.

In FY 2016, the Budget includes an additional $21 million for this effort, to total $56 million, and will result in an additional 5,600 professionals and paraprofessionals entering the behavioral health workforce annually.

assistance, and evaluation efforts, including dissemination of successful approaches.

***Responding to Abuse, Misuse, and Overdose of Prescription Drugs and Opiates including Heroin:*** Across the nation, over 20,000 individuals die from prescription opioids and heroin use each year. Preventing opioid misuse and abuse, including opioid-related overdoses and deaths, requires prevention, treatment, and recovery support services. The Budget addresses each of these key areas and provides funding to expand access to medication-assisted treatment for opioid addiction and to equip first responders with training and emergency devices used to rapidly reverse the effects of opioid overdoses.

The Budget proposes $99 million in new funding across the Department, including $35 million in SAMHSA, to address prescription drug and opioid misuse, abuse, and prevention of overdose death. Within SAMHSA, this new investment will include $13 million to increase access to medication assisted treatment in communities suffering from high rates of addiction to opioids such as heroin. This program will allow grantees to offer pharmacotherapies such as methadone, buprenorphine, and others as part of a full array of evidence-based opioid addiction treatment services and recovery supports. It will also increase provider and community awareness of this important, evidence-based approach.

This initiative also includes $12 million for a new grant program to complement current opioid overdose prevention efforts through grants to states to purchase naloxone, an overdose-reversing drug, equip first responders in high-risk communities with this drug and training on its use, prepare overdose kits, and provide education to the public.

In addition, the Budget includes $10 million in grants to states to enhance, implement, and evaluate strategies to prevent prescription drug misuse and abuse, and to improve collaboration on the risks of overprescribing and the use of monitoring systems between states' public health and education authorities, and pharmaceutical and medical communities.

**Promoting Continuous Innovation**

***Enabling Americans to Live Healthy and Productive Lives through Innovative Approaches to Heath Care:*** SAMHSA's Programs of Regional and National Significance have long fostered innovative solutions to emerging issues in substance abuse and mental health services. These programs are intended to be small and agile, and are a key part of SAMHSA's role in the health care system: to evaluate promising approaches to the nation's most challenging behavioral health concerns. For example, SAMHSA's National Registry of Evidence-Based Programs and Practices, a searchable online database of independently assessed mental health and substance abuse interventions, now includes more than 340 interventions, up from 320 last year. This resource helps inform the public and the medical community about the effectiveness and readiness for dissemination of interventions. The Budget includes $909 million, $2 million above FY 2015, for Programs of Regional and National Significance.

Programs in these areas are in most cases proposed at the same level as last year or are discontinued because the programs have been tested and if successful are able to be supported through other funding sources such as block grants or public or private insurance.

For example, after the successful launch of a Mental Health First Aid program associated with the President's *Now is the Time* initiative, the Budget proposes to establish a sister program of $4 million to reach or train 55,000 individuals to focus on veterans and their families. The Budget discontinues the Access to Recovery program. SAMHSA will provide training and technical assistance in FY 2015 to states and Access to Recovery grantees to increase the adoption and implementation of integrated, peer-driven recovery services and supports for people with substance use disorders and mental health problems. This effort will ensure that essential recovery support services typically not paid for by insurance, such as

transportation, housing, and employment support, will continue from other sources of funding such as block grants. The integration of proven interventions into larger, more flexible sources of funding allows SAMHSA to broaden the evidence base and promote continuous innovation through targeted use of limited resources.

### Responsible Management and Program Integrity

***Health Surveillance and Program Support:*** The Budget provides a one-time increase of $7 million for additional costs associated with the end of SAMHSA's building lease. These costs include rent, move, and reconfiguration costs and are part of government-wide efforts to reduce long-term rent and utility costs by reducing per person space use and periodically re-evaluating competing lease offers.

The Budget continues support at the same level as FY 2015 for national survey efforts, the administration and monitoring of SAMHSA programs and grantees, and public awareness activities. The Budget also includes a focus on program integrity to ensure that scarce resources are appropriately and responsibly monitored. SAMHSA's national surveys and the analyses conducted through them are used by federal, state, and local authorities, as well as other health care stakeholders, to inform mental health and substance abuse policy.

# Agency for Healthcare Research and Quality

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| ***Health Costs, Quality and Outcomes Research (HCQO)*** | | | | |
| Patient Safety | 72 | 77 | 76 | -1 |
| Health Information Technology Research | 30 | 28 | 23 | -5 |
| Health Services Research, Data and Dissemination | 111 | 112 | 112 | — |
| *PHS Evaluation Funds (non-add)* | *111* | *0* | *88* | *+88* |
| *Budget Authority (non-add)* | *0* | *112* | *24* | *-88* |
| Prevention/Care Management | 23 | 12 | 12 | — |
| *PHS Evaluation Funds (non-add)* | *16* | — | — | — |
| *Budget Authority (non-add)* | *0* | *12* | *12* | — |
| *Prevention and Public Health Fund (non-add)* | *7* | *0* | — | — |
| Value | 3 | — | — | — |
| Subtotal, Program Level, HCQO | 238 | 229 | 223 | -6 |
| *Subtotal, PHS Evaluation Fund Appropriation, HCQO (non-add)* | *231* | — | *88* | *+88* |
| *Subtotal, Budget Authority, HCQO (non-add)* | — | *229* | *135* | *-94* |
| *Subtotal, Prevention Fund (non-add)* | *7* | — | — | — |
| ***Medical Expenditure Panel Survey*** | | | | |
| *PHS Evaluation Fund Appropriation* | 64 | — | — | — |
| *Budget Authority* | — | 65 | 69 | +4 |
| ***Program Support*** | | | | |
| *PHS Evaluation Fund Appropriation* | 69 | — | — | — |
| *Budget Authority* | — | 70 | 72 | +2 |
| | | | | |
| ***Patient-Centered Outcomes Research Trust Fund Transfer****/1* | 65 | 101 | 116 | +14 |
| | | | | |
| **Total, Program Level** | **436** | **465** | **479** | **+14** |
| **Less Funds From Other Sources** | | | | |
| PHS Evaluation Fund Appropriation | -364 | — | -88 | -88 |
| Patient-Centered Outcomes Research Trust Fund | -65 | -101 | -116 | -14 |
| Prevention and Public Health Fund | -7 | — | — | — |
| **Total, Discretionary Budget Authority** | **—** | **364** | **276** | **-100** |
| | | | | |
| Full-time Equivalents | 307 | 325 | 325 | — |

1/ AHRQ receives mandatory funds transferred from the Patient-Centered Outcomes Research Trust Fund to implement section 937 of the Public Health Services Act.

*The mission of the Agency for Healthcare Research and Quality is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used.*

The FY 2016 Budget includes a total program level of $479 million for the Agency for Healthcare Research and Quality (AHRQ), $14 million above the FY 2015 level. Within this total, the Budget funds $88 million of AHRQ's activities with Public Health Service (PHS) Evaluation Funds and $276 million with discretionary budget authority. AHRQ will also receive $116 million from the Patient Centered Outcomes Research Trust Fund, an increase of $14 million above FY 2015, which accounts for the entirety of the increase of AHRQ's total program level.

AHRQ conducts and supports a broad range of health services research within hospitals, research institutions, and health care systems that informs and enhances decision-making, and improves healthcare services, organization, and financing. AHRQ's research provides evidence that becomes the foundation for large scale implementation by other HHS Operating Divisions, such as the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS), and nationwide improvement of the healthcare system. For example, AHRQ has developed evidence-based practices for preventing healthcare-associated infections in hospital intensive care units. These practices have been adopted and implemented across the country by the Partnership for Patients, funded by the Center for Medicare and Medicaid Innovation. AHRQ translates evidence from research into practical solutions that health care organizations can implement to prevent and mitigate patient safety risks and hazards, and improve the quality of care. The FY 2016 Budget continues support for core health services research on delivery system quality, safety, cost, and outcomes. The Budget also supports key data collections on changes in health costs, the use of health services, and insurance coverage.

### Health Costs, Quality, and Outcomes

The FY 2016 Budget includes a program level of $223 million, $7 million below FY 2015, for research on how to improve the value, effectiveness, quality, and results of health care services. AHRQ organizes these activities into four main research portfolios: patient safety; health information technology; prevention and care management; and health services research, data, and dissemination.

**Improving Patient Safety Through Evidence-Based Practices: TeamSTEPPS**

Patient safety experts agree that teamwork, communication, and culture are widely recognized as foundational bases on which patient safety can be improved. AHRQ actively works to address these factors by supporting the Team Strategies and Tools to Enhance Performance and Patient Safety program, also known as TeamSTEPPS®.

TeamSTEPPS is an evidence-based program aimed at optimizing performance among teams of healthcare professionals – enabling them to respond quickly and effectively to whatever situations arise in their facilities. This curriculum was developed by a panel of experts, incorporating over 26 years of scientific research. The Budget provides $1 million for this program in FY 2016 to perform needs assessments, tool dissemination, and training in health care organizations across the country to prevent and mitigate medical errors and patient harm.

***Enhancing Patient Safety:*** The Budget includes $76 million, a decrease of $1 million below FY 2015, for the AHRQ patient safety research portfolio. The lifesaving research and dissemination projects supported by this portfolio actively reduce the number of medical errors and patient safety risks. AHRQ's patient safety projects seek to implement initiatives to advance patient safety and quality, establish cultures in healthcare organizations that support patient safety and maintain vigilance through adverse event reporting to prevent patient harm, while also conducting research to strengthen the science base and develop more effective patient safety interventions. The FY 2016 Budget includes ongoing support for the dissemination and implementation of successful initiatives that integrate the use of evidence-based resources such as toolkits for improving safety and quality of care, and Team Strategies and Tools to Enhance Performance and Patient Safety, which provides training and tools for health care providers to create a culture of safety. AHRQ's research in this area provides the evidence base that CMS and other HHS agencies use to improve patient safety on a national scale.

In FY 2016, AHRQ will provide $34 million, the same level as FY 2015, to prevent healthcare-associated infections by advancing new knowledge and

accelerating the widespread adoption of proven methods for preventing these dangerous infections. Within this amount, the Budget includes $10 million, a $4 million increase, for healthcare-associated infections activities that will support expanding AHRQ's efforts to address the growing threat of antibiotic resistant bacteria. This goal will be achieved by developing and pilot testing effective approaches for conducting stewardship programs, which seek to reduce inappropriate antibiotic use. These efforts will contribute to the Administration's National Strategy for Combating Antibiotic Resistant Bacteria.

The FY 2016 Budget also provides $4 million for the Comprehensive Unit-based Safety Program, which has been shown to be highly effective at reducing healthcare-associated infections by improving patient safety culture and implementing practices informed by research. In FY 2016, this program will focus on addressing catheter associated urinary tract infections and central line associated blood stream infections in intensive care units, a subset of which have persistently elevated infection rates in need of targeted improvement, as well as conducting further phases of current projects that are implementing the safety program. AHRQ is actively collaborating with CMS and CDC on the Agency Priority Goal that seeks to reduce catheter-associated urinary tract infections by 10 percent by the end of 2015. AHRQ's prevention efforts have contributed significantly to a nationwide 17 percent reduction in hospital-acquired conditions from 2010 to 2013, which translates to an estimated 1.3 million fewer incidents, 50,000 fewer patient deaths, and $12 billion saved in health costs.

***Health Information Technology Research:*** The Budget provides $23 million, $5 million less than FY 2015, for the AHRQ health information technology (health IT) research portfolio. This program area develops and disseminates research findings and evidence-based tools to inform policy and practice on how health IT can improve the quality of American health care. In FY 2016, this portfolio will devote $20 million to support 55 grants to continue building foundational evidence necessary to successfully leverage the significant national investment in health IT to improve the effectiveness, safety, and efficiency of the U.S. health care system. In recent years, grants in this area have examined the information needs of clinicians and patients, and evaluated the barriers to health IT adoption in rural America.

This portfolio operates in close coordination with other federal health IT programs in order to leverage resources and maximize their impact. For example, this research creates the evidence base and data that are utilized by the HHS Office of the National Coordinator for Health Information Technology to inform Meaningful Use Stage 3.

***Prevention and Care Management:*** The Budget includes $12 million, the same level as FY 2015, for the AHRQ Prevention and Care Management research portfolio, which is focused on supporting improved evidence-based clinical decision-making for preventive services through the U.S. Preventive Services Task Force (Task Force). The Task Force is an independent non-governmental panel that evaluates the risks and benefits of clinical preventive services, makes recommendations about which services should be incorporated to improve primary medical care, and identifies research priorities. In FY 2016, AHRQ will continue to support systemic evidence reviews, research methods development, public engagement, transparency, and public dissemination of research findings.

***Advancing Health Services Research, Data and Dissemination:*** The Budget provides a total of $112 million, the same level as FY 2015, for research focused on improving health care quality, effectiveness, and efficiency. This portfolio conducts crosscutting research to identify the most effective ways to organize, manage, finance, and deliver high quality care.

The Budget includes $5 million for a new effort to reduce prescription drug and opioid overdoses. This funding is a component of a department-wide action plan being developed to ensure that this public health epidemic is addressed with resources commensurate with the national need.

Increasing access to substance abuse treatment, including medication assisted treatment, is essential to effectively addressing prescription drug use. Primary care settings offer a tremendous opportunity for expanding access to medication assisted treatment, especially in rural areas that may lack access to community-based, specialty treatment centers. To date, relatively few primary care professionals and practices are providing evidence-based substance abuse treatment including medication assisted treatment. To respond to this need, AHRQ will invest $1 million to conduct a systematic evidence review on

the implementation of medication assisted treatment in primary care settings. The evidence review will summarize what works for current providers and identify where more research is needed. In addition, AHRQ will support $4 million of grants to develop and test new methods, processes, and tools for better implementing these treatment strategies.

Additionally, in FY 2016 the Budget proposes $12 million for a new project to develop clinician tools to improve care for individuals with multiple chronic conditions. The Budget also proposes over $1 million for new research to the identify types of health care that are most likely to respond to financial incentives.

In FY 2016 AHRQ will provide $44 million for investigator-initiated research grants, of which approximately $14 million will be used to fund new grants. New investigator initiated research grants ensure resources are available to support new and innovative ideas each year. The Budget reduces funding for less effective activities in this portfolio and dissemination and translation projects, which will be re-scaled and focused on leveraging external partnerships. This portfolio's grant activities also include continuing support for several rapid cycle research networks that are designed to accelerate the diffusion of new research findings into practice, which contributes to increased quality, a stronger evidence-based culture of practice, and ultimately to better health for patients.

### Medical Expenditure Panel Survey

The FY 2016 Budget includes $69 million, an increase of $4 million above FY 2015, for Medical Expenditure Panel Survey to continue providing vital national-level data on health status, medical expenditures, demographic disparities, and health care access, coverage and quality. This survey provides the only national source of annual data on how Americans, including the uninsured, use and pay for health care. The Survey's data help the public and researchers know how employer-sponsored health insurance plans are changing over time, how much families can expect to pay for care, which types of doctor visits are increasing, and how health costs and service patterns are evolving. The Medical Expenditure Panel Survey includes three interrelated survey components: household, medical provider, and insurance.

Three million of the requested funding increase for the Medical Expenditure Panel Survey in FY 2016 is for the new Optimizing Care Patients with Multiple Chronic Conditions initiative, and will support data collection for the project. The funds will support additional targeted sampling to fulfill the need for nationally representative data on care management, coordination, and satisfaction of patients with multiple chronic conditions.

**Optimizing Care for Patients with Multiple Chronic Conditions**

The FY 2016 Budget includes $12 million for a new initiative to improve the care of patients with multiple chronic conditions. This initiative addresses the challenges of a high-cost, high-need growing patient population by developing tools with promise to improve care coordination, and quality of life, while reducing unnecessary expenses.

Health care for patients with multiple conditions is often fragmented, inefficient, costly, and ineffective. To address this problem, AHRQ is launching a project that will develop and evaluate evidence-based tools for clinicians to use to better coordinate health care for these complex patients. These tools will be based on integrated care plans, which are a new model that takes into account clinical and non-clinical factors to improve the comprehensiveness of, and adherence to, health care regimens. The project will also address information gaps by collecting national data to better understand care management and coordination for this population. Funding for this project is divided into two parts: $9 million in the Health Services Research, Data, and Dissemination portfolio, and $3 million in the Medical Expenditure Panel Survey.

This effort also supports the quality improvement goals of the HHS Strategic Framework on Multiple Chronic Conditions published in December 2010, and builds upon earlier research by the AHRQ-funded Multiple Chronic Conditions Research Network that investigated the safety and effectiveness of medical interventions for this population.

### Program Support

The FY 2015 Budget includes $72 million, which is $2 million above the FY 2015 level, to support costs essential to AHRQ's ability to conduct and manage research. The largest single expense category supported by these funds is staff salaries, and other large expenses include employee benefits and rent. The majority of the requested increase in FY 2016 is for temporary costs associated with AHRQ's move to a different building.

### Patient Centered Health Research

In FY 2016 AHRQ will receive $116 million from the Patient Centered Outcomes Research Trust Fund, for Patient Centered Health Research (also known as

Patient Centered Outcomes Research or Comparative Effectiveness Research). In FY 2016, projects will continue to drive systemic improvement and adoption of best practices in health care settings by supporting the training of researchers and the public dissemination and translation of comparative clinical effectiveness research findings.

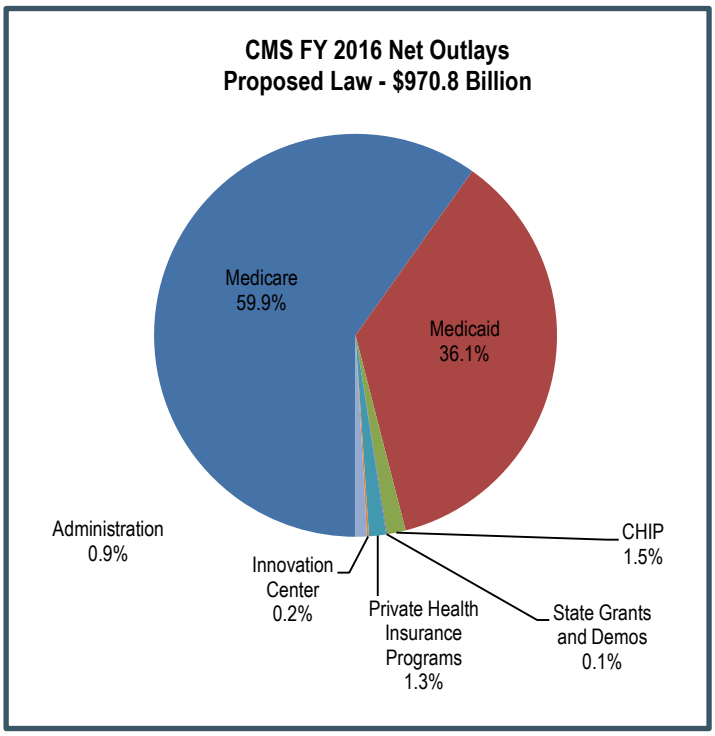
# Centers for Medicare & Medicaid Services: Overview

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Current Law** | | | | |
| Medicare /1 | 511,693 | 530,451 | 583,519 | +53,068 |
| Medicaid | 301,472 | 328,595 | 344,447 | +15,852 |
| CHIP | 9,319 | 10,608 | 14,010 | +3,402 |
| State Grants and Demonstrations | 508 | 572 | 593 | +21 |
| Private Health Insurance Programs | 2,689 | 15,252 | 13,254 | -1,998 |
| Center for Medicare and Medicaid Innovation | 997 | 1,291 | 1,590 | +299 |
| **Total Net Outlays, Current Law** | **826,678** | **886,768** | **957,413** | **+70,645** |
| **Adjusted Baseline** | | | | |
| Prevent Reduction in Medicare Physician Payments | — | 5,337 | 8,786 | +3,449 |
| **Total Net Outlays, Adjusted Baseline** | **826,678** | **892,106** | **966,199** | **+74,093** |
| **Proposed Law** | | | | |
| Medicare | — | 630 | -2,413 | -3,043 |
| Medicaid | — | 4,485 | 6,617 | +2,132 |
| CHIP | — | — | 560 | +560 |
| State Grants and Demonstrations | — | — | 25 | +25 |
| Private Health Insurance Programs | — | — | — | — |
| Program Management | — | — | 656 | +656 |
| **Total Proposed Law** | **—** | **5,115** | **5,445** | **+330** |
| **Total Net Outlays, Proposed Law** /2 | **826,678** | **897,221** | **971,664** | **+74,423** |
| Savings from Program Integrity Investments /3 | — | — | -870 | -870 |
| **Total Net Outlays, Proposed Policy** | **826,678** | **897,221** | **970,774** | **+73,553** |
| | | | | |
| 1/ Current law Medicare outlays net of offsetting receipts. | | | | |
| 2/ Total net proposed law outlays equal current law outlays plus the impact of proposed legislation and offsetting receipts. | | | | |
| 3/ Includes savings not subject to PAYGO from additional program integrity investments above savings already assumed in current law. | | | | |

*The Centers for Medicare & Medicaid Services ensures availability of effective, up-to-date health care coverage and promotes quality care for beneficiaries.*

The FY 2016 Budget estimate for the Centers for Medicare & Medicaid Services (CMS) is $970.8 billion in mandatory and discretionary outlays, a net increase of $74 billion above the FY 2015 level. This request finances Medicare, Medicaid, the Children's Health Insurance Program (CHIP), private health insurance programs and oversight, program integrity efforts, and operating costs. The Budget continues CMS's work to implement the Affordable Care Act by improving health care for tens of millions of Americans through comprehensive insurance reforms, policies to enhance quality, and providing access to health insurance coverage. The Budget proposes targeted reforms to improve the long-term sustainability of Medicare and Medicaid by increasing the efficiency of health care delivery without compromising the quality of care for the elderly, children, low income families, and people with disabilities.




## Budgetary Request

***Medicare:*** The Budget includes net projected Medicare savings of $423 billion over 10 years. Most notably, the Budget invests $44 billion above the President's Budget adjusted baseline to reform the Medicare physician payment system to accelerate physician participation in high quality and efficient healthcare delivery systems. Other proposals improve payment efficiency across providers and increase the value of the care that is provided to Americans.

***Medicaid:*** The Budget includes legislative proposals in Medicaid which have an impact of $3.7 billion on net federal spending over 10 years[1], including $26.7 billion in Medicaid investments, to make the program more flexible, efficient, and accountable. The Budget, as part of the Workforce Initiative, extends and refocuses the rate increase for Medicaid primary care providers. The Budget also extends free preventive care services to all Medicaid beneficiaries, creates a new state plan option to provide continuous Medicaid coverage and limit churning, expands access to home and community-based long-term care services and supports and provides permanent flexibility to facilitate enrollment of children into Medicaid.

***CHIP:*** The Budget extends CHIP funding for four additional years, through 2019, to ensure continued comprehensive and affordable coverage for CHIP children. The proposal is paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives. The Budget includes an additional $490 million in CHIP investments to permanently extend express lane eligibility.

***Program Integrity:*** The Budget includes $201 million in new program integrity investments in FY 2016, as part of a multi-year strategy to enable HHS and the Department of Justice to detect, prevent, and prosecute health care fraud. Additionally, the Budget proposes $25 million in discretionary funding to support program integrity activities in private insurance, including the Health Insurance Marketplaces. These investments, plus new legislative authorities to strengthen program integrity oversight, yield $21.7 billion in savings over 10 years.

***Discretionary Program Management:*** The Budget for Program Management enables reforms in health care delivery while supporting the ongoing administration of the Medicare, Medicaid, and CHIP programs, as well as the Health Insurance Marketplaces. The request invests of $36.2 million to address growing Medicare appeals workloads and $50 million for a multiyear process of removing Social Security Numbers from Medicare beneficiary identification cards.

[1] This includes $23 billion in savings to Marketplaces subsidies and related impacts, reflected in the Department of Treasury program and accounts.

# Medicare

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Current Law Outlays and Offsetting Receipts** | | | | |
| Benefits Spending (gross) /1 | 590,441 | 613,530 | 672,599 | +59,069 |
| Less: Premiums Paid Directly to Part D Plans /2 | -7,455 | -8,437 | -10,212 | -1,776 |
| Subtotal, Benefits Net of Direct Part D Premium Payments | 582,986 | 605,093 | 662,386 | +57,293 |
| Related-Benefit Expenses /3 | 14,833 | 14,195 | 14,104 | -91 |
| Administration /4 | 8,350 | 8,766 | 8,834 | +68 |
| **Total Outlays, Current Law** | 606,169 | 628,054 | 685,324 | +57,270 |
| Premiums and Offsetting Receipts | -94,476 | -97,603 | -101,805 | -4,203 |
| **Current Law Outlays, Net of Offsetting Receipts** | 511,693 | 530,451 | 583,519 | +53,068 |
| Prevent Reduction in Medicare Physician Payments (Net) | 0 | 5,337 | 8,786 | +3,449 |
| **Adjusted Baseline Outlays, Net of Offsetting Receipts** | 511,693 | 535,788 | 592,305 | +56,517 |
| **Proposed Law** | | | | |
| Medicare Proposals, Net of Offsetting Receipts /5 | 0 | 630 | -2,413 | -3,043 |
| Program Management | 0 | 0 | 630 | +630 |
| **Total Medicare Proposals, Net of Offsetting Receipts** | 0 | 630 | -1,783 | -2,413 |
| Savings from Program Integrity Investments /6 | 0 | 0 | -811 | -811 |
| **Total Net Outlays, Adjusted Baseline, Savings from Program Integrity Investments and Proposed Law** | 511,693 | 536,418 | 589,711 | +53,293 |
| **Mandatory Proposed Law** | | | | |
| **Mandatory Total Net Outlays, Proposed Policy /7** | 505,307 | 529,991 | 582,972 | +52,981 |
| 1/ Represents all spending on Medicare benefits by either the Federal government or through beneficiary premiums. Includes Medicare Health Information Technology Incentives. | | | | |
| 2/ In Part D only, some beneficiary premiums are paid directly to plans and are netted out here because those payments are not paid out of the Trust Funds. | | | | |
| 3/ Includes related benefit payments, including refundable payments made to providers and plans, transfers to Medicaid, and additional Medicare Advantage benefits. | | | | |
| 4/ Includes CMS Program Management, non-CMS administration, HCFAC and QIOs. | | | | |
| 5/ Represents all scorable costs and savings under PAYGO rules of legislative proposals that affect the Medicare trust funds, including transfers to Medicaid of $370 million in FY 2015 and $775 million in FY 2016 to extend the Qualified Individuals (QI) Program. | | | | |
| 6/ Includes non-PAYGO savings from HHS and Social Security program integrity investments on the Medicare baseline. | | | | |
| 7/ Removes total Medicare discretionary amount: FY 2014- $6,386 million; FY 2015- $6,427 million; and FY 2016- $6,739 million. | | | | |

In FY 2016, the Office of the Actuary has estimated that gross current law spending on Medicare benefits will total $672.6 billion. Medicare will provide health insurance to 57 million individuals who are 65 or older, disabled, or have end-stage renal disease.

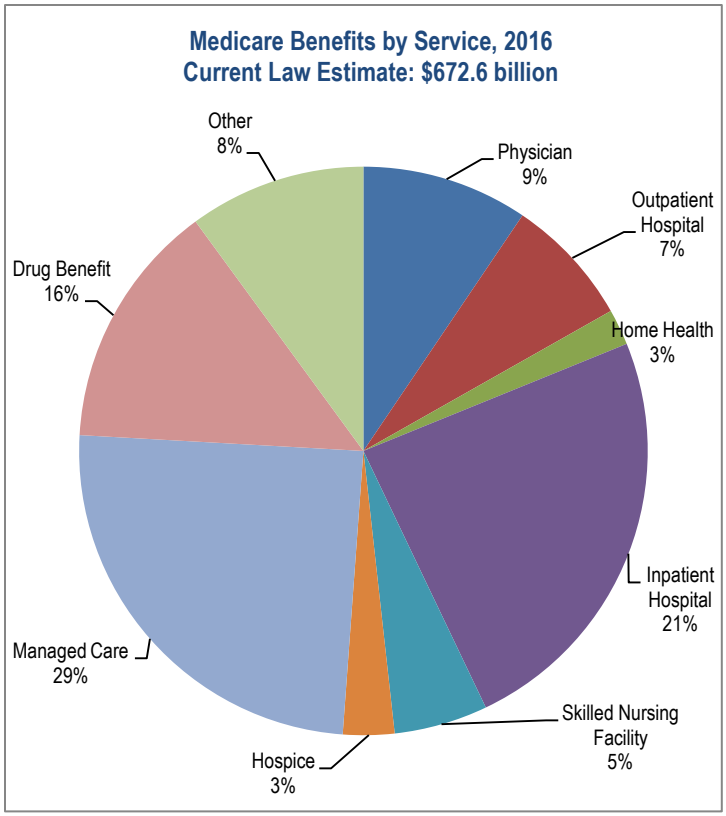
## The Four Parts of Medicare

***Part A ($195.4 billion gross fee-for-service spending in 2016):*** Medicare Part A pays for inpatient hospital, skilled nursing facility, home health related to a hospital stay, and hospice care. Part A financing comes primarily from a 2.9 percent payroll tax paid by both employees and employers.

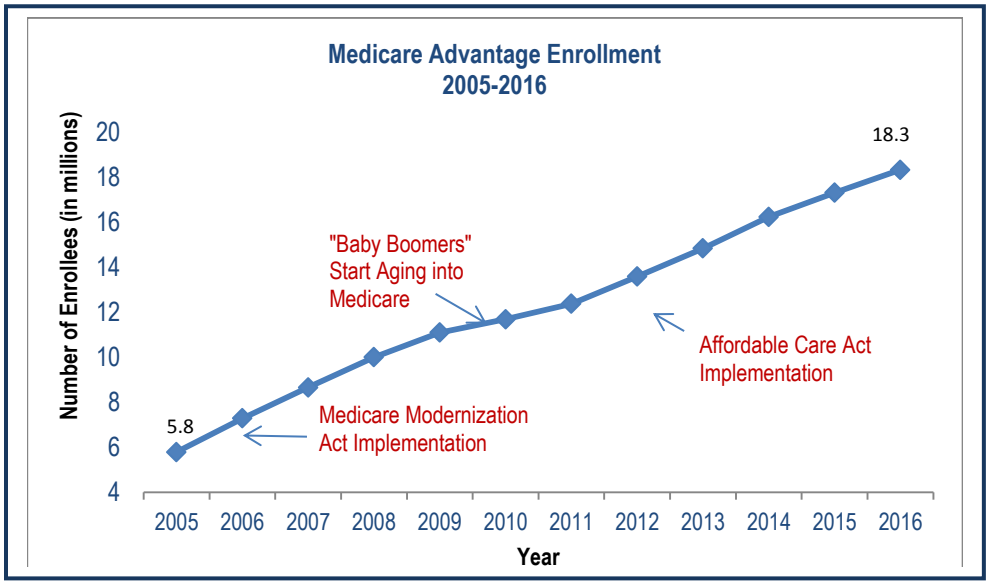
Generally, individuals with 40 quarters of Medicare-covered employment are entitled to Part A without paying a premium, but most services require a beneficiary co-payment or coinsurance. In 2015, beneficiaries pay a $1,260 deductible for a hospital stay of 1–60 days, and $157.50 daily coinsurance for days 21–100 in a skilled nursing facility.

***Part B ($171.2 billion gross fee-for-service spending in 2016):*** Medicare Part B pays for physician, outpatient hospital, end-stage renal disease, laboratory, durable medical equipment, certain home health, and other medical services. Part B coverage is voluntary, and about 91 percent of all Medicare beneficiaries are enrolled in Part B. Approximately 25 percent of Part B costs are financed by beneficiary premiums, with the remaining 75 percent covered by general revenues.

The standard monthly Part B premium is $104.90 in 2015, the same as the 2014 and 2013 premium. The Part B deductible remains unchanged at $147. Some beneficiaries pay a higher Part B premium based on their income: those with annual incomes above $85,000 (single) or $170,000 (married) will pay from $146.90 to $335.70 per month in 2015.




***Part C ($198.0 billion gross spending in 2016):*** 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 2015, Medicare Advantage enrollment will total approximately 17 million. Over the past ten years, Medicare Advantage enrollment as a percentage of total enrollment has increased by 138 percent. CMS data confirm that beneficiary access to a Medicare Advantage plan remains strong and stable in 2015 at 99 percent,

**Healthcare-Associated Infections**

CMS in partnership with the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the Office of the Secretary is working to improve patient safety and reduce the national rate of hospital-acquired catheter-associated urinary tract infections. The goal is to reduce the national standardized hospital-acquired catheter-associated urinary tract infection ratio by 10 percent by September 2015 over the current March 2013 infection ratio baseline of 1.02 per 1,000 days of treatment.

premiums have remained stable, Medicare Advantage supplemental benefits have increased, and enrollment is growing faster than traditional Medicare.

***Part D ($108.0 billion gross spending in 2016):***
Medicare Part D offers a standard prescription drug benefit with a 2015 deductible of $320 and an average estimated monthly premium of $32. Enhanced and alternative benefits are also available with varying deductibles and premiums. Beneficiaries who choose to participate are responsible for covering a portion of the cost of their prescription drugs. This portion may vary depending on whether the medication is generic or a brand name and how much the beneficiary has already spent on medications that year. Low-income beneficiaries are responsible for varying degrees of cost-sharing, with co-payments ranging from $0 to $6.60 in 2015 and low or no monthly premiums.

In 2016, the number of beneficiaries enrolled in Medicare Part D is expected to increase by about 3.5 percent to 43.7 million, including about 12.6 million beneficiaries who receive the low-income subsidy. In 2015, approximately 58 percent of those with Part D coverage are enrolled in a stand-alone Part D prescription drug plan, 37 percent are enrolled in a Medicare Advantage Prescription Drug Plan, and the remaining beneficiaries are enrolled in an employer plan or the Limited Income Newly Eligible Transition plan. Overall, approximately 90 percent of all Medicare beneficiaries receive prescription drug coverage through Medicare Part D, employer-sponsored retiree health plans, or other creditable coverage.

The Affordable Care Act closes the Medicare Part D coverage gap, or "donut hole," through a combination of manufacturer discounts and gradually increasing federal subsidies. Beneficiaries fall into the coverage gap once their total drug spending exceeds an initial coverage limit ($2,960 in 2015), until they reach the threshold for qualified out-of-pocket spending ($4,700 in 2015), at which point they are generally responsible for five percent of their drug costs. Prior to the Affordable Care Act, beneficiaries were responsible for 100 percent of their drug costs in the coverage gap. Under the Affordable Care Act, in 2016, non-Low-Income Subsidy beneficiaries who reach the coverage gap will pay 45 percent of the cost of covered Part D brand drugs and biologics, and 58 percent of the costs for all generic drugs in the coverage gap. Cost-sharing in the coverage gap will continue to decrease each year until beneficiaries are required to pay only 25 percent of the costs of covered Part D drugs in 2020 and beyond.

In 2014, more than 5 million beneficiaries reached the coverage gap and saved more than $4.7 billion on their medications. These savings averaged about $941 per person. Cumulatively since enactment of the Affordable Care Act, 9.4 million beneficiaries have saved a total of $15 billion on prescription drugs.

### 2016 Legislative Proposals

The FY 2016 Budget includes a package of Medicare legislative proposals that will save a net $423.1 billion over 10 years. The proposals are scored off the President's Budget adjusted baseline, which assumes a zero percent update to Medicare physician payments. These reforms will strengthen Medicare by more closely aligning payments with the costs of providing care, encouraging health care providers to deliver better care and better outcomes for their patients, and improving access to care for beneficiaries. The Budget includes investments to reform Medicare physician payments and accelerate physician participation in

**Medicare Enrollment**
(Enrollees in millions)

| Group | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Aged | 44.6 | 46.3 | 47.9 | +1.6 |
| Disabled | 8.9 | 9.0 | 9.1 | +0.1 |
| **Total Beneficiaries** | **53.5** | **55.3** | **57.0** | **+1.7** |

high-quality and efficient healthcare delivery systems. Finally, it makes structural changes in program financing that will reduce Federal subsidies to high income beneficiaries and create incentives for beneficiaries to seek high value services. Together, these measures will extend the Hospital Insurance Trust Fund solvency by approximately five years.

### *Encourage Delivery System Reform*

***Reform Medicare Physician Payments to Promote Participation in High-quality and Efficient Health Care Delivery Systems:*** This proposal would accelerate physician participation in high-quality and efficient health care delivery systems by repealing the Medicare Sustainable Growth Rate formula and reforming Medicare physician payments in a manner consistent with the reforms included in recent bipartisan, bicameral legislation [$44.0 billion in costs over 10 years]

***Encourage Efficient Care by Improving Incentives to Provide Care in the Most Appropriate Ambulatory Setting:*** The Budget proposes to improve incentives to provide ambulatory care in the most appropriate clinical setting. Evidence suggests that in recent years, billing of many ambulatory services has been shifting from physicians' offices to the usually higher paid hospital outpatient department setting, increasing Medicare spending and beneficiary cost-sharing. This proposal helps mitigate the financial implications of this trend by lowering payment for services provided in off-campus hospital outpatient departments under the Outpatient Prospective Payment System to either the Medicare Physician Fee Schedule-based rate or the rate for surgical procedures covered under the Ambulatory Surgical Center payment system. These changes would be phased in over four years beginning in CY 2017, and Secretarial authority would be provided to adjust payments in the event beneficiary access problems arise. [$29.5 billion in savings over 10 years]

**Medicare Physician Payment Reform**

The Budget adopts the following policies for reforming the way Medicare pays physicians, consistent with recent bipartisan, bicameral legislation:

- Terminates the Sustainable Growth Rate formula for updating physician payments;
- Provides a period of stability while promoting participation in alternative payment models that encourage high quality, efficient care; and
- Streamlines value-based incentives for those physicians remaining outside of alternative payment models.

***Implement Bundled Payment for Post-Acute Care:*** Beginning in 2020, this proposal would implement bundled payment for post-acute care providers, including long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health providers. Payments would be bundled for at least half of the total payments for post-acute care providers. Rates based on patient characteristics and other factors will be set so as to produce a permanent and total cumulative adjustment of -2.85 percent by 2022. Beneficiary coinsurance would equal that under current law (e.g., to the extent the beneficiary uses skilled nursing facilities, they would be responsible for the current law coinsurance rate). [$9.3 billion in savings over 10 years]

***Allow CMS to Assign Beneficiaries to Federally Qualified Health Centers and Rural Health Clinics Participating in the Medicare Shared Savings Program:*** This proposal would allow the Secretary to assign more Medicare fee-for-service beneficiaries to Federally Qualified Health Centers and Rural Health Clinics that participate in an Accountable Care Organization under the Medicare Shared Savings Program. Federally Qualified Health Centers and Rural Health Clinics are important providers of primary care services and part of the safety net for the nation's health care system. This proposal could result in assignment of a greater number of Medicare fee-for-service beneficiaries to Accountable Care Organizations and would stimulate greater interest in the program by Federally Qualified Health Centers and Rural Health Clinics and support the program's goals to improve quality of care for Medicare fee-for-service beneficiaries while reducing overall growth in costs. [$80 million in savings over 10 years]

***Expand Basis for Beneficiary Assignment for Accountable Care Organizations to include Nurse Practitioners, Physicians Assistants, and Clinical Nurse Specialists.*** This proposal would allow the Secretary to base beneficiary assignment in the Medicare Shared Savings Program on a broader set of primary care providers. Under the proposal, beneficiaries would be able to be assigned to an Accountable Care Organization on the basis of services delivered by nurse practitioners, physician assistants and clinical nurse

specialists. Statute requires that assignment of beneficiaries to an Accountable Care Organization be based on their utilization of primary care services provided by physicians. Expanding the assignment of beneficiaries to nurse practitioners, physician assistants and clinical nurse specialists, in addition to physicians, could broaden the scope of Accountable Care Organizations to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries. Further, it could result in a greater number of Medicare fee-for-service beneficiaries being assigned to Accountable Care Organizations that rely on non-physician practitioners for a majority of primary care services, such as those in rural or underserved areas. [$60 million in savings over 10 years]

***Allow Accountable Care Organizations to Pay Beneficiaries for Primary Care Visits up to the Applicable Medicare Cost Sharing Amount:*** This proposal would allow Accountable Care Organizations participating in two-sided risk models to pay beneficiaries for a primary care visit. Beneficiaries with no supplemental insurance would have all or part of their cost sharing covered by the Accountable Care Organization, and beneficiaries with supplemental insurance, would receive a payment from the Accountable Care Organization. Participation is voluntary, and no additional payments will be made to the Accountable Care Organization to cover the costs of this investment. [No budget impact]

***Establish a Hospital-Wide Readmissions Reduction Measure:*** This proposal would make revisions to the Hospital Readmissions Reduction Program to allow the Secretary to use a comprehensive Hospital-Wide Readmission Measure that encompasses broad categories of conditions rather than discrete applicable conditions. The Secretary would be permitted to make adjustments determined necessary to accurately measure readmissions and implement the program in a budget neutral manner. [No budget impact]

***Establish Quality Bonus Payments for Part D Plans:*** This proposal would allow Medicare to revise the Part D plan payment methodology to reimburse plans based on their quality star ratings. Plans with quality ratings of four stars or higher would have a larger portion of their bid subsidized by Medicare, while plans with lower ratings would receive a smaller subsidy. This proposal is modeled after the Medicare Advantage quality bonus program, but would be implemented in a budget neutral fashion. It would not impact risk corridor payments, reinsurance, low-income subsidies, or other components of Part D payments. [No budget impact]

***Expand Sharing Medicare Data with Qualified Entities:*** The Affordable Care Act includes a provision which allows CMS to make Medicare Parts A, B, or D claims data available to qualified entities for the purpose of publishing reports evaluating the performance of providers and suppliers. This proposal would expand the scope of how qualified entities can use Medicare data beyond simply performance measurement. For example, entities would be allowed to use the data for fraud prevention activities and value-added analysis for physicians. In addition, qualified entities would be able to release raw claims data, instead of simply summary reports, to interested Medicare providers for care coordination and practice improvement. This proposal includes additional resources for CMS by making claims data available to a qualified entity for a fee equal to Medicare's cost of providing the data. [No budget impact]

***Extend Accountability for Hospital-acquired Conditions*** This proposal would require hospitals to code conditions as "present on arrival" at a hospital instead of "present on admission" to the hospital for the purposes of Medicare Hospital Acquired Conditions payment policy and quality reporting. [No budget impact]

***Implement Value-Based Purchasing for Additional Providers:*** This proposal would implement a budget neutral value-based purchasing program for several additional provider types, including skilled nursing facilities, home health agencies, ambulatory surgical centers, hospital outpatient departments, and community mental health centers beginning in 2017. At least two percent of payments must be tied to the quality and efficiency of care in the first two years of implementation, and at least five percent beginning in 2019. [No budget impact]

***Make Permanent the Medicare Primary Care Incentive Payment in a Budget Neutral Manner:*** Beginning CY 2016, this proposal would convert the temporary 10 percent primary care incentive payment program enacted under the Affordable Care Act into a permanent program that is budget neutral within the Medicare Physician Fee Schedule. Under current law, the program is due to expire after CY 2015. Making

this temporary program permanent would provide valuable long-term incentives for the provision of primary care services. [No budget impact]

### *Increase Value in Medicare Provider Payments*

***Eliminate the 190-day Lifetime Limit on Inpatient Psychiatric Facility Services:*** The 190-day lifetime limit on inpatient services delivered in specialized psychiatric hospitals is one of the last obstacles to behavioral health parity in the Medicare benefit. Beginning in FY 2016, this proposal would eliminate the 190-day limit and more closely align the Medicare mental health care benefit with the current inpatient physical health care benefit. Many beneficiaries who utilize psychiatric services are eligible for Medicare due to a disability, which means they are often younger beneficiaries who can easily reach the 190-day limit over their lifetimes. Therefore, this proposal would expand the psychiatric benefit and bring parity to the sites of service, while also containing the additional costs of removing the 190-day limit. [$5.0 billion in costs over 10 years]

***Align Medicare Drug Payment Policies with Medicaid Policies for Low-Income Beneficiaries:*** Currently, drug manufacturers are required to pay specified rebates for drugs dispensed to Medicaid beneficiaries. In contrast, Medicare Part D plan sponsors negotiate with manufacturers to obtain plan-specific rebates at unspecified levels. Analysis has found substantial differences in rebate amounts and prices paid for brand name drugs under the two programs, with Medicare receiving significantly lower rebates and paying higher prices than Medicaid. Prior to the establishment of Medicare Part D, manufacturers paid Medicaid rebates for drugs provided to the dual eligible population. This proposal would allow Medicare to benefit from the same rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy, beginning in 2017. The proposal would require manufacturers to pay the difference between rebate levels they already provide Part D plans and the Medicaid rebate levels. Manufacturers would also be required to provide an additional rebate for brand name and generic drugs whose prices grow faster than inflation. [$116.1 billion in savings over 10 years]

***Adjust Payment Updates for Certain Post-Acute Care Providers:*** This proposal reduces market basket updates for inpatient rehabilitation facilities, long-term care hospitals, and home health agencies by 1.1 percentage points in each year 2016 through 2025. Payment updates for these providers would not drop below zero as a result of this proposal. This proposal will reduce market basket updates for skilled nursing facilities under an accelerated schedule, beginning with a -2.5 percent update in FY 2016 tapering down to a -0.97 percent update in FY 2023. [$102.1 billion in savings over 10 years]

***Increase the Minimum Medicare Advantage Coding Intensity Adjustment:*** Starting in 2017, this proposal changes the yearly increase to the minimum coding intensity adjustment from 0.25 percentage points to 0.67 percentage points until the minimum adjustment plateaus at 8.76 percent in 2021 and thereafter. [$36.2 billion in savings over 10 years]

***Reduce Medicare Coverage of Bad Debts:*** For most institutional provider types, Medicare currently reimburses 65 percent of bad debts resulting from beneficiaries' non-payment of deductibles and coinsurance after providers have made reasonable efforts to collect the unpaid amounts. Starting in 2016, this proposal would reduce bad debt payments to 25 percent over 3 years for all providers who receive bad debt payments. This proposal would more closely align Medicare policy with private payers, who do not typically reimburse for bad debt. [$31.1 billion in savings over 10 years]

***Strengthen the Independent Payment Advisory Board to Reduce Long-term Drivers of Medicare Cost Growth:*** The Independent Payment Advisory Board has been highlighted by economists and health policy experts as a key contributor to Medicare's long-term solvency when implemented. Under current law, if the projected Medicare per capita growth rate exceeds a predetermined target growth rate, the Independent Payment Advisory Board will recommend policies to Congress to reduce the Medicare growth rate to meet a specified target. To further moderate Medicare cost growth, this proposal would lower the target rate for triggering Board action applicable for 2018 and after from gross domestic product per capita growth plus 1 percentage point to gross domestic product per capita growth plus 0.5 percentage points. [$20.9 billion in savings over 10 years]

***Better Align Graduate Medical Education Payments with Patient Care Costs:*** MedPAC has found that existing Medicare add-on payments to teaching

hospitals for the indirect costs of medical education significantly exceed the actual added patient care costs these hospitals incur. This proposal would partially correct this imbalance by reducing these payments by 10 percent, beginning in 2016. In addition, the Secretary would be granted the authority to set standards for teaching hospitals receiving Graduate Medical Education payments to encourage training of primary care residents and emphasize skills that promote high-quality and high-value health care. [$16.3 billion in savings over 10 years]

***Accelerate Manufacturer Drug Discounts to Provide Relief to Medicare Beneficiaries in the Coverage Gap:*** Prior to the passage of the Affordable Care Act, beneficiaries were responsible for the full cost of their medications while in the Medicare Part D coverage gap. The law closes this gap by 2020 through a combination of manufacturer discounts and federal subsidies. Currently, beneficiaries in the Medicare Part D coverage gap receive a 50 percent discount from pharmaceutical manufacturers on their brand drugs. Beginning in plan year 2017, this proposal would increase manufacturer discounts to 75 percent, effectively closing the coverage gap for brand drugs three years earlier than under current law. The phase-out for generic drugs would continue through 2020. [$9.4 billion in savings over 10 years]

***Modify Reimbursement of Part B Drugs:*** To reduce excessive payment of Part B drugs administered in the physician office and hospital outpatient settings, this proposal lowers payment from 106 percent of the average sales price to 103 percent of average sales price starting in 2016. If a physician's cost for purchasing the drug exceeds average sales price + 3 percent, the drug manufacturer would be required to provide a rebate such that the net cost to the provider to acquire the drug equals average sales price + 3 percent minus a standard overhead fee to be determined by the Secretary. This rebate would not be used in calculating average sales price. The Secretary would also be given authority to pay a portion or the entire amount above average sales price in the form of a flat fee rather than a percentage, with the modification to be made in a budget neutral manner relative to average sales price + 3 percent. [$7.4 billion in savings over 10 years]

***Align Employer Group Waiver Plan Payments with Average Medicare Advantage Plan Bids:*** Beginning in payment year 2017, this proposal would establish payment amounts for Employer Group Waiver Plans based on the average Medicare Advantage plan bid in each individual market. [$7.2 billion in savings over 10 years]

***Exclude Certain Services from the In-Office Ancillary Services Exception:*** The in-office ancillary services exception to the physician self-referral law was intended to allow physicians to self-refer for certain services to be furnished by their group practices for patient convenience. While there are many appropriate uses for this exception, certain services, such as advanced imaging and outpatient therapy, are rarely furnished on the same day as the related physician office visit. Additionally, there is evidence that suggests that this exception may have resulted in overutilization and rapid growth of certain services. Effective calendar year 2017, this proposal would seek to encourage more appropriate use of ancillary services by amending the in-office ancillary services exception to prohibit referrals for radiation therapy, therapy services, advanced imaging, and anatomic pathology services, except in cases where a practice is clinically integrated and required to demonstrate cost containment, as defined by the Secretary. [$6.0 billion in savings over 10 years]

***Encourage Appropriate Use of Inpatient Rehabilitation Facilities:*** This proposal would adjust the standard for classifying a facility as an inpatient rehabilitation facility. Under current law, at least 60 percent of patient cases admitted to an inpatient rehabilitation facility must meet one or more of 13 designated severity conditions. This standard was changed to 60 percent from 75 percent in the Medicare, Medicaid, and SCHIP Extension Act of 2007. Beginning in 2016, this proposal would reinstitute the 75 percent standard to ensure that health facilities are classified appropriately based on the patients they serve. [$2.2 billion in savings over 10 years]

***Reduce Critical Access Hospital Reimbursements from 101 Percent of Reasonable Costs to 100 percent of Reasonable Costs:*** Critical access hospitals are small, rural hospitals that provide their communities with access to basic emergency and inpatient care. Critical access hospitals receive enhanced cost-based Medicare payments (rather than the fixed-fee payments most hospitals receive). Medicare currently pays critical access hospitals 101 percent of reasonable costs. This proposal would reduce this rate to 100 percent

beginning in 2016. [$1.7 billion in savings over 10 years]

***Prohibit Critical Access Hospital Designation for Facilities that are Less Than 10 Miles from the Nearest Hospital:*** Beginning in 2016, this proposal would prevent hospitals that are within 10 miles of another hospital from maintaining designation as a critical access hospital and receiving the enhanced rate. These hospitals would instead be paid under the applicable prospective payment system. [$770 million in savings over 10 years]

***Require Mandatory Reporting of Other Prescription Drug Coverage:*** Although health plans offered by employers and unions are required by Medicare secondary payer-related law to report enrollment information on certain active employees, there is no requirement for other group health plans that offer a prescription drug benefit to report their plan enrollees with drug coverage to HHS or the Part D plan sponsors. This proposal would extend mandatory reporting requirements to include prescription drug coverage. This would ensure that all prescription drug coverage provided by group health plans that is primary to Medicare coverage is communicated to HHS and to Part D sponsors, thereby permitting sponsors to comply with the statutory Medicare secondary payer requirements. [$480 million in savings over 10 years]

***Expand Coverage of Dialysis Services for Beneficiaries with Acute Kidney Injury:*** This proposal would expand the Part B scope of benefits to cover short-term scheduled dialysis at a Medicare-certified End Stage Renal Disease facility for the treatment of acute kidney injury. This proposal would make payment for these services by designating facilities, both freestanding and hospital-based, as providers when billing for dialysis to treat patients with an acute kidney injury. [$200 million in savings over ten years]

***Allow the Secretary to Negotiate Prices for Biologics and High Cost Prescription Drugs:*** The Administration looks forward to working with Congress to address growing pharmaceutical costs. The Budget proposes one potential solution that would give the Secretary the authority to negotiate with manufacturers to determine drug prices under the Part D program for biologics, as well as high-cost drugs eligible for placement on a plan's specialty tier. As a condition of participation in the Part D program, manufacturers must engage in negotiations with HHS. As part of the negotiation, manufacturers would be required to supply HHS with all data and information necessary to come to an agreement on price. The final price would be indexed to the Consumer Price Index and plan sponsors would be permitted to negotiate additional discounts off this price. HHS will monitor for increased introductions of physician administered drugs and excess price inflation for Part D drugs currently on the market. [No budget impact]

***Clarify the Medicare Fraction in the Medicare DSH Statute:*** This proposal would clarify that individuals who have exhausted inpatient benefits under Part A or who have elected to enroll in Part C plan should be included in the calculation of the Medicare fraction of hospitals' Disproportionate Share Hospital patient percentages. [No budget impact]

**Closing the Coverage Gap**
**Medicare Part D Coverage Gap Cost-Sharing by Year/1**

| Year | Percent Cost Sharing Paid by Enrollee for Branded Drugs (Current Law) | Percent Cost Sharing Paid by Enrollee for Branded Drugs (Proposed Law) | Percent Cost Sharing Paid by Enrollee for Generic Drugs (Proposed and Current Law) |
|---|---|---|---|
| **2010** /2 | 100% | 100% | 100% |
| **2011** | 50% | 50% | 93% |
| **2012** | 50% | 50% | 86% |
| **2013** | 47.5% | 47.5% | 79% |
| **2014** | 47.5% | 47.5% | 72% |
| **2015** | 45% | 45% | 65% |
| **2016** | 45% | 45% | 58% |
| **2017** | 40% | 25% | 51% |
| **2018** | 35% | 25% | 44% |
| **2019** | 30% | 25% | 37% |
| **2020** | 25% | 25% | 25% |
| **2021** | 25% | 25% | 25% |
| **2022** | 25% | 25% | 25% |

1/ Savings only apply to applicable beneficiaries who do not receive the low-income subsidy.
2/ Percent cost sharing does not include a $250 rebate for each beneficiary who hits the coverage gap in 2010.

***Establish Authority for a Program to Prevent Prescription Drug Abuse in Medicare Part D:*** HHS requires Part D sponsors to conduct drug utilization review, which assesses the prescriptions filled by a particular enrollee. These efforts can identify overutilization that results from inappropriate or even illegal activity by an enrollee, prescriber, or pharmacy. HHS's statutory authorities to take preventive measures in response to this information are limited. This proposal would give the HHS Secretary the authority to establish a program in Part D that would require that high-risk Medicare beneficiaries only utilize certain prescribers and/or pharmacies to obtain controlled substance prescriptions, similar to many state Medicaid programs. The Medicare program would be required to ensure that beneficiaries retain reasonable access to services of adequate quality. [No budget impact]

***Modify the Documentation Requirement for Face-to-face Encounters for Durable Medical Equipment Claims:*** Currently, a physician must document a beneficiary's face-to-face encounter with a physician or non-physician practitioner as a condition for Medicare payment for an order. This proposal would modify that requirement by allowing certain non-physician practitioners to document the face-to-face encounter. [No budget impact]

***Suspend Coverage and Payment for Questionable Part D Prescriptions and Incomplete Clinical Information:*** This proposal would provide the Secretary authority to suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing or overprescribing drugs with abuse potential. The Secretary would also be able to suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients. In addition, the proposal would provide the Secretary authority to require additional information on certain Part D prescriptions, such as diagnosis codes, as a condition of coverage. [No budget impact]

### *Medicare Structural Reforms*

***Increase Income Related Premiums under Medicare Parts B and D:*** Under Medicare Parts B and D, certain beneficiaries pay higher premiums based on their higher levels of income. Beginning in 2019, this proposal would restructure income-related premiums under Medicare Parts B and D by increasing the applicable percent for calculating the lowest income-related premiums by five percentage points, from 35 percent to 40 percent of program costs, and creating new tiers every 12.5 percentage points until capping the highest tier at 90 percent. The proposal maintains the current income thresholds associated with these premiums until 25 percent of beneficiaries under Parts B and D are subject to these premiums. This proposal would help improve the financial stability of the Medicare program by reducing the federal subsidy of Medicare costs for those who need the subsidy the least. [$66.4 billion in savings over ten years]

***Encourage the Use of Generic Drugs by Low-Income Beneficiaries:*** Beginning in plan year 2017, this proposal would induce greater generic utilization by lowering copayments for generic drugs. Brand copayments would be increased to twice the level required under current law. The Secretary would have the authority to exclude brand drugs in therapeutic classes from this policy if therapeutic substitution is determined not to be clinically appropriate or a generic is not available. Brand drugs could be obtained at current law cost-sharing levels if beneficiaries successfully appeal. In addition, the change in cost-sharing would be applied to low income beneficiaries receiving a partial subsidy upon reaching the catastrophic coverage level. Beneficiaries qualifying for institutionalized care, who currently face no copayments, would be excluded from these changes. [$8.9 billion in savings over 10 years]

***Introduce a Part B Premium Surcharge for New Beneficiaries who Purchase Near First-dollar Medigap Coverage:*** Medicare requires cost-sharing for various services, but Medigap policies sold by private insurance companies provide beneficiaries with additional coverage for these out-of-pocket expenses. Some Medigap plans cover all or almost all copayments, even for routine care. This practice gives beneficiaries less incentive to consider the cost of services, leading to higher Medicare costs and Part B premiums. This proposal would introduce a Part B premium surcharge for new beneficiaries who purchase Medigap policies with particularly low cost-sharing requirements, starting in 2019. Other Medigap plans that meet minimum cost-sharing requirements would be exempt. The surcharge would be equivalent to approximately 15 percent of the average Medigap premium (or about 30 percent of the Part B premium). [$4.0 billion in savings over 10 years]

**Medicare Proposal: Increase Income Related Premiums under Part B and D**

| Current Law | | President's Budget 2016 Proposal | |
|---|---|---|---|
| Modified adjusted gross income threshold (MAGI) | Applicable premium percentage (Percentage) | MAGI | Percentage |
| Less than $85,000 | 25 percent for Part B; around 25.5 percent for Part D | Less than $85,000 | 25 percent for Part B; around 25.5 percent for Part D |
| More than $85,000 but not more than $107,000 | 35% | More than $85,000 but not more than $107,000 | 40% |
| More than $107,000 but not more than $160,000 | 50% | More than $107,000 but not more than $133,500 | 52.5% |
| | | More than $133,500 but not more than $160,000 | 65% |
| More than $160,000 but not more than $214,000 | 65% | More than $160,000 but not more than $196,000 | 77.5% |
| | | More than $196,000 | 90% |
| More than $214,000 | 80% | | |

The table reflects MAGI thresholds for Medicare beneficiaries who file an individual tax return with income.

***Modify the Part B Deductible for New Beneficiaries:*** Beneficiaries who are enrolled in Medicare Part B are required to pay an annual deductible ($147 in calendar year 2015). This deductible helps to share responsibility for payment of Medicare services between Medicare and beneficiaries. To strengthen program financing and encourage beneficiaries to seek high-value health care services, this proposal would apply a $25 increase to the Part B deductible in 2019, 2021, and 2023 respectively for new beneficiaries beginning in 2019. Current beneficiaries or near retirees would not be subject to the revised deductible. [$3.7 billion in savings over 10 years]

***Introduce Home Health Copayments for New Beneficiaries:*** This proposal would create a co-payment for new beneficiaries of $100 per home health episode, starting in 2019. Consistent with MedPAC recommendations, this co-payment would apply only for episodes with five or more visits not preceded by a hospital or inpatient post-acute stay. Home health services represent one of the few areas in Medicare that do not currently include some beneficiary cost-sharing. This proposal aims to encourage appropriate use of home health services while protecting beneficiary access. [$830 million in savings over 10 years]

### *Increase the Availability of Generic Drugs and Biologics*

***Prohibit Brand and Generic Drug Manufacturers from Delaying the Availability of New Generic Drugs and Biologics:*** Beginning in 2016, this proposal would prohibit anticompetitive pay-for-delay agreements between branded and generic pharmaceutical companies. This proposal increases the availability of generic drugs and biologics by authorizing the Federal Trade Commission to stop companies from entering into anticompetitive agreements which block consumer access to safe and effective generics. This proposal would save money in Medicare and Medicaid. [$10.1 billion in Medicare savings over 10 years]

***Modify Length of Exclusivity to Facilitate Faster Development of Generic Biologics:*** This proposal would increase competition for biological products by reducing the number of years (from 12 to 7) that a drug company has exclusivity or monopoly pricing power and prohibits additional years of exclusivity due to minor formulation changes. The proposal also modifies how Part B pays for biosimilar and innovator biological products. For these products, reimbursement would be based on the weighted average sales price of the reference biological product and all of its biosimilars, plus 6 percent. This proposal would save money in Medicare and Medicaid. [$4.4 billion in Medicare savings over 10 years]

### *Reforming the Medicare Appeals Process*

***Provide Office of Medicare Hearings and Appeals and Departmental Appeals Board Authority to Use Recovery Audit Contractor Collections:*** This proposal would expand the Secretary's authority to retain a portion of Recovery Audit Contractor recoveries for the purpose of administering the recovery audit program. This proposal will allow program recoveries to fully fund related appeals at the Office of Medicare Hearings and Appeals and the Departmental Appeals Board. [$1.3 billion in costs over 10 years]

***Establish a Refundable Filing Fee:*** This proposal would institute a refundable, per claim filing fee for providers, suppliers, and State Medicaid agencies, including those acting as a representative of a beneficiary, at each level of Medicare appeal. This filing fee would allow HHS to invest in the appeals system to improve responsiveness and efficiency. Fees will be returned to appellants who receive a fully favorable appeal determination. [No budget impact]

***Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold:*** This proposal would allow the Office of Medicare Hearings and Appeals to use attorney adjudicators for appealed claims below the federal district court amount in controversy threshold ($1,460 in calendar year 2015 and updated annually), reserving Administrative Law Judges for more complex and higher amount in controversy appeals. [No budget impact]

***Expedite Procedures for Claims with No Material Fact in Dispute:*** This proposal would allow the Office of Medicare Hearings and Appeals to issue decisions without holding a hearing if there is no material fact in dispute. These cases include appeals, for example, in which Medicare does not cover the cost of a particular drug or the Administrative Law Judge cannot find in favor of an appellant due to binding limits on authority. [No budget impact]

***Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review:*** This proposal would increase the minimum amount in controversy required for adjudication by an Administrative Law Judge to the Federal Court amount in controversy requirement ($1,460 in 2015). This 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. The minimum amount in controversy would increase consistent with the amount in controversy set for Federal Court. [No budget impact]

***Remand Appeals to the Redetermination Level with the Introduction of New Evidence:*** This proposal would remand an appeal to the first level of review 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 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]

***Sample and Consolidate Similar Claims for Administrative Efficiency:*** This proposal would allow the Secretary to adjudicate appeals through the use of sampling and extrapolation techniques. Additionally, this proposal would authorize the Secretary to consolidate appeals into a single administrative appeal at all levels of the appeals process. Parties who are appealing claims included within an extrapolated overpayment, or consolidated previously, will be required to file one appeal request for any such claims in dispute. [No budget impact]

### *Other Proposals*

***Clarify Calculation of the Late Enrollment Penalty for Medicare Part B Premiums:*** This proposal would clarify

that the cap on increases to the Part B premium, commonly referred to as the hold harmless provision, does not apply to the calculation of the Part B late enrollment penalty, but applies only to the annual increase to the basic Part B premium. The hold harmless provision imposes a cap on increases to the basic Part B premium based on the amount of the cost-of-living adjustment increase in a beneficiary's Social Security benefits. This clarification is consistent with current CMS practice. [No budget impact]

### Affordable Care Act Highlights Strengthening Medicare

The Affordable Care Act takes numerous steps to strengthen the quality, accessibility, and sustainability of care provided to Medicare beneficiaries.

***Accountable Care Organizations:*** Accountable Care Organizations are a transformative aspect of the Affordable Care Act. Accountable Care Organizations are groups of doctors, hospitals, and other health care providers who join together voluntarily to deliver coordinated, high quality care to the patients they serve. Coordinated care helps ensure that beneficiaries get the right care at the right time, with the goal of avoiding unnecessary duplication of services, preventing medical errors, and reducing Medicare costs. CMS has launched a four-part Accountable Care Organization (ACO) initiative from provisions of the Affordable Care Act: the Medicare Shared Savings Program, the Advance Payment ACO Model, the Pioneer ACO Model, and the ACO Investment Model. In total, there are 424 Medicare ACOs as of January 2015. These ACOs are working to improve the care experience for more than 7.8 million Medicare fee-for-service beneficiaries nationwide. Savings from CMS's ACO programs have already reached $417 million. On December 1, 2014, CMS released a new proposal to further strengthen the Medicare Shared Savings Program. The proposed rule reflects input from program participants, experts, consumer groups, and the stakeholder community at large.

***Improving Quality and Value:*** Medicare continues its transformation from a passive payer to an effective purchaser of high-quality, efficient care. The Affordable Care Act established a value-based purchasing program for hospitals and required CMS to develop plans to implement value-based purchasing for skilled nursing facilities, home health agencies, and ambulatory surgical centers. Implementing these provisions will continue to be a high priority for CMS in FY 2016, which will be the fourth year of quality-based payment adjustments for hospitals, and will include patient mortality measures for the first time.

CMS continues to move beyond payment for volume to payment aligned with quality, using the CMS Quality Strategy as the overall framework. The Medicare Quality Improvement Organizations work toward the goals of lower costs through improvement by providing assistance to acute care facilities, outpatient departments, ambulatory surgery centers, critical care hospitals, psychiatric facilities, cancer hospitals, and physicians in reporting clinical quality measures for purposes of public reporting and, in the case of hospitals, value based purchasing.

The Affordable Care Act also required CMS to implement a quality-based bonus payment for Medicare Advantage plans based on a five-star rating system beginning in 2012. In 2015, the number and market share of four or five-star plans continue to increase significantly, demonstrating that the rating system has begun to encourage quality improvement.

### Highlights of the Protecting Access to Medicare Act

On April 1, 2014, the President signed the Protecting Access to Medicare Act into law. The law prevented an estimated reduction in physician payments of over 20 percent due to the Sustainable Growth Rate Formula by applying a 0.5 percent update for physician payments through the rest of Calendar year (CY) 2014 and a zero percent update for the first three months of CY 2015. The 12-month patch itself was estimated by the Congressional Budget Office (CBO) to cost $15.8 billion over 11 years (FY 2014- FY 2024). However other provisions in the law, including extenders, Medicare savers, and other health provisions reduced the CBO estimate to an overall savings of $1.2 billion over 11 years.

***Medicare Extenders:*** The Protecting Access to Medicare Act included additional provisions that extended current Medicare payment policies for 12 months. Some examples of these policies include extending: the exceptions process for outpatient therapy caps; the work geographic practice cost index floor at 1.0; and the add-on payments for ambulance services. CBO estimated the cost of all the Medicare

extenders to be approximately $2.0 billion over 11 years (2014 – 2024).

***Mandatory Savings:*** The Act also included some provisions that reduced expenditures. CBO estimated the total savings (including Medicare and Medicaid) from these provisions at $22.1 billion over 11 years. Major Medicare savers include:

- Skilled Nursing Facility Value-based Purchasing: The Act establishes a value-based purchasing program for Medicare nursing facilities to begin FY 2019.
- Clinical Laboratory Payments: The Act improves Medicare policies for clinical diagnostic laboratory tests by linking Medicare payment for laboratory tests to private sector payment rates.
- End Stage Renal Disease Payments: The Act revises the Medicare End Stage Renal Disease prospective payment system by: delaying the date that oral only drugs are included in the payment system bundle from CY 2016 to CY 2023; reducing the market basket percentage used to increase payments for renal dialysis services; and adding specific measures to the Quality Incentive Program specific to the results from oral only drugs.
- Computed Tomography Services: The Act establishes quality incentives for the provision of computed tomography services. It also requires the Secretary to establish a program that promotes appropriate use criteria for advanced diagnostic imaging.
- Misvalued Physician Services: The Act expands the list of criteria the Secretary can use to identify potentially misvalued services under the physician fee schedule and sets a target for identifying misvalued services in specified years. If CMS meets or exceeds the target, the reduced expenditures that result from the adjustments to the misvalued services are redistributed in accordance with the physician fee schedule budget neutrality adjustment.

### Highlights of the Improving Medicare Post-Acute Care Transformation Act of 2014

The Improving Medicare Post-Acute Care Transformation Act mandates that CMS develop and implement a post-acute care standardized and interoperable measurement tool to allow comparison of data across settings. The law defines Medicare post-acute care as long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health services.

The Act also establishes a quality reporting program for skilled nursing facilities starting in FY 2018 that reduces market basket payments by two percent for nursing homes that fail to report assessment and quality data. The law also provides funds to improve the accuracy of the five-star rating system on the Nursing Home Compare website by requiring the use of payroll data to measure nursing home staffing levels.

### Medicare Quality Improvement Organizations

The mission of the Quality Improvement Organization program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. The Organizations are experts in the field working to drive local change which can translate into national quality improvement. The current five year contract cycle, or 11th Statement of Work, began on August 1, 2014 and provides approximately $549.2 million in FY 2016 and $4 billion over 5 years.

The 11th statement implements for the first time several changes to the program enacted in the Trade Adjustment Assistance Extension Act of 2011. For instance, there are now 14 Quality Innovation Network contracts and five Beneficiary and Family Centered Care contracts in accordance with Institute of Medicine recommendations to separate the case review and quality technical assistance work, and reorganize the geographic scope of the contracts. Formerly, in prior statements of work, there was one organization per state performing both case review and quality work.

### Major Planned Activities

***Clinical Quality Improvement:*** The key goals for FY 2016 are improving the health status of communities; delivering patient-centered, reliable, accessible, and safe care; and better care at lower costs. Through improving cardiac health, reducing disparities in diabetic care, using immunization information systems and meaningful use of health IT to improve prevention coordination, CMS aims to improve the health status of beneficiaries. These goals will also be achieved by efforts to reduce healthcare-associated infections, healthcare-associated conditions in nursing homes, and hospital readmissions and adverse drug events.

**Estimated Quality Improvement Organization Funding**
**11th Statement of Work (2014-2018)**
*Dollars in Millions*

| | |
|---|---|
| Clinical Quality Improvement | |
| Subtotal, Clinical Quality Improvement | $839.9 |
| Value-based Purchasing Support Contracts and Quality Measures | $1,129.4 |
| Infrastructure, Coordinating Centers, and Special Initiatives | $568.0 |
| Beneficiary and Family-centered Care | $402.5 |
| Other Support Contracts and Staff | $1,100.6 |
| Subtotal | $4,040.4 |

***Value Based Purchasing Support Contracts and Quality Measures:*** The program supports the hospital value-based purchasing and readmission reduction programs, as well as the physician quality reporting system. Additionally, this funding supports long-term care hospital, inpatient rehabilitation facility, hospice, ambulatory surgical center and cancer hospital public reporting programs.

***Beneficiary and Family Centered Care:*** This traditional case review work includes handling beneficiary complaints, concerns related to early discharge from health care settings, and patient and family engagement. In the three year 10th Statement of Work (2011-2014), the organizations resolved more than 200,000 concerns and appeals received from beneficiaries and their families.

***Other Support Contracts and Staff:*** This work supports consumer assessment of healthcare providers and systems surveys, quality information for compare websites, the quality improvement and evaluation system, and staff.

# FY 2016 Medicare Legislative Proposals

*(Negative numbers reflect savings and positive numbers reflect costs)*

| *dollars in millions* | *2016* | *2016 -2020* | *2016 -2025* |
|---|---|---|---|
| **Encourage Delivery System Reform** | | | |
| Reform Medicare Physician Payments to Promote Participation in High-quality and Efficient Health Care Delivery Systems | 430 | 9,090 | 43,990 |
| Encourage Efficient Care by Improving Incentives to Provide Care in the Most Appropriate Ambulatory Setting | — | -6,740 | -29,500 |
| Implement Bundled Payment for Post-Acute Care | — | -430 | -9,260 |
| Allow CMS to Assign Beneficiaries to Federally Qualified Health Centers and Rural Health Clinics Participating in the Medicare Shared Savings Program | — | -20 | -80 |
| Expand Basis for Beneficiary Assignment for Accountable Care Organizations to include Nurse Practitioners, Physicians Assistance, and Clinical Nurse Specialists | — | -10 | -60 |
| Allow Accountable Care Organizations to Pay Beneficiaries for Primary Care Visits up to the Applicable Medicare Cost Sharing Amount | — | — | — |
| Establish a Hospital-Wide Readmissions Reduction Measure | — | — | — |
| Establish Quality Bonus Payments for High-Performing Part D Plans | — | — | — |
| Expand Sharing Medicare Data with Qualified Entities | — | — | — |
| Extend Accountability for Hospital-acquired Conditions | — | — | — |
| Implement Value-Based Purchasing for Additional Providers | — | — | — |
| Make Permanent the Medicare Primary Care Incentive Payment in a Budget Neutral Manner | — | — | — |
| **Increase Value in Medicare Provider Payments** | | | |
| Eliminate the 190-day Lifetime Limit on Inpatient Psychiatric Facility Services | 400 | 2,150 | 5,000 |
| Align Medicare Drug Payment Policies with Medicaid Policies for Low-Income Beneficiaries | — | -32,790 | -116,130 |
| Adjust Payment Updates for Certain Post-Acute Care Providers | -1,600 | -25,170 | -102,070 |
| Increase the Minimum Medicare Advantage Coding Intensity Adjustment | — | -6,780 | -36,240 |
| Reduce Medicare Coverage of Bad Debts | -370 | -10,530 | -31,080 |
| Strengthen the Independent Payment Advisory Board to Reduce Long-term Drivers of Medicare Cost Growth | — | — | -20,879 |
| Better Align Graduate Medical Education Payments with Patient Care Costs | -1,000 | -6,700 | -16,260 |
| Accelerate Manufacturer Discounts for Brand Drugs to Provide Relief to Medicare Beneficiaries in the Coverage Gap | — | -2,490 | -9,430 |
| Modify Reimbursement of Part B Drugs | -320 | -2,880 | -7,380 |
| Align Employer Group Waiver Plan Payments with Average Medicare Advantage Plan Bids | — | -2,730 | -7,160 |
| Exclude Certain Services from the In-Office Ancillary Services Exception | — | -2,120 | -6,020 |

| *dollars in millions* | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **Increase Value in Medicare Provider Payments (Continued)** | | | |
| Encourage Appropriate Use of Inpatient Rehabilitation Facilities | -170 | -1,010 | -2,230 |
| Reduce Critical Access Hospital Reimbursements from 101 Percent of Reasonable Costs to 100 percent of Reasonable Costs | -110 | -710 | -1,730 |
| Prohibit Critical Access Hospital Designation for Facilities that are less than 10 Miles from the Nearest Hospital | -50 | -320 | -770 |
| Require Mandatory Reporting of Other Prescription Drug Coverage | -10 | -170 | -480 |
| Expand Coverage of Dialysis Services for Beneficiaries with Acute Kidney Injury | -10 | -90 | -200 |
| Allow the Secretary to Negotiate Prices for Biologics and High Cost Prescription Drugs | — | — | — |
| Clarify the Medicare Fraction in the Medicare DSH Statute | — | — | — |
| Establish Authority for a Program to Prevent Prescription Drug Abuse in Medicare Part D | — | — | — |
| Modify the Documentation Requirement for Face-to-face Encounters for Durable Medical Equipment Claims | — | — | — |
| Suspend Coverage and Payment for Questionable Part D Prescriptions and Incomplete Clinical Information | — | — | — |
| **Medicare Structural Reforms** | | | |
| Increase Income Related Premiums under Medicare Parts B and D | — | -7,880 | -66,410 |
| Encourage the Use of Generic Drugs by Low-Income Beneficiaries | — | -3,090 | -8,860 |
| Introduce a Part B Premium Surcharge for New Beneficiaries who Purchase Near First-dollar Medigap Coverage | — | -310 | -3,970 |
| Modify the Part B Deductible for New Beneficiaries | — | -120 | -3,740 |
| Introduce Home Health Copayments for New Beneficiaries | — | -70 | -830 |
| **Increase the Availability of Generic Drugs and Biologics** | | | |
| Prohibit Brand and Generic Drug Manufacturers from Delaying the Availability of New Generic Drugs and Biologics (Medicare impact) | -690 | -4,070 | -10,060 |
| Modify Length of Exclusivity to Facilitate Faster Development of Generic Biologics (Medicare impact) | — | -910 | -4,400 |
| **Medicare-Medicaid Enrollee Proposals** | | | |
| Allow for Federal/State Coordinated Review of Duals Special Need Plan Marketing Materials | — | — | — |
| Create Pilot to Expand PACE Eligibility to Individuals Between Ages 21 and 55 | — | — | — |
| Ensure Retroactive Part D Coverage of Newly-Eligible Low Income Beneficiaries | — | — | — |
| Establish Integrated Appeals Process for Medicare-Medicaid Enrollees | — | — | — |
| **Reforming the Medicare Appeals Process** | | | |
| Provide Office of Medicare Hearings and Appeals and Department Appeals Board Authority to Use Recovery Audit Contractor Collections | 127 | 635 | 1,270 |
| Establish a Refundable Filing Fee | — | — | — |
| Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold | — | — | — |
| Expedite Procedures for Claims with No Material Fact in Dispute | | | |
| Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review | — | — | — |
| Remand Appeals to the Redetermination Level with the Introduction of New Evidence | — | — | — |
| Sample and Consolidate Similar Claims for Administrative Efficiency | — | — | — |

| *dollars in millions* | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **Other proposals** | | | |
| Extend the Qualified Individuals Program through CY 2016 (Medicare interaction)/1 | 775 | 975 | 975 |
| Clarify Calculation of the Late Enrollment Penalty for Medicare Part B Premiums | — | — | — |
| Reduce Fraud, Waste, and Abuse in Medicare | 140 | 1,038 | 2,559 |
| Interactions/2 | 45 | 1,782 | 18,348 |
| **Total** | **-2,413** | **-102,470** | **-423,087** |
| | | | |
| 1/ States pay Medicare Part B premium costs for Qualified Individuals (QIs) that are in turn offset by a reimbursement from Medicare Part B. Costs of the proposal to extend the QI program are reflected in Medicare outlays. | | | |
| 2/ Adjusts for savings realized through IPAB and other Medicare interactions. | | | |

# Program Integrity

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| HCFAC Discretionary /1 | 294 | 672 | 706 | +34 |
| HCFAC Mandatory /2 | 1,264 | 1,273 | 1,342 | +69 |
| *Affordable Care Act (non-add)* | *142* | *152* | *169* | *+17* |
| **Total, Budget Authority** | **1,558** | **1,945** | **2,048** | **+103** |

1/ The FY 2014 and FY 2015 mandatory base includes sequester reductions.

2/ Does not include Deficit Reduction Act funding for the Medicaid Integrity Program, which is discussed in this chapter but is in the State Grants and Demonstrations account.

The FY 2016 Budget supports fraud prevention and the reduction of improper payments, which are top priorities of the Administration. For FY 2016, the Budget includes an additional $201 million in mandatory and discretionary investments to address healthcare fraud, waste, and abuse. Together the program integrity investments in the Budget will yield a $21.7 billion in savings for Medicare and Medicaid over 10 years. The Budget also proposes legislative changes to give HHS important new tools to enhance program integrity oversight and cut fraud, waste, and abuse in Medicare, Medicaid, and Children's Health Insurance Program (CHIP).

## Health Care Fraud and Abuse Control (HCFAC) Funding

The FY 2016 Budget proposes to build on recent progress by increasing support for the HCFAC program through both mandatory and discretionary funding streams. The FY 2016 HCFAC program level is $2.1 billion. Of the total FY 2016 program level, $1.3 billion is mandatory funding and $706 million is requested in discretionary funding.

***HCFAC Discretionary Funds:*** The Budget requests $706 million in discretionary HCFAC funding, which is $34 million above the FY 2015 enacted. Consistent with the Budget Control Act of 2011 and FY 2015 policy, the Budget requests base discretionary funds of $311 million plus a discretionary cap adjustment of $395 million.

Within discretionary funding total, $474 million is allocated to CMS program integrity activities, $113 million to the Department of Justice, and $119 million to the Office of Inspector General. Relative to FY 2015, the request includes more funds from the cap adjustment for law enforcement to expand Strike Force capacity, support rigorous data analysis and an increased focus on civil fraud, such as off label marketing and pharmaceutical fraud. The request also includes $25 million to monitor and prevent fraud, waste and abuse in the private health insurance market, including Marketplaces.

**HCFAC Multi-Year Investment and Savings (in millions)**

| | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2016-2020 | 2016-2025 |
|---|---|---|---|---|---|---|---|---|
| Mandatory Funding | 1,273 | 1,342 | 1,346 | 1,374 | 1,405 | 1,437 | 6,904 | 14,544 |
| Discretionary Funding | 672 | 706 | 725 | 745 | 765 | 786 | 3,727 | 7,991 |
| **Total Program Level** /1 | **1,945** | **2,048** | **2,071** | **2,119** | **2,170** | **2,223** | **10,631** | **22,535** |
| *Savings from Discretionary Investment /2* | — | *-749* | *-795* | *-844* | *-894* | *-947* | *-4,229* | *-9,663* |

1/ Total Program Levels may not add due to rounding.
2/ Savings are the gross savings attributable only to the discretionary investment. Savings are not scorable under PAYGO.

**Enhanced Provider Screening**

The Affordable Care Act provided CMS new tools to protect Medicare, Medicaid, and CHIP from fraud, waste, and abuse. One of these new authorities is enhanced provider screening, which creates a rigorous risk-based screening process for all new and re-enrolling providers and suppliers in Medicare, Medicaid, and CHIP.

Through this new authority and the additional resources provided for this activity in the Affordable Care Act, CMS has:

- Taken a leap forward in fraud prevention by keeping bad actors out of the programs;
- Screened over 1 million Medicare providers;
- Deactivated over 380,000 Medicare provider practice locations; and
- Revoked 24,000 Medicare providers' billing privileges.
- The FY 2016 Budget proposes to enhance the Medicare provider screening program by establishing a registration process for clearing houses and billing agents and charging an application fee like that which currently applies to institutional providers.

The HCFAC investment also supports efforts to reduce the Medicare-fee-for service improper payment rate, reinforced oversight of both Medicare and Medicaid managed care, and strengthen the Health Care Fraud Prevention Partnership among the federal government, private insurers, and other stakeholders. CMS will also make further investments in innovative prevention initiatives, such as the Fraud Prevention System.

***HCFAC Mandatory Funds:*** The $1.3 billion in mandatory base funds for FY 2016 are financed from the Medicare Hospital Insurance Trust Fund. The funding is allocated to: the Medicare Integrity Program; the HCFAC Account, which is divided annually among the HHS OIG, other HHS agencies, the Federal Bureau of Investigation, and DOJ. These dollars fund comprehensive efforts to combat health care fraud, waste, and abuse, including prevention-focused activities, improper payment reduction, provider education, data analysis, audits, investigations, and enforcement.

***Return on Investment:*** Program integrity returns on investment are measured by program area and separately reported by activity type. Programs supported by HCFAC mandatory funds have a proven record of returning more money to the Medicare Trust Funds and the Treasury than the dollars spent. There are three key ways in which returns from program integrity activities are described. First, the most recent estimate of the Medicare Integrity Program 3-year average return on investment is 14.4 to 1, and the program has yielded an average return of $10 billion annually from recoveries, claims denials, and accounts receivables over the past decade.

Second, the 3-year average return on investment for HCFAC law enforcement activities is a record 8.1 to 1. From 1997 to 2013, programs supported by HCFAC have returned over $25.9 billion to the Medicare Trust Funds. In FY 2013 alone, $4.3 billion was recovered, including $2.85 billion returned to the Medicare Trust Funds and $576 million in federal Medicaid recoveries returned to the Treasury.

Third, CMS actuaries conservatively project that for every new dollar spent by HHS to combat health care fraud about $2 is saved or avoided. Based on these projections, the $4.9 billion in additional discretionary HCFAC funding, as part of a multi-year HCFAC investment included in the Budget, will yield additional Medicare and Medicaid savings of $9.7 billion over 10 years. Further, the HCFAC return-on-investment demonstrates that in recent years the actual recoveries from HCFAC law enforcement efforts have far exceeded the projected savings.

### New Affordable Care Act Programs

The Affordable Care Act included an additional $350 million in program integrity resources over 10 years, plus an inflation adjustment. It provides unprecedented tools to CMS and law enforcement to protect Medicare, Medicaid, and CHIP from fraud, waste, and abuse. (See "Program Integrity Enhanced Provider Screening" for one example of expanded authorities.) These program integrity tools fight fraud and safeguard taxpayer dollars while ensuring patient access to care is not interrupted.

*Open Payments:* The Affordable Care Act created the Open Payment Program which collects and publicly reports information about financial relationships between the health care industry, physicians, and teaching hospitals. Payments and other transfers of value, such as research, consulting, travel, and gifts from manufacturers of drugs and devices to physicians and teaching hospitals are reported. In September 2014, CMS released data from transactions that occurred between August and December 2013. CMS released more records in December 2014. The data contain over 4.4 million payments valued at nearly $3.7 billion and attributable to 546,000 individual physicians

and almost 1,360 teaching hospitals. Future reports will be published annually and will include a full 12 months of payment data for 2014, beginning in June 2015.

### Fraud Prevention System

In its second year of implementation, the Fraud Prevention System prevented or identified $210 million in inappropriate billing in the Medicare program, which is almost twice the amount of identified savings yielded in the first year of the program. This system marks a significant shift from a pay and chase model to a prevention approach using technology similar to the credit card industry.

The system screens all Medicare Part A and Part B claims, including claims for Durable Medical Equipment, using a series of predictive models to detect suspicious billing activity, focus on emerging fraud trends, and identify patterns of improper payments. The system prioritizes leads for CMS's program integrity contractors to investigate and determine whether to stop payment or make a referral to law enforcement.

### Medicare Strike Force Success

The Medicare Fraud Strike Force is a partnership between HHS and DOJ in nine health care fraud hot spots around the country. Strike Force teams use advanced data analysis techniques to identify high billing levels so that interagency teams can target emerging or migrating schemes and chronic fraud by criminals masquerading as health care providers or suppliers. This Budget allows HHS and DOJ to continue strengthening Strike Force presence across the country.

Since its inception, Strike Force prosecutors filed more than 788 cases charging more than 1,727 defendants who collectively billed the Medicare program more than $5.5 billion. Strike Force prosecutors secured 1,137 guilty pleas and 148 others were convicted in jury trials, and 1,087 defendants were sentenced to imprisonment for an average term of nearly 4 years.

### Medicaid Integrity Program

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

States have the primary responsibility for combating fraud, waste, and abuse in the Medicaid program, but the Medicaid Integrity Program plays an important role supporting state efforts, including through contracting with eligible entities to carry out reviews, audits, identification of overpayments, education activities, and technical support. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded through HCFAC. This program includes a collaborative effort across CMS to transform the Medicaid data enterprise through the Medicaid and CHIP Business Information and Solutions program.

### Program Integrity Legislative Proposals

The Budget includes legislative proposals to further strengthen program integrity for Medicare, Medicaid, and CHIP. These proposals include new investments in Medicaid and corrective actions stemming from Recovery Audit Contractor actions in program integrity that yield billions in net savings over ten years.

**Medicaid Integrity Program Multi-Year Investment and Savings**
(In millions)

| | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2016-2020 | 2016-2025 |
|---|---|---|---|---|---|---|---|---|
| Mandatory Base Funding /1 | 77 | 84 | 85 | 87 | 89 | 91 | 437 | 925 |
| Proposed Mandatory Funding /1 | 0 | 25 | 30 | 35 | 40 | 50 | 180 | 580 |
| **Total Program Level** | **77** | **109** | **115** | **122** | **129** | **141** | **617** | **1,505** |
| *Savings from Mandatory Investment /2:* | *0* | *-55* | *-60* | *-65* | *-70* | *-80* | *-330* | *-850* |

1/ Funding numbers reflect sequestration of base funding for FY 2015 and include annual Consumer Price Index for All Urban Consumers adjustment.
2/ Savings are attributable only to the proposed Medicaid Integrity Program investment. Savings are not scored under PAYGO.

*Medicare:*

***Retain a Portion of Medicare Recovery Audit Contractor Recoveries to Implement Actions That Prevent Fraud and Abuse:*** Under current law, CMS can use the recovered funds from Recovery Audit Contractors to administer the program but cannot use these funds to implement corrective actions, such as new processing edits and provider education and training, to prevent future improper payments. This proposal removes this funding restriction. [$2.7 billion in costs and $4.4 billion in non-PAYGO savings over 10 years]

***Allow Prior Authorization for Medicare Fee-for-service Items:*** Currently, CMS has authority to require prior authorization for Medicare Durable Medical Equipment service items. This proposal would extend that authority to all Medicare fee-for-service items, particularly those that are at the highest risk for improper payment. By allowing prior authorization on additional items, CMS can ensure that the correct payment goes to the right provider for the appropriate service, and prevent the need for targeted claims audits on those payments. In addition, this proposal would require the Secretary to implement prior authorization in two service areas: power mobility devices and advanced imaging. [$90 million in savings over 10 years]

***Allow Civil Monetary Penalties for Providers and Suppliers who Fail to Update Enrollment Records:*** Currently, providers and suppliers are required to update enrollment records to remain in compliance with the Medicare program. This proposal would allow penalties if providers and suppliers fail to update their records, providing an additional incentive to report up to date information and helping reduce program vulnerability to fraud. [$29 million in savings over 10 years]

***Assess a Fee on Physicians and Practitioners Who Order Services or Supplies without Proper Documentation:*** This proposal would allow the Secretary to assess an administrative fee on providers for high risk, high cost claims that have not been properly documented. The proposal only applies when there is insufficient documentation and would not apply to the determination of whether a fully documented ordered item or service was reasonable and necessary. The fee would be $50 per Part B item/service and $100 per Part A service. [No budget impact]

**Medicaid Program Integrity at a Glance**

In 2014, state and federal program integrity officials worked together to successfully fight fraud, waste, and abuse, including the following activities:

- CMS partnered with states to avert $228 million in questionable reimbursements and recovered $727 million in questionable costs.
- The Medicaid Integrity Institute enrolled 909 state employees in 19 program integrity training courses and 2 workgroups.
- Collaborative audits with states identified $19.9 million in overpayments.

***Establish a Registration Process for Clearinghouses and Billing Agents:*** This proposal would expand the provider screening authorities included in the Affordable Care Act by establishing a registration process for clearinghouses and billing agents that act on behalf of Medicare providers and suppliers. This proposal would also allow CMS to obtain organizational information from clearinghouses and billing agents. [No budget impact]

***Allow Collection of Application Fees from Individual Providers:*** This proposal allows the Secretary to require a Medicare application fee for individual providers, similar to the existing fee on institutional providers. The fee will start at $50 and be adjusted by inflation annually thereafter. This fee would support provider screening by preventing bad actors from being in the program and improperly billing Medicare. [No budget impact]

***Increase the Amount of Home Health Agency Surety Bond:*** The proposal would increase the required surety bond amount for Medicare home health agencies to an amount that is no less than $50,000 and commensurate with the volume of payments to the agency. This policy would make home health consistent with the durable medical equipment surety bond requirement in current law. The Government Accountability Office and HHS Office of Inspector General also recommend implementation of a home health surety bond. A bond will ensure that any potential overpayments can be collected from new agencies with whom HHS has no prior payment history. [No budget impact]

*Medicaid:*

***Expand Funding and Authority for the Medicaid Integrity Program:*** This proposal increases the Medicaid Integrity Program by $580 million over ten years on top of the current funding level. The additional investment would start with an additional $25 million in FY 2016 and increase gradually to an additional $100 million in 2025. Thereafter, the total would be annually adjusted by the Consumer Price Index. This funding will give CMS the ability to address additional program integrity vulnerabilities, including expansion of Medicaid Financial Management program reviews of state financing practices; critical updates to Medicaid claims and oversight systems needed to enhance auditing; and other efforts to assist states to fight fraud, waste, and abuse. Over time, the inflation adjusted investment will support initiatives that respond to emerging vulnerabilities. This proposal also expands the statutory authority for the Medicaid Integrity Program to increase program flexibility in protecting state and federal resources. [$580 million in costs and $850 million in non-PAYGO savings over 10 years]

***Support Medicaid Fraud Control Units for the Territories:*** Medicaid Fraud Control Units in states have demonstrated success in recovering Medicaid dollars. This proposal would encourage territories to establish Medicaid Fraud Control Units to protect their Medicaid programs by exempting federal support for these units from the cap on Medicaid funding for the territories and by exempting territories from the statutory ceiling on quarterly federal payments for the units. [$10 million in costs and $2 million in non-PAYGO savings over 10 years]

***Expand Medicaid Fraud Control Unit Review to Additional Care Settings:*** The Budget proposes to allow Medicaid Fraud Control Units to receive federal matching funds for the investigation or prosecution of abuse and neglect in non-institutional settings, such as home-based care—in which a beneficiary may be harmed in the course of receiving health care services. The current limitation on federal matching was established in 1978, at a time when Medicaid services were typically provided in an institutional setting, but does not reflect the shift in delivery and payment for health services to in-home and community based settings. [No budget impact, but $66 million in non-PAYGO savings over 10 years]

**Strengthening Program Integrity Tools**

The FY 2016 Budget builds on the Affordable Care Act's unprecedented fraud-fighting authorities with program integrity legislative proposals. These proposals enhance pre-payment scrutiny, increase penalties for improper actions, strengthen CMS's ability to implement corrective actions, and promote integrity in federal-state financing.

***Track High Prescribers and Utilizers of Prescription Drugs in Medicaid:*** This proposal would track high prescribers and utilizers of prescription drugs in Medicaid. States are currently authorized to implement prescription drug monitoring activities, but not all states have adopted such activities. Under this proposal, states will be required to monitor high risk billing activity to identify and remediate prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs in the Medicaid program. States may choose one or more drug classes and must develop or review and update their care plan to reduce utilization and remediate any preventable episodes to improve Medicaid integrity and beneficiary quality of care. [$710 million in savings over 10 years]

***Consolidate Redundant Error Rate Measurement Programs:*** This proposal would alleviate state program integrity reporting requirements and create a streamlined audit program by consolidating the Medicaid Eligibility Quality Control and Medicaid Payment Error Rate Measurement programs. [No budget impact]

***Prevent Use of Federal Funds to Pay the State Share of Medicaid or CHIP:*** Federal regulations prohibit federal funds from being used as the state share for Medicaid unless authorized in federal law. By codifying this principle in statute, this proposal would prevent states from using federal funds to pay the state share of Medicaid or CHIP, unless specifically authorized under law. [No budget impact]

*Medicare and Medicaid:*

***Permit Exclusion from Federal Health Care Programs if Affiliated with Sanctioned Entities:*** This proposal would expand the current authority to exclude individuals and entities from federal health programs if they are affiliated with a sanctioned entity by: eliminating the loophole in current law that allows an officer, managing employee, or owner of a sanctioned entity to evade exclusion by resigning his or her

position or divesting his or her ownership; and extending the exclusion authority to entities affiliated with a sanctioned entity. [$70 million in savings over 10 years]

***Establish Gifting Authority for the Healthcare Fraud Prevention Partnership:*** This proposal would give the authority to accept gifts made to the Trust Funds for particular activities funded through the HCFAC Account, such as the Healthcare Fraud Prevention Partnership. Currently, the HCFAC account can only receive gifts that are made for an unspecified purpose. This proposal would allow for gifts to be made to support the Partnership directly, and allow both public and private partners to support the anti-fraud program. [No budget impact]

***Strengthen Penalties for Illegal Distribution of Beneficiary Identification Numbers:*** In an effort to protect beneficiaries from illegal distribution of their personal identification numbers, this proposal would strengthen penalties for knowingly distributing Medicare, Medicaid, or CHIP beneficiary identification or billing privileges. [No budget impact]

# FY 2016 Program Integrity Legislative Proposals

*(Non-Add: Proposed Law impacts incorporated into Medicare, Medicaid, and State Grants and Demonstration Tables)*

| *(dollars in millions)* | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **Medicare** | | | |
| Retain a Portion of Medicare Recovery Audit Recoveries to Implement Actions That Prevent Fraud and Abuse | 141 | 1,109 | 2,748 |
| Allow Prior Authorization for Medicare Fee-for-service Items | — | -40 | -90 |
| Allow Civil Monetary Penalties or Intermediate Sanctions for Providers and Suppliers who Fail to Update Enrollment Records | -1 | -11 | -29 |
| Assess a Fee on Physicians and Practitioners Who Order Services or Supplies without Proper Documentation | — | — | — |
| Establish Registration Process for Clearinghouses and Billing Agents | — | — | — |
| Allow Collection of Application Fees from Individual Providers | — | — | — |
| Increase the Amount of Home Health Agency Surety Bond | — | — | — |
| **Medicaid** | | | |
| Expand Funding and Authority for the Medicaid Integrity Program | 25 | 180 | 580 |
| Support Medicaid Fraud Control Units for the Territories | 1 | 5 | 10 |
| Track High Prescribers and Utilizers of Prescription Drugs in Medicaid | -20 | -310 | -710 |
| Consolidate Redundant Error Rate Measurement Programs | — | — | — |
| Expand Medicaid Fraud Control Unit Review to Additional Care Settings | — | — | — |
| Prevent Use of Federal Funds to Pay State Share of Medicaid or CHIP | — | — | — |
| **Medicare & Medicaid** | | | |
| Permit Exclusion from Federal Health Care Programs if Affiliated with Sanctioned Entities | — | -20 | -70 |
| *Medicare [non-add]* | — | *-20* | *-70* |
| *Medicaid [non-add]* | — | — | — |
| Establish Gifting Authority for the Healthcare Fraud Prevention Partnership | — | — | — |
| Strengthen Penalties for Illegal Distribution of Beneficiary Identification Numbers | — | — | — |
| **Total, Program Integrity Legislative Impact** | **146** | **913** | **2,439** |
| *Subtotal, Medicare Impact [non-add]* | *140* | *1,038* | *2,559* |
| *Subtotal, Medicaid Impact [non-add]* | *6* | *-125* | *-120* |
| **Non-PAYGO Savings/1** | | | |
| Savings from Discretionary HCFAC Investment | -749 | -4,229 | -9,663 |
| Savings from Retention of Medicare Recovery Audit Recoveries to Implement Actions | -30 | -1,110 | -4,380 |
| Savings from Supporting Medicaid Fraud Control Units for the Territories | — | -2 | -2 |
| Savings from Expanding Medicaid Fraud Control Unit Review to Additional Care Settings | -5 | -29 | -66 |
| Savings from Expand Funding and Authority for the Medicaid Integrity Program | -55 | -330 | -850 |
| Savings from Social Security Program Integrity Investment | -31 | -1,726 | -6,696 |
| **Subtotal, Medicare and Medicaid Savings from Program Integrity Investment** | **-870** | **-7,426** | **-21,657** |
| **Total, Net Savings Program Integrity Proposed Policy** | **-724** | **-6,513** | **-19,218** |

1/ Includes non-PAYGO savings from increased program integrity investments in HCFAC, Medicaid Fraud Control Units, the Medicaid Integrity Program, and Social Security disability reviews above savings assumed in current law.

# Medicaid

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Current Law** | | | | |
| Benefits /1 | 286,284 | 309,373 | 326,680 | +17,307 |
| State Administration | 15,188 | 19,222 | 17,767 | -1,455 |
| Total Net Outlays, Current Law | **301,472** | **328,595** | **344,447** | **+15,852** |
| **Proposed Law** | | | | |
| **Legislative Proposals** /2 | — | 4,485 | 6,617 | +2,132 |
| **Extend Qualified Individual (QI) Program** /3 | — | +370 | +775 | +405 |
| **Adjustment for QI Transfer from Medicare** /3 | — | -370 | -775 | -405 |
| Total Net Outlays, Proposed Law | **301,472** | **333,080** | **351,064** | **+17,984** |
| **Investment Impact** | | | | |
| **Impacts of Program Integrity Investments** /4 | — | — | -59 | -59 |
| Total Net Outlays, Proposed Policy | **301,472** | **333,080** | **351,005** | **+17,925** |

1/ Includes outlays from the Vaccines for Children Program, administered by the Centers for Disease Control and Prevention.

2/ Includes a proposal to extend Transitional Medical Assistance currently authorized through March 31, 2015; excludes program integrity investments other than those for Medicaid Fraud Control Units.

3/ States pay the Medicare Part B premium costs for Qualified Individuals (QIs) that are in turn offset by a 100 percent reimbursement from Medicare Part B. Costs of the proposal to extend the QI program through CY 2016 are reflected in Medicare outlays. The QI program is currently authorized through March 31, 2015.

4/ Includes the net impact of the HHS and Social Security Administration program integrity investments on the Medicaid baseline.

Note: Numbers may not add due to rounding

Medicaid is the primary source of medical assistance for millions of low income and disabled Americans, providing health coverage to many of those who would otherwise be unable to obtain health insurance. In FY 2013, more than 1 in 5 individuals were enrolled in Medicaid for at least 1 month during the year, and in FY 2015, nearly 69 million people on average will receive health care coverage through Medicaid.

Growth in per-enrollee Medicaid costs has been historically low in recent years. Specifically, Medicaid spending per enrollee grew by only 1.0 percent annually between 2007 and 2013, compared to 3.2 percent annual growth in per capita national health expenditures over the same time period. [2]

[2] Hartman, Micah, et al. *National Health Spending In 2013: Growth Slows, Remains In Step With The Overall Economy.* Journal of Health Affairs. December 2014. http://content.healthaffairs.org/content/34/1/150

### How Medicaid Works

Although the federal government establishes general guidelines for the program, states design, implement, and administer their own Medicaid programs. The federal government matches state expenditures on medical assistance based on the federal medical assistance percentage, which can be no lower than 50 percent. In FY 2016, the federal share of current law Medicaid outlays is expected to be approximately $344.4 billion. States are required to cover individuals who meet certain minimum categorical and financial eligibility standards. Medicaid beneficiaries include children, pregnant women, adults in families with dependent children, the aged, blind, and/or disabled, and individuals who meet certain minimum income eligibility criteria that vary by category. States also have the flexibility to extend coverage to higher income groups, including medically needy individuals through waivers and amended state plans. Medically needy individuals are those individuals who do not

**Medicaid Enrollment**
(person-years in millions)

| | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Aged 65 and Over | 5.4 | 5.6 | 5.8 | +0.2 |
| Blind and Disabled | 10.2 | 10.2 | 10.3 | +0.1 |
| Children | 28.9 | 29.6 | 30.3 | +0.7 |
| Adults | 19.3 | 22.4 | 25.5 | +3.1 |
| Territories | 1.0 | 1.0 | 1.0 | — |
| **Total** | **64.8** | **68.8** | **72.9** | **+4.1** |

Source: CMS Office of the Actuary estimates.
Note: Numbers may not add due to rounding

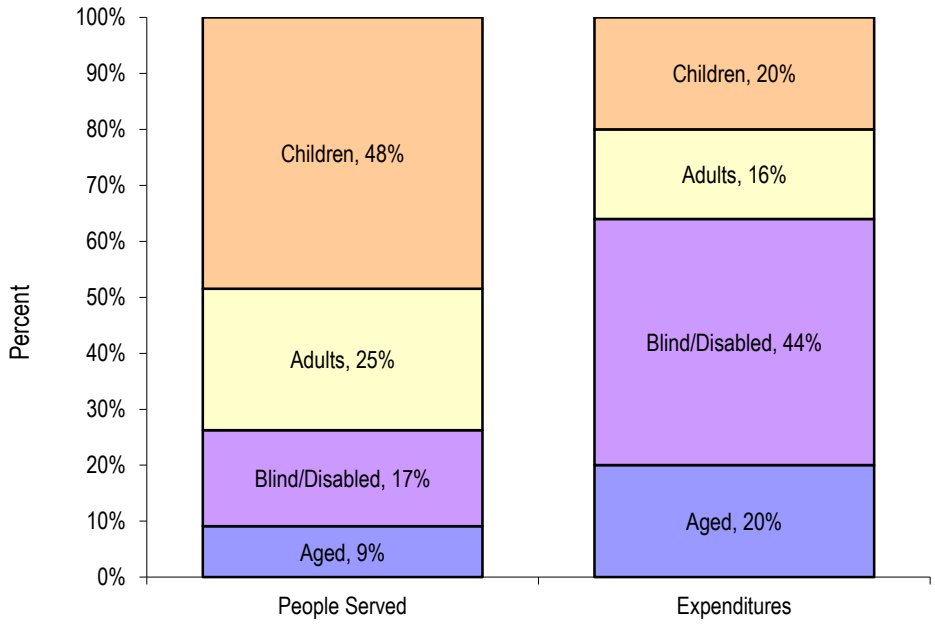
meet the income standards of the categorical eligibility groups, but incur large medical expenses such that when subtracted from their income, they fall within the financial eligibility standards.

Under Medicaid, states must cover certain medical services and are provided the flexibility to offer additional benefits to beneficiaries. Medicaid has a major responsibility for providing long-term care services because Medicare and private health insurance often furnish only limited coverage of these benefits.

## Recent Program Developments

***Affordable Care Act (P.L. 111-148 and P.L. 111-152):***
The Affordable Care Act's Medicaid expansion, which began in 2014, allows states the option to expand Medicaid eligibility to individuals under age 65 with family incomes up to 133 percent of the federal poverty level (or $32,253 for a family of four in 2015). As of January 2015, 28 states and the District of Columbia have elected to expand Medicaid.

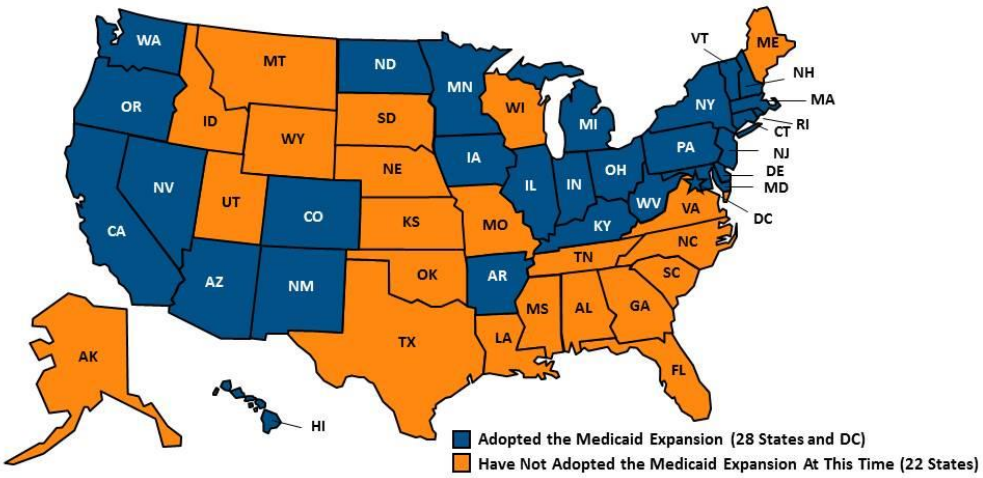
**FY 2013 – Percent of Medicaid Beneficiaries vs. Federal Medical Assistance Expenditures by Eligibility Group /1**




Source: CMS Office of the Actuary
1/ Totals and components exclude disproportionate share hospital expenditures, territorial enrollees and expenditures, and financial adjustments.
Note: Percentages may not add to 100% due to rounding.

The federal government will pay 100 percent of state expenditures related to coverage for newly eligible individuals through calendar year 2016. The federal matching rate will then drop gradually to 90 percent in 2020 where it will remain. In addition, the Affordable Care Act also strengthens Medicaid program integrity efforts, improves services to Medicaid beneficiaries and supports home and community-based settings rather than institutions.

## Status of Medicaid Expansion Decisions, January 27, 2015




SOURCE: "Status of State Action on the Medicaid Expansion Decision," Kaiser Family Foundation State Health Facts.

***The Protecting Access to Medicare Act of 2014 (P.L. 113-93):*** This law extended the Qualified Individual and Transitional Medical Assistance programs through March 31, 2015 and extends Express Lane Eligibility authority through September 2015. The law also delays Medicaid Disproportionate Share Hospital reductions until FY 2017 and applies additional reductions to the allotments scheduled for FYs 2017-2024.

### 2016 Legislative Proposals

The FY 2016 Budget includes a package of legislative proposals with a net impact to the Federal government of $3.7 billion[3], including $26.7 billion in Medicaid program investments over 10 years by improving benefits and facilitating coverage for Medicaid beneficiaries while also strengthening the cost-effectiveness of Medicaid. The Budget also includes proposals that impact those who are dually eligible for both Medicare and Medicaid.

#### *Improve Benefits and Facilitate Coverage for Medicaid Beneficiaries*

***Require Full Coverage of Preventive Health and Tobacco Cessation Services for Adults in Traditional Medicaid:*** The Budget would require coverage of preventive health services as defined in section 2713 of the Public Health Service Act without cost-sharing for all adults enrolled in the Medicaid program, and also expand section 4107 of the Affordable Care Act, which provides tobacco cessation services (including counseling) to pregnant women, to all Medicaid eligible populations. Such services are already required for most other populations without cost sharing, including individuals in private health plans, the Medicaid expansion population, and various other Medicaid beneficiaries. [$754 million in costs over 10 years]

***Create State Option to Provide 12-Month Continuous Medicaid Eligibility for Adults:*** Currently, individuals enrolled in Medicaid are required to report changes in income, assets, or other life circumstances that may affect eligibility between regularly scheduled redeterminations. This proposal would create a state plan option to allow 12 months of continuous eligibility for individuals who would otherwise be at risk of moving between insurance coverage, often referred to as churning, that disrupts existing provider relationships or increasing the odds of becoming uninsured. States already have a state plan option for continuous eligibility for children in Medicaid and CHIP and that authority would be broadened to include all adults or, at state option, only adults determined eligible for Medicaid on the basis of Modified Adjusted Gross Income. [$4.7 billion in net federal costs including $27.7 billion in Medicaid costs over 10 years]

[3] This includes $23 billion in savings to the Marketplace subsidies and related impacts reflected in the Department of Treasury programs and accounts.

***Extend the Medicaid Primary Care Payment Increase through CY 2016 and Include Additional Providers:*** Effective for dates of service provided on January 1, 2013 through December 31, 2014, states were required to reimburse qualified providers at the rate that would be paid for the primary care service under Medicare. The federal government covered 100 percent of the difference between the Medicaid and Medicare payment rate. This increased payment rate expired at the end of CY 2014. As part of the Administration's workforce initiative, this proposal would extend the enhanced rate through December 31, 2016, expand eligibility to obstetricians, gynecologists, and non-physician practitioners, including physician assistants and nurse practitioners, and exclude emergency room codes to better target primary care. [$6.3 billion in costs over 10 years]

***Pilot Comprehensive Long-Term Care State Plan Option:*** This eight-year pilot program would create a comprehensive long-term care state plan option for up to five states. Participating states would be authorized to provide home and community-based care at the nursing facility level of care, creating equal access to home and community-based care and nursing facility care. The Secretary would have the discretion to make these pilots permanent at the end of the eight years. This proposal works to end the institutional bias in long-term care and simplify state administration. [$4.1 billion in costs over 10 years]

***Allow States to Develop Age-Specific Health Home Programs:*** The Affordable Care Act includes a provision that allows states to create Health Homes for Medicaid enrollees with chronic conditions. Under a Health Home program, states can develop a comprehensive system of care coordination for the purpose of integrating and coordinating all primary, acute, behavioral health, and long-term services and supports to treat the whole person. States receive an increased federal match for Health Home services for the first eight quarters of their program. This proposal would allow states to target their Health Home programs by age. Currently, states are required to cover Health Home services for all categorically needy individuals with the specified chronic condition(s), regardless of age. Many states have voiced support for allowing age-specific targeting of their Health Home model to better serve the needs of youth with chronic conditions. [$1 billion in costs over 10 years]

***Permanently Extend Express Lane Eligibility Option for Children:*** The Children's Health Insurance Program Reauthorization Act (P.L. 111-3) authorized Express Lane Eligibility through FY 2014 under which state Medicaid or CHIP agencies can use another public program's eligibility findings to streamline eligibility and enrollment into Medicaid or CHIP. The Protecting Access to Medicare Act of 2014 (P.L. 113-93) extended the authorization to use Express Lane Eligibility through September 30, 2015. As of January 1, 2015, 14 states and 1 territory used this authority to partner with programs like the Supplemental Nutrition Assistance Program or Temporary Assistance for Needy Families to identify, enroll, and retain children who are eligible for Medicaid or CHIP. The Budget supports a permanent extension of this tool to aid states in furthering their efforts to enroll Medicaid and CHIP eligible children. [$1.2 billion including $680 million in Medicaid costs over 10 years]

***Expand Eligibility for the 1915(i) Home and Community-Based Services State Plan Option:*** The Budget proposes to update eligibility requirements to increase states' flexibility in expanding access to home and community-based services under section 1915(i) of the Social Security Act. Under current law, certain non-categorically eligible individuals who meet the needs-based criteria can only qualify for home and community-based services through the 1915(i) state plan option if they are also eligible for home and community-based services through a waiver program. Removing this requirement would reduce administrative burden on states and increase access to home and community-based services for the elderly and individuals with disabilities. [$1.3 billion in costs over 10 years]

***Allow Full Medicaid Benefits for Individuals in a Home and Community-Based Services State Plan Option:*** This proposal would provide states with the option to offer full Medicaid eligibility to medically needy individuals who access home and community-based services through the state plan option under section 1915(i) of the Social Security Act. Under current law, when a state elects to not apply the community income and resource rules for the medically needy, these individuals can only receive 1915(i) services and no other Medicaid services. This option will provide states with more opportunities to support the comprehensive health care needs of individuals with disabilities and the elderly. [$38 million in costs over 10 years]

***Allow Pregnant Women Choice of Medicaid Eligibility Category:*** Pregnant women are categorically eligible for Medicaid if they have income under 133 percent of

the Federal Poverty Level, so under current law they are excluded from the new adult Medicaid expansion group. Because the benefits and delivery system may differ between the pregnant women and the new adult groups in states that elect to expand, women enrolled in the new adult group who become pregnant as well as postpartum women may have to change providers which would disrupt continuity of care. This proposal addresses this concern by allowing pregnant women enrolled in Medicaid to choose the eligibility category most suited to their needs. [No budget impact]

***Require Coverage of Early and Periodic Screening, Diagnostic and Treatment Benefit for Children in Inpatient Psychiatric Treatment Facilities:*** While Medicaid coverage is available for children and young adults under age 21 receiving inpatient psychiatric services, they are excluded from coverage of comprehensive preventive and medically necessary items and services to which Medicaid enrolled children are otherwise entitled. This proposal would lift the federal Medicaid exclusion of comprehensive children's coverage to reduce the financial burden on states and Medicaid families and encourage the provision of critical mental health services to children in Medicaid. [$425 million in costs over 10 years]

***Provide Home and Community-Based Waiver Services to Children Eligible for Psychiatric Residential Treatment Facilities:*** This proposal would provide states with additional tools to manage their children's mental health care service delivery systems by expanding the non-institutional options available to these Medicaid beneficiaries. By adding psychiatric residential treatment facilities to the list of qualified inpatient facilities, this proposal provides access to home and community-based waiver services for children and youth in Medicaid who are currently institutionalized and/or meet the institutional level of care. Without this change to provisions in the Social Security Act, children and youth who meet this institutional level of care do not have the choice to receive home and community-based waiver services and can only receive care in an institutional setting where residents are eligible for Medicaid. This proposal builds upon findings from the five year Community Alternatives to Psychiatric Residential Treatment Facilities Demonstration Grant Program authorized in the Deficit Reduction Act of 2005 that showed improved overall outcomes in mental health and social support for participants with average cost savings of $36,500–$40,000 per year per participant. [$1.6 billion in costs over 10 years]

***Expand State Flexibility to Provide Benchmark Benefit Packages:*** States currently have the option to provide certain populations with alternative benefit packages called benchmark or benchmark-equivalent plans. This proposal provides states the flexibility to allow benchmark equivalent benefit coverage for non-elderly, non-disabled adults with income that exceeds 133 percent of the federal poverty level. [No budget impact]

***Extend Transitional Medical Assistance through CY 2016:*** The Transitional Medical Assistance program extends Medicaid coverage for at least 6 months and up to 12 months for low income families who lose cash assistance due to an increase in earned income or hours of employment. This proposal extends the Transitional Medical Assistance program through December 31, 2016. This proposal would allow determination of eligibility for Transitional Medical Assistance to be calculated using Modified Adjusted Growth Income to be consistent with the Affordable Care Act. States that adopt the Medicaid expansion will be able to opt out of Transitional Medical Assistance, consistent with a related Medicaid and CHIP Payment and Access Commission recommendation. Current law extends this program through March 31, 2015. [$1.8 billion in costs over 10 years]

***Extend the Qualified Individual Program through CY 2016:*** The Qualified Individual program provides states 100 percent federal funding to pay the Medicare Part B premiums of low income Medicare beneficiaries with incomes between 120 and 135 percent of the Federal Poverty Level. This proposal extends authorization and funding of the program through December 31, 2016. Current law extends this program through March 31, 2015. [$975 million in costs over 10 years]

***Expand Eligibility Under the Community First Choice Option:*** This proposal would provide states with the option to make medical assistance available to individuals who would be eligible under the state plan if they were in a nursing facility. Under current law, any state interested in the Community First Choice Option must create or maintain a 1915(c) waiver with at least one waiver service to make the benefit available to the special income group or provide eligibility for the Community First Choice benefit through another eligibility pathway. This approach is administratively burdensome for states. This proposal would provide equal access to services under the state plan option and provide states with additional tools to

manage their long-term care home and community-based service delivery systems. [$3.6 billion in costs over 10 years]

### *Strengthen Cost-Effectiveness of Medicaid*

***Rebase Future Medicaid Disproportionate Share Hospital Allotments:*** As the number of uninsured individuals decreases due to the coverage expansions in the Affordable Care Act, uncompensated care costs for hospitals will also decrease, reducing the level of Disproportionate Share Hospital funding needed. Legislation has extended and revised aggregate Disproportionate Share Hospital funding reductions through FY 2024, but in FY 2025, allotments revert to levels that had been in effect prior to the Affordable Care Act. This proposal would determine future allotments based on states' actual prior year allotments as reduced by the Affordable Care Act and subsequent legislation. [$3.3 billion in savings over 10 years]

***Limit Medicaid Reimbursement of Durable Medical Equipment Based on Medicare Rates:*** Through the Durable Medical Equipment Competitive Bidding Program, Medicare is in the process of implementing innovative ways to increase efficiency for durable medical equipment payments. These efforts are expected to save Medicare more than $30.2 billion over 10 years. This proposal extends some of these efficiencies to Medicaid by limiting federal reimbursement for a state's Medicaid spending on certain durable medical equipment to what Medicare would have paid in the same state for the same services. [$4.3 billion in savings over 10 years]

***Lower Medicaid Drug Costs and Strengthen the Medicaid Drug Rebate Program***: The Budget includes targeted policies to lower drug costs in Medicaid. First, the Budget strengthens the Medicaid Drug Rebate Program by clarifying the definition of brand drugs, collecting an additional rebate for generic drugs whose prices grow faster than inflation, and clarifying the inclusion of certain prenatal vitamins and fluorides in the rebate program. The Budget also corrects a technical error to the Affordable Care Act alternative rebate for new drug formulations, limits to twelve quarters the timeframe for which manufacturers can dispute drug rebate amounts, and excludes authorized generic drugs from average manufacturer price calculations for determining manufacturer rebate obligations for brand drugs. Additionally, the Budget improves Medicaid drug pricing by calculating Medicaid Federal Upper Limits based only on generic drug prices. Finally, the Budget would exempt emergency drug supply programs from the Medicaid rebate calculations. [$6.3 billion in savings over 10 years]

***Promote Program Integrity for Medicaid Drug Coverage:*** The Budget would enhance program integrity for the Medicaid prescription drug program in four ways. First, the Budget would require manufacturers to pay states back for drugs in cases where the manufacturer has either improperly reported non-drug products to CMS or has reported drugs that the FDA has found to be less than effective. Second, the Budget would enhance existing enforcement of manufacturer compliance with drug rebate requirements by allowing more regular audits and surveys of drug manufacturers where cost effective. Third, the Budget would require drugs to be electronically listed with FDA in order for them to be included in Medicaid coverage, thereby aligning Medicaid drug coverage requirements with Medicare drug coverage requirements. Finally, the Budget would increase penalties for fraudulent noncompliance on rebate agreements—particularly where drug manufacturers knowingly report false information under their drug rebate agreements. [$10 million in savings over 10 years]

***Increase Access to and Transparency of Medicaid Drug Pricing Data:*** The Deficit Reduction Act of 2005 (P.L. 109-171) provided funding for this survey which expired in FY 2010. This proposal fully funds a nationwide retail pharmacy survey incorporating prices paid by cash-paying, third-party insured, and Medicaid insured consumers. The funding also permits collection of the actual invoice prices from retail community pharmacies to enable states to set reasonable payment rates to pharmacies. Finally, these proposals provide CMS the authority to collect wholesale acquisition costs for all Medicaid covered drugs. [$30 million in costs over 10 years]

***Reduce Fraud, Waste, and Abuse 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. See the Program Integrity chapter for proposal descriptions. [$700 million in 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.

***Allow for Federal/State Coordinated Review of Dual Special Need Plan Marketing Materials:*** This proposal would introduce flexibility to rules around the review of marketing materials provided by Dual Special Needs Plans to beneficiaries. Under existing statute, all marketing materials provided by the plans to beneficiaries must be reviewed by CMS staff for accuracy, content, and other stated requirements. Because the plans also market to Medicaid beneficiaries, many of the same marketing materials must also go through a separate review from a state Medicaid agency for compliance with a different set of rules and regulations. Providing CMS with the ability to perform coordinated reviews of these marketing materials for compatibility with a unified set of standards will reduce the burden on CMS and the states, while also potentially improving the quality of the products available to beneficiaries. [No budget impact]

***Create Pilot to Expand PACE Eligibility to Individuals between Ages 21 and 55:*** This program provides comprehensive long-term services and supports to Medicaid and Medicare beneficiaries through an interdisciplinary team of health professionals who provide coordinated care to beneficiaries in the community. For most participants, the comprehensive service package includes medical and social services and enables them to receive care in the community rather than to receive care in a nursing home or other facility. Under current law, the program is limited to individuals who are 55 years old or older and who meet, among other requirements, the state's nursing facility level of care. This proposal would create a pilot demonstration in selected states to expand eligibility to qualifying individuals between 21 years and 55 years of age. This effort would test whether the Program for All-Inclusive Care for the Elderly can effectively serve a younger population without increasing costs. The pilot would promote access to community services in line with the integration of the landmark Olmstead Supreme Court decision[4]; supporting self-determination and achieving better health outcomes. [No budget impact]

***Ensure Retroactive Part D Coverage of Newly Eligible Low-Income Beneficiaries:*** This proposal would allow CMS to contract with a single plan to provide Part D coverage to low income beneficiaries while their eligibility is processed. This plan would serve as the single point of contact for beneficiaries seeking reimbursement for retroactive claims. These beneficiaries are assigned at random under current law to a qualifying Part D plan, which is reimbursed based on the standard Part D prospective payment, regardless of their utilization of Part D services during this period. Under this proposal, the plan would be paid using an alternative methodology whereby payments are closer to actual costs incurred by beneficiaries during this period. A current demonstration, which was recently extended through 2019, has shown the proposed approach to be more efficient and less disruptive to beneficiaries. [No budget impact]

***Integrate the Appeals Process for Medicare-Medicaid Enrollees:*** Medicare and Medicaid have different appeals processes governed by different provisions of the Social Security Act, resulting in different requirements related to timeframes and limits, amounts in controversy, and levels of appeals. At times, these requirements may conflict and can result in confusion for beneficiaries and inefficiencies and administrative burdens for states and providers. This proposal provides authority for the Secretary to implement a streamlined appeals process to more efficiently integrate Medicare and Medicaid program rules and requirements, while maintaining the important beneficiary protections included in both programs. [No budget impact]

### *Multi-Agency Proposals*

***Establish Hold Harmless for Federal Poverty Guidelines:*** To protect access to programs, including Medicaid, for low income families and individuals, this proposal would treat the Consumer Price Index for All Urban Consumers adjustment for the poverty guidelines consistent with the treatment of the annual cost of living adjustments for Social Security Benefits. The poverty guidelines would only be adjusted when there is an increase in the Index, not a decrease. [No budget impact]

[4] The U.S. Supreme Court's 1999 landmark decision in Olmstead v. L.C. (Olmstead) found the unjustified segregation of people with disabilities is a form of unlawful discrimination under the Americans with Disabilities Act (ADA). Olmstead requires States to administer programs in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

**Extension of Enhanced Medicaid Matching Funds for Upgrading and Integrating Eligibility and Enrollment Systems**

In October 2014, CMS announced its intention to promulgate regulations to permanently extend the enhanced Federal matching rate for eligibility and enrollment systems modernization. The increase is scheduled to expire on December 31, 2015 which would decrease the federal matching rate from 90 percent to 50 percent, thereby increasing the cost to states. Through December 2014, under the enhanced match, CMS has approved $4.7 billion for states to enhance their systems in order to incorporate the new Affordable Care Act eligibility criteria and create a streamlined and automated consumer experience. Some elements of this successful strategy include pre-populated online renewal forms, real time eligibility determinations, and integration of Medicaid, CHIP, and Marketplace enrollment decisions and notifications. As a condition of the extension, CMS will propose states meet new criteria including completing Modified Adjusted Gross Income based system functionality and incorporating best practices for systems development and management. In addition, to support the integration of eligibility systems between Medicaid and human services programs, such as Supplemental Nutrition Assistance Program and Temporary Assistance for Needy Families, the Federal government extended a waiver of cost allocation requirements set forth in OMB Circular A87 for three additional years, through December 2018.

# FY 2016 Medicaid Legislative Proposals

*(dollars in millions)*

*(negative numbers reflect savings and positive numbers reflect costs)*

| ***dollars in millions*** | **2016** | **2016 -2020** | **2016 -2025** |
|---|---|---|---|
| **Improve Benefits and Facilitate Coverage for Medicaid Beneficiaries** | | | |
| Require Full Coverage of Preventive Health and Tobacco Cessation Services for Adults in Traditional Medicaid | 95 | 431 | 754 |
| *Create State Option to Provide 12-Month Continuous Medicaid Eligibility for Adults (non-add) /1* | *299* | *1,844* | *4,713* |
| Medicaid Impact | *600* | 10,200 | 27,700 |
| *Marketplace Subsidies and Related Impacts (non-add)* | *-301* | *-8,152* | *-22,987* |
| Extend the Medicaid Primary Care Payment Increase through CY 2016 and Include Additional Providers | 5,010 | 6,290 | 6,290 |
| Pilot Comprehensive Long-term Care State Plan Option | 0 | 2,345 | 4,085 |
| Allow States to Develop Age-Specific Health Home Programs | 200 | 570 | 1,010 |
| *Permanently Extend Express Lane Eligibility Option for Children (non-add) /2* | 30 | 465 | 1,170 |
| Medicaid Impact | 20 | 215 | 680 |
| *CHIP Impact (non-add)* | *10* | *250* | *490* |
| Expand Eligibility for the 1915(i) Homes and Community-Based Services State Plan Option | 26 | 439 | 1,341 |
| Allow Full Medicaid Benefits to All Individuals in a Home and Community Based Services State Plan Option | 1 | 15 | 38 |
| Allow Pregnant Women Choice of Medicaid Eligibility Category | — | — | — |
| Require Coverage of Early and Periodic Screening, Diagnostic, and Treatment for Children in Inpatient Psychiatric Treatment Facilities | 30 | 180 | 425 |
| Provide Home and Community-Based Waiver Services to Children Eligible for Psychiatric Residential Treatment Facilities | 0 | 597 | 1,625 |
| Expand State Flexibility to Provide Benchmark Benefit Packages | — | — | — |
| Extend the Transitional Medical Assistance Program through CY 2016 /3 | 1,075 | 1,825 | 1,825 |
| Extend the Qualified Individual Program through CY 2016 /4 | 775 | 975 | 975 |
| Adjustment for Qualified Individuals Transfer from Medicare /4 | -775 | -975 | -975 |
| Expand Eligibility Under the Community First Choice Option | 238 | 1,451 | 3,581 |
| | | | |
| **Strengthen Cost-Effectiveness of Medicaid** | | | |
| Rebase Future Medicaid Disproportionate Share Hospital Allotments | 0 | 0 | -3,290 |
| Limit Medicaid Reimbursement of Durable Medical Equipment Based on Medicare Rates | -305 | -1,780 | -4,270 |
| Lower Medicaid Drug Costs and Strengthen the Medicaid Drug Rebate Program | -276 | -2,543 | -6,325 |
| *Clarify the Medicaid Definition of Brand Drugs (non-add)* | *-16* | *-78* | *-160* |
| *Apply Inflation-Associated Penalty to Medicaid Rebates for Generic Drugs (non-add)* | — | *-145* | *-1,165* |
| *Require Coverage of Prescribed Prenatal Vitamins and Fluorides under the Medicaid Drug Rebate Program (non-add)* | — | — | — |
| *Correct the ACA Medicaid Rebate Formula for New Drug Formulations (non-add)* | *-210* | *-1,890* | *-4,020* |

| dollars in millions | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **Strengthen Cost-Effectiveness of Medicaid (cont'd)** | | | |
| *Limit Dispute Resolution Timeframe in the Medicaid Drug Rebate Program to Twelve Quarters (non-add)* | — | — | — |
| *Exclude Authorized Generics from Medicaid Brand-Name Rebate Calculations (non-add)* | *-20* | *-100* | *-200* |
| *Exclude Brand and Authorized Generic Drug Prices from the Medicaid Federal Upper Limits (FUL) (non-add)* | *-30* | *-330* | *-780* |
| *Exempt Emergency Drug Supply Programs from Medicaid Drug Rebate Calculation (non-add)* | — | — | — |
| Promote Program Integrity for Medicaid Drug Coverage | -1 | -5 | -10 |
| *Require Manufacturers that Improperly Report Items for Medicaid Drug Coverage to Fully Repay States (non-add)* | *-1* | *-5* | *-10* |
| *Enforce Manufacturer Compliance with Drug Rebate Requirements (non-add)* | — | — | — |
| *Require Drugs be Electronically Listed with the Food and Drug Administration to Receive Medicaid Coverage (non-add)* | — | — | — |
| *Increase Penalties for Fraudulent Noncompliance on Rebate Agreements (non-add)* | — | — | — |
| Increase Access to and Transparency of Medicaid Drug Pricing Data | 6 | 30 | 30 |
| *Provide Continued Funding for Survey of Retail Pharmacy Prices (non-add)* | *6* | *30* | *30* |
| *Require Drug Wholesalers to Report Wholesale Acquisition Costs to CMS (non-add)* | — | — | — |
| Reduce Fraud, Waste, and Abuse in Medicaid /5 | -19 | -305 | -700 |
| ***Total Outlays, Medicaid Proposals*** | **3,350** | **19,955** | **34,789** |
| | | | |
| **Medicare-Medicaid Enrollee Proposals** | | | |
| Allow for Federal/State Coordinated Review of Dual Special Need Plan Marketing Materials | — | — | — |
| Create Pilot to Expand PACE Eligibility to Individuals Between Ages 21 and 55 | — | — | — |
| Ensure Retroactive Part D Coverage of Newly Eligible Low-Income Beneficiaries | — | — | — |
| Integrate Appeals Process for Medicare-Medicaid Enrollees | — | — | — |
| ***Total Outlays, Medicare-Medicaid Enrollee Proposals*** | — | — | — |
| | | | |
| **Medicaid Interactions** | | | |
| Extend CHIP Funding through FY 2019 /6 | -100 | -7,300 | -7,300 |
| Establish Hold-Harmless for Federal Poverty Guidelines | — | — | — |
| Create Demonstration to Address Over-Prescription of Psychotropic Medications for Foster Care Children /7 | 114 | 608 | 552 |
| Extend Special Immigrant Visa Program /8 | 12 | 66 | 121 |
| Extend Supplemental Security Income Time Limits for Qualified Refugees /9 | 10 | 22 | 22 |
| Modernize Child Support /10 | 0 | 32 | 130 |
| Modify Length of Exclusivity to Facilitate Faster Development of Generic Biologics /11 | 0 | -30 | -130 |
| Prohibit Brand and Generic Drug Manufacturers from Delaying the Availability of New Generic Drugs and Biologics /11 | -120 | -640 | -1,450 |
| **Total Outlays, Medicaid Interactions** | **-84** | **-7,242** | **-8,055** |
| | | | |

| dollars in millions | 2016 | 2016 - 2020 | 2016 -2025 |
|---|---|---|---|
| **Total Outlays, Medicaid Legislative Proposals** | **6,617** | **12,713** | **26,734** |
| | | | |
| **Total Outlays, Total Federal Impact /12** | **6,315** | **4,561** | **3,747** |
| | | | |
| **Note: Totals may not add due to rounding** | | | |
| 1/ The score reflects the impact on Medicaid, other HHS programs, and U.S. Department of Treasury programs and accounts. | | | |
| 2/ The score reflects the impact on both Medicaid and the Children's Health Insurance Program. | | | |
| 3/ Currently authorized through March 31, 2015. | | | |
| 4/ States pay the Medicare Part B premium costs for Qualified Individuals (QIs) that are in turn offset by a reimbursement from Medicare Part B. Costs of the proposal to extend the Qualified Individuals program are reflected in Medicare outlays. The Qualified Individuals program is currently authorized through March 31, 2015. | | | |
| 5/ This includes proposals described in the Program Integrity chapter, excluding savings not subject to PAYGO and excluding the proposal to Expand Funding and Authority for the Medicaid Integrity Program, which is described in the Program Integrity chapter but accounted for in the tables in the State Grants and Demonstrations chapter. | | | |
| 6/ This score reflects the impact on the Medicaid program. Please see the Children's Health Insurance Program chapter for more information on this proposal. | | | |
| 7/ This is a joint proposal with the Administration for Children and Families (ACF). The score reflects the impact on the Medicaid baseline. Please see the ACF and State Grants and Demonstration chapters for more information on this proposal. | | | |
| 8/ This proposal is included in the State Department's FY 2016 Budget Request. | | | |
| 9/ This proposal is included in the Social Security Administration's FY 2016 Budget Request. | | | |
| 10/ This proposal is included in the Administration for Children and Families' FY 2016 Budget Request. | | | |
| 11/ This proposal is a multi-agency proposal with savings to Medicaid. See Medicare chapter for proposal descriptions. | | | |
| 12/ The total Federal impact of this proposal reflects $23 billion in savings to the Marketplace subsidies and related impacts reflected in the Department of Treasury programs and accounts | | | |

## Budget Overview

*(dollars in millions)*

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Current Law** | | | | |
| Children's Health Insurance Program | 9,316 | 10,558 | 14,010 | +3,452 |
| Child Enrollment Contingency Fund | 3 | 50 | 0 | -50 |
| **Total Outlays, Current Law** | **9,319** | **10,608** | **14,010** | **+3,402** |
| **Proposed Law** | | | | |
| Extend CHIP Funding through FY 2019 /1/2 | — | — | +550 | +550 |
| *Children's Health Insurance Program (non-add)* | — | — | *+500* | *+500* |
| *Child Enrollment Contingency Fund (non-add)* | — | — | *+50* | *+50* |
| *Performance Bonus Fund (non-add)* | — | — | — | — |
| Permanently Extend Express Lane Eligibility for Children /3 | — | — | +10 | +10 |
| **Total Outlays, Proposed Law /4** | **9,319** | **10,608** | **14,570** | **+3,962** |
| 1/ The net cost of this proposal is $130 million in FY 2016, which reflects impacts to CHIP and interactions with Medicaid, the Marketplace subsidies, and related impacts. See Medicaid chapter for Medicaid impact. | | | | |
| 2/ The proposal is paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives. | | | | |
| 3/ The net federal impact of this proposal is $30 million in FY 2016, which reflects the impacts to CHIP and Medicaid. See Medicaid chapter for Medicaid impact. | | | | |
| 4/ There are a number of Medicaid and Program Integrity legislative proposals that have a non-budgetary impact on the CHIP program. | | | | |

The Children's Health Insurance Program (CHIP) was originally created under the Balanced Budget Act of 1997 (P.L. 105-33). In 2009, CHIP was reauthorized under the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. 111-3), which provided an additional $44 billion in funding through FY 2013 and created several new initiatives to improve and increase enrollment in the program. The Affordable Care Act (P.L. 111-148 and P.L. 111-152) extended funding for CHIP through FY 2015. The Budget proposes a four-year extension of CHIP through FY 2019. Since September 1999, every state, the District of Columbia, and all five territories have approved CHIP plans.

**Increasing Enrollment of Eligible Children**

CMS's goal is to improve availability and accessibility of health insurance coverage by increasing enrollment of eligible children in CHIP and Medicaid.

- FY 2013 actual: 45.3 million children (Target: 45.6 million)
- FY 2014 target: 46.6 million children
- FY 2015 target: 47.6 million children
- FY 2016 target: 48.7 million children

Source: CMS Office of the Actuary

### How CHIP Works

CHIP is a partnership between the federal government and states and territories to help provide low income children with the health insurance coverage they need. The program improves access to health care and the quality of life for millions of vulnerable children less than 19 years of age. In general, CHIP reaches children whose families have incomes too high to qualify for Medicaid, but too low to afford private health insurance. In FY 2014, the CMS Office of the Actuary estimated that an average of 5.6 million individuals received health insurance funded through CHIP allotments at some point during the year.

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

States have a high degree of flexibility in designing their programs. States can implement CHIP by expanding Medicaid, creating a separate program, or a combination of both approaches. As of January 1, 2015, there were 13 Medicaid expansion programs, 2 separate programs, and 41 combination programs among the states, District of Columbia, and territories.

A Child Enrollment Contingency Fund was established for states that predict a funding shortfall based on higher than expected enrollment. The Contingency Fund received an initial appropriation of $2.1 billion in FY 2009 and is invested in interest bearing securities of the United States. Payments from the Fund are currently authorized through FY 2015.

Through FY 2013, the Performance Bonus Fund authorized payments to states that performed five out of eight specific enrollment and retention activities set out in the Children's Health Insurance Program Reauthorization Act of 2009. In FY 2014, CMS awarded $307 million to 23 states based on actual FY 2013 performance.

**CHIP Extension is Fully Paid for with Tobacco Tax Increase**

The net cost of $11.9 billion to extend CHIP for four years through FY 2019 is fully paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives.

| ***dollars in millions*** | **FYs 2016-2025** *(10 year)* |
|---|---|
| Extend CHIP Funding through FY 2019 | 10,281 |
| *CHIP Impact (non-add) (HHS)* | *33,000* |
| *Medicaid Impact (non-add) (HHS)* | *-7,300* |
| *Marketplace Subsidies and Related Impacts (non-add) (Treasury)* | *-15,419* |
| Extend the Children's Enrollment Contingency Fund for Four Years | 200 |
| Extend the Performance Bonus Fund for Four Years | 1,400 |
| Subtotal, Cost of CHIP Proposals | 11,881 |
| Offset from Increase in Tobacco Tax | -11,881 |
| **Total Net Federal Cost** | **0** |

## Recent Program Developments

***Financing:*** In addition to extending funding for state allotments through FY 2015, the Affordable Care Act increased each state's enhanced federal match rate by 23 percentage points, not to exceed a total match rate of 100 percent, between FY 2016 and FY 2019.

***Eligibility and Coverage:*** Under the Affordable Care Act, states use a simplified Modified Adjusted Gross Income standard to determine eligibility for coverage under a state's CHIP program. States can offer continuous eligibility for 12 months regardless of changes in family income, can fast track enrollment using Express Lane Eligibility authority, and can enroll children who are eligible for family coverage under a state employee health plan into CHIP.

***Enrollment and Retention Outreach:*** The Affordable Care Act increased funding for grants and a national campaign to improve outreach and enrollment to children who are eligible for but unenrolled in Medicaid and CHIP from $100 million to $140 million and extended the funds' availability through FY 2015. Of the total appropriation, $112 million was allocated for state and local governments as well as private organizations and $14 million was allocated to increase enrollment of American Indians and Alaska Natives. Outlay totals for Outreach and Enrollment Grants are reflected in the State Grants and Demonstrations chapter.

***Improving Quality:*** The Children's Health Insurance Program Reauthorization Act of 2009 provided $225 million over 5 years for activities that improve child health quality in Medicaid and CHIP, and in FY 2014, 18 states (across 10 grants) continued Quality Demonstrations to test ways to strengthen the quality of and access to children's health care through a variety of health care delivery and measurement approaches at both the provider and patient levels. The Protecting Access to Medicare Act of 2014 (P.L. 113-93) allocates $15 million of Adult Health Quality funding provided under the ACA for the pediatric quality measures program, increasing the total appropriation to $240 million.

## CHIP Proposals

***Extend CHIP Funding through FY 2019:*** The Budget proposes to extend funding for CHIP for four years through FY 2019, to ensure continued comprehensive and affordable coverage for CHIP children. This proposal would also extend the contingency fund and the performance bonus fund authorizations through 2019. The proposal is paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives.

This extension aligns with the Affordable Care Act requirement for states to maintain the eligibility and enrollment policies that were in place as of March 2010 through FY 2019 for children in Medicaid and CHIP. A four-year funding extension will provide budgetary stability to states. Continuing funding for CHIP will also protect children's coverage and ensure continuity of care for families who rely on the program.

Without Congressional action, CMS estimates states will begin to experience funding shortfalls in December 2015 and all but two states will run out of funding before the end of fiscal year 2016.

Once states exhaust their CHIP allotments, children in Medicaid-expansion CHIP programs would continue to be covered by Medicaid, though states would see a reduction in the federal matching rate for that population. While many children would be eligible for premium tax credits and cost-sharing reductions through the Marketplaces, some would transition to other forms of coverage, and others could become uninsured. Recent research also indicates that families with children transitioning from CHIP could face a substantial increase in cost-sharing, and a reduction of certain child-specific benefits, which may be particularly important for children with special health care needs.

***Permanently Extend Express Lane Eligibility for Children:*** The authority to operate Express Lane Eligibility expires at the end of FY 2015, and the Budget supports an extension of this tool to aid states in furthering their efforts to enroll Medicaid and CHIP eligible children. See the Medicaid chapter for additional information on this proposal. [$1.2 billion including $490 million in CHIP costs over 10 years]

# FY 2016 CHIP Legislative Proposals

*(negative numbers reflect savings and positive numbers reflect costs)*

| *dollars in millions* | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **CHIP Proposals** | | | |
| Extend CHIP Funding through FY 2019 /1/2 | 550 | 34,450 | 34,600 |
| *Children's Health Insurance Program (non-add)* | *500* | *33,000* | *33,000* |
| *Child Enrollment Contingency Fund (non-add)* | *50* | *200* | *200* |
| *Performance Bonus Fund (non-add)* | *—* | *1,250* | *1,400* |
| Permanently Extend Express Lane Eligibility for Children /3 | 10 | 250 | 490 |
| **Total Outlays, CHIP Proposals /4** | **560** | **34,700** | **35,090** |

1/ The net cost of this proposal is $11.9 billion over 10 years, which reflects impacts to CHIP and interactions with Medicaid, the Marketplace subsidies, and related impacts. See Medicaid chapter for Medicaid impact.

2/ The proposal is paid for through an increase in tobacco taxes that will help reduce youth smoking and save lives.

3/ The net federal impact of this proposal is $1.2 billion over 10 years, which reflects the impacts to CHIP and Medicaid. See Medicaid chapter for Medicaid impact.

4/ There are a number of Medicaid and Program Integrity legislative proposals that have a non-budgetary impact on the CHIP program.

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Current Law Budget Authority** | | | | |
| Medicaid Integrity Program /1 | 76 | 77 | 84 | +7 |
| Money Follows the Person Demonstration | 417 | 416 | 449 | 33 |
| Money Follows the Person Evaluations | 1 | 1 | 1 | — |
| Demonstration Program to Improve Community Mental Health Services | 2 | — | 25 | — |
| Funding for the Territories | 928 | — | — | — |
| **Total, Current Law Budget Authority** | **1,424** | **494** | **559** | **+65** |
| **Proposed Law Budget Authority** | | | | |
| Create Demonstration to Address Over-Prescription of Psychotropic Medications for Children in Foster Care/2 | — | — | 500 | 500 |
| Expand Funding and Authority for the Medicaid Integrity Program /1 | — | — | 25 | +25 |
| Extend and Improve the Money Follows the Person Demonstration | — | — | — | — |
| **Total, Proposed Law Budget Authority** | — | — | **525** | **+525** |
| **Total, Current and Proposed Law Budget Authority** | **1,424** | **494** | **1,084** | **+590** |
| **Current Law Outlays** | | | | |
| Incentives for Prevention of Chronic Diseases in Medicaid /3 | 16 | 22 | 23 | +1 |
| Medicaid Emergency Psychiatric Demonstration /3 | 25 | 32 | 4 | -28 |
| CHIP Outreach and Enrollment Grants /3 /4 | 18 | 17 | 9 | -8 |
| Medicaid Integrity Program /1 | 53 | 70 | 82 | +12 |
| Psychiatric Residential Treatment Demo and Evaluation /3 | 28 | 23 | 20 | -3 |
| Money Follows the Person Demonstration | 351 | 400 | 425 | +25 |
| Money Follows the Person Evaluations | 1 | 2 | 2 | — |
| Expansion of State Long-Term Care Partnership Program /3 | * | * | * | — |
| Ticket to Work Grant Programs /3 | 1 | 1 | 1 | — |
| Medicaid Transformation Grants /3 | * | — | — | — |
| Emergency Services for Undocumented Aliens /3 | 15 | 4 | 2 | -2 |
| Demonstrations to Improve Community Mental Health Services | — | 1 | 25 | +24 |
| **Total, Current Law Outlays** | **508** | **572** | **593** | **+21** |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Proposed Law Outlays** | | | | |
| Create Demonstration to Address Psychotropic Medication Over-Prescription for Foster Care Children /2 | — | — | — | — |
| Expand Funding and Authority for the Medicaid Integrity Program /1 | — | — | 25 | +25 |
| Extend and Improve the Money Follows the Person Demonstration | — | — | — | — |
| **Total, Proposed Law Outlays** | — | — | **25** | **+25** |
| **Total, Current and Proposed Law Outlays** | **507** | **569** | **591** | **+22** |

1/ Budget authority for the Medicaid Integrity Program is adjusted annually by Consumer Price Index for All Urban Consumers. This program and the related legislative proposal are described in the Program Integrity chapter.

2/ This is a joint proposal with the Administration for Children and Families (ACF). These totals represent the proposed law budget authority and outlays for State Grants and Demonstrations. Please see the ACF Chapter for more information.

3/ Outlays are from prior year budget authority.

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

The State Grants and Demonstrations account funds a diverse set of program activities. Many activities were authorized in the Affordable Care Act, Children's Health Insurance Program Reauthorization Act, the Deficit Reduction Act of 2005, and the Ticket to Work and Work Incentives Improvement Act of 1999. Such activities include strengthening Medicaid program integrity, supporting enrollment of children into Medicaid and the Children's Health Insurance Program (CHIP) through funding for outreach activities, and promoting prevention and wellness by providing grants to states to prevent chronic diseases.

***Incentives for Prevention of Chronic Diseases in Medicaid:*** The Affordable Care Act provides $100 million for states to award incentives to Medicaid beneficiaries of all ages who participate in prevention programs and demonstrate changes in risky health behaviors and outcomes related to chronic disease, including by adopting healthy behaviors. Funds are available through December 31, 2015, and states must commit to operating prevention programs for a minimum of three years. In September 2011, CMS awarded the first year of grants to 10 states. All ten state grantees are operational and currently enrolling beneficiaries. The initial Report to Congress was submitted on December 16, 2013.

***Medicaid Emergency Psychiatric Demonstration:*** Section 2707 of the Affordable Care Act, authorizes a demonstration project where selected States may provide payment under the State Medicaid plan, under Title XIX of the Social Security Act, to an institution for mental diseases that is not publicly owned or operated for eligible Medicaid beneficiaries ages 21 through the age of 64, who require medical assistance to stabilize a psychiatric emergency medical condition. The Affordable Care Act authorized $75 million for the demonstration, of which $68 million is for federal matching share payments to the participating states, and $7 million was set aside for implementation and evaluation of the demonstration. In March of 2012, CMS announced 11 participating states and the District of Columbia to participate in the demonstration. The demonstration will be conducted for a period of three consecutive years from July 1, 2012 through June 30, 2015 with the funding for the demonstration ending on December 31, 2015. In January of 2014, an evaluation report was submitted to Congress as mandated by the demonstration's authorization. The report indicated there were 2,791 participants in the program constituting 3,458 admissions to Institutions for Mental Disease through June 30, 2013. Data continues to be collected on outcomes for the enrolled participants and impacts on Medicaid costs; an updated evaluation of the demonstration in 2016.

***Money Follows the Person Demonstration:*** This demonstration, extended by the Affordable Care Act through FY 2016, helps states support individuals to achieve independence. 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. Approximately $3 billion has been awarded to 44 states and the District

of Columbia since the program's inception. This demonstration is funded at $450 million for each fiscal year through FY 2016. Funding awarded to states in FY 2016 is available to states for expenditures through FY 2020. These additional funds will enable state grantees to continue to develop their home and community based programs and increase the number of beneficiaries served while continuing to rebalance their long-term care systems between institutional and community settings. As of December 31, 2013, over 40,600 individuals across 44 states and the District of Columbia have transitioned to community services and supports through this effort. In 2013, CMS issued a funding opportunity announcement to offer states and tribes the resources to build sustainable community based long-term services and supports specifically for American Indians through the tribal initiative.

### State Grants and Demonstrations Legislative Proposals

#### *Create Demonstration to Address Over-Prescription of Psychotropic Medications for Children in Foster Care:*

The Budget proposes a five-year Medicaid demonstration in partnership with the Administration for Children and Families beginning in FY 2016 to encourage states to implement evidence-based psychosocial interventions targeting children and youth in the foster care system, as an alternative to the current over-prescription of psychotropic medications in this population. States would receive performance-based Medicaid incentive payments to improve care coordination and delivery for children and youth in foster care through increased access to evidence-based psychosocial interventions with the goal of reducing the over-prescription of psychotropic medications and improving outcomes for these young people. The Medicaid investment of $500 million over five years would provide incentive payments to states that demonstrate measured improvement in outcomes. This investment is paired with $250 million from the Administration for Children and Families to support state efforts to build provider and systems capacity.
[$500 million in Medicaid State Grants and Demonstrations costs and $250 million in mandatory child welfare costs over 10 years]

#### *Improve and Extend Money Follows the Person rebalancing demonstration:*

This proposal would extend the Money Follows the Person demonstration period through FY 2020 to enable states to continue to rebalance their long-term care systems and transition individuals to home and community-based services as well as providing additional flexibility to states to support individuals remaining in the community within the existing appropriation. Currently, individuals must enter institutions to qualify for covered home and community based services in the Money Follows the Person Demonstration. To support individuals remaining in the community, this proposal would modify the demonstration to allow funds to be used to prevent individuals from entering an institution in the first place, as well as transition services. This proposal would also reduce the institutional requirement from 90 to 60 days and allow skilled nursing facility days to be counted towards the institutional requirement. Lastly, this proposal would allow individuals in certain mental health facilities to transition to home and community-based services under the demonstration.
[No budget impact]

#### *Expand Funding and Authority for the Medicaid Integrity Program:*

This proposal is described in the Program Integrity chapter.

# FY 2016 State Grants and Demonstrations Legislative Proposals

*(negative numbers reflect savings and positive numbers reflect costs)*

| *dollars in millions* | 2016 | 2016 -2020 | 2016 -2025 |
|---|---|---|---|
| **State Grants and Demonstrations Proposals** | | | |
| Create Demonstration to Address Over-Prescription of Psychotropic Medications for Children in Foster Care /1 | — | 390 | +500 |
| Expand Funding and Authority for the Medicaid Integrity Program /2 | 25 | 180 | +580 |
| Extend and Improve the Money Follows the Person Demonstration | — | — | — |
| **Total Outlays, State Grants and Demonstrations Proposals** | **25** | **570** | **1,080** |
| | | | |
| 1/ This is a joint proposal with CMS and the Administration for Children and Families. | | | |
| 2/ The totals represent proposed budget authority for the Medicaid Integrity Program rather than outlays. | | | |

# Private Health Insurance Protections and Programs

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Outlays** | | | | |
| Affordable Insurance Exchange Grants /1 | 1,803 | 2,144 | 380 | -1,764 |
| Early Retiree Reinsurance Program | 13 | 2 | — | -2 |
| Consumer Operated and Oriented Plan Program | 311 | 320 | 168 | -152 |
| Pre-Existing Condition Insurance Plan Program | 535 | 33 | — | -33 |
| Rate Review Grants to States | 27 | 54 | 40 | -14 |
| Transitional Reinsurance Program /2 | — | 9,289 | 6,756 | -2,533 |
| Risk Adjustment Program /2 | — | 3,410 | 5,910 | +2,500 |
| *Risk Corridors (non-add)/3* | — | *5,450* | *6,390* | *+940* |
| **Total Outlays, Current Law** | **2,689** | **15,252** | **13,254** | **-1,998** |
| **Receipts (Non-add)** | | | | |
| *Transitional Reinsurance Program, Receipts* | — | *10,020* | *6,025* | *-3,995* |
| *Risk Adjustment Program, Receipts* | — | *3,679* | *5,641* | *+1,962* |
| *Risk Corridors Program, Receipts (non-add)/3* | *0* | *5,450* | *6,390* | *+940* |
| ***Total Receipts, Current Law*** | ***0*** | ***13,699*** | ***11,666*** | ***-2,033*** |

1/ The Affordable Care Act appropriates such sums as necessary for the Secretary to award grants to states for certain activities to fund their Marketplaces.

2/ Outlay amounts for Transitional Reinsurance and Risk Adjustment reflect sequestration of 7.3 percent in FY 2015, and that sequestered amounts become available in the following fiscal year.

3/ Risk Corridors outlays are part of the Program Management account.

Note: Totals may not add due to rounding.

The Affordable Care Act provides vital new protections for consumers receiving or shopping for private health insurance. New reforms ensure that essential care is becoming a standard part of most private health insurance plans, and that consumers can continue to rely upon their insurance when they become ill. Consumers receive more value from their health insurance coverage due to rate review and medical loss ratio protections. Furthermore, millions of Americans now have access to affordable coverage as a result of the Health Insurance Marketplaces which began coverage in 2014.

## Improving Coverage

***Marketplaces:*** The Affordable Care Act provides access to improved insurance coverage for millions of Americans through qualified health plans offered in the Marketplaces. By providing one stop shopping, Marketplaces have helped individuals better understand their insurance options and assisted them in selecting and enrolling in high quality private health insurance plans. From the beginning of open enrollment for 2015 through January 16, 2015, more than 7.1 million consumers selected a plan or were automatically re-enrolled through the Healthcare.gov platform. In addition, during the first month of open enrollment over 600,000 people selected 2015 Marketplace plans in the 14 states that are using their own Marketplace platforms. The Marketplaces have made purchasing health insurance more transparent and easier to understand, providing individuals and small businesses with more options and greater control over their health insurance purchases.

***State Work to Implement Marketplaces:*** Currently, 16 states and the District of Columbia operate State-based Marketplaces, and 7 states partner with HHS to operate some functions in State Partnership Marketplaces. HHS is operating Federally-facilitated Marketplaces in the remaining 27 states. In addition to

enrolling individuals, Marketplaces also determine eligibility for advance payment of the premium tax credits and cost sharing reductions, or Medicaid and CHIP in some states; ensure health plans meet certain standards; operate a hotline and website to provide consumer assistance; and assist individuals in locating and obtaining affordable health coverage.

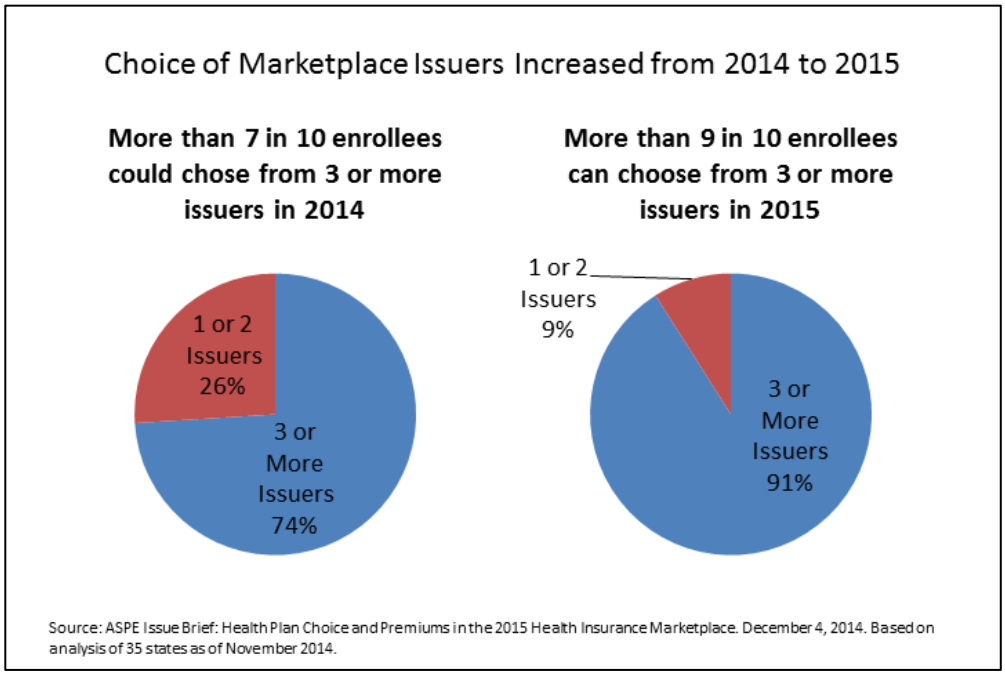
***Marketplace Establishment Grants:*** The Affordable Care Act provides grant funding to enable states to plan for and establish Marketplaces. The final round of grants was awarded to states in December 2014. Overall, 37 states and the District of Columbia have received over $5.5 billion in grants to establish and build Marketplaces since 2011. States may use Establishment grants to fund their start-up costs, whether for State-based or State Partnership Marketplace functions, or to support the Federally-facilitated Marketplaces, but ongoing operations are self-funded through user fees or other funding.

***Basic Health Program:*** The Affordable Care Act included a state option to provide affordable health benefits coverage to low-income residents otherwise eligible for reduced-cost coverage through the Marketplaces. Minnesota is the first state to establish a Basic Health Program with coverage beginning January 1, 2015.

***Consumer Operated and Oriented Plans (CO-OPs):*** The CO-OP loan program fosters the creation of new, private, qualified nonprofit, member-governed health insurance issuers to offer qualified health plans in the individual and small group markets in the states in which the issuers are licensed. The Affordable Care Act required that any profits a CO-OP makes must be used to lower premiums, improve benefits, or improve the quality of health care delivered to plan members. CO-OPs will contribute to the success of the Marketplaces by offering more choices to consumers and increasing competition in state insurance markets.

Currently, 23 CO-OP loan recipients are licensed and have enrolled members in 25 states, which CMS anticipates will increase to 26 states in 2016. CO-OPs offer coverage both inside and outside of the new Marketplaces. CMS has approved four CO-OP loan recipients to expand operations into additional states. Loan awards as of December 31, 2014 total $2.5 billion. Of the total loans awards, $1.09 billion is from the direct appropriation loan subsidy and the remaining $1.4 billion is from Treasury borrowing. For 2015, many CO-OPs are offering the lowest-cost silver plans in several states. The Affordable Care Act appropriated $6 billion for the program. In FY 2011, Congress rescinded $2.2 billion; in FY 2012 Congress rescinded an additional $400 million; and the American Taxpayer Relief Act rescinded $2.3 billion, leaving $253 million in a contingency fund for oversight and assistance to existing loan entities.

Each of the CO-OP awardees underwent a thorough application review loan negotiation process. Loans were made only to CO-OPs that demonstrated sustainability, viability, and the ability to fully repay their loans. CMS closely monitors CO-OPs to ensure they are meeting program goals and will be able to repay loans.




## Improving Benefits

***Private Insurance Market Reforms:*** Many important Affordable Care Act protections took effect on January 1, 2014. For example, non-grandfathered health plans in the individual and small group markets now have to

offer a comprehensive package of items and services, known as essential health benefits. Essential health benefits must include items and services within at least the following 10 categories: ambulatory services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Offering essential health benefits ensures that plans cover a core set of items and services, giving consumers a consistent way to compare plans. The law also prohibits most plans from putting an annual dollar limit on the essential health benefits.

In addition, non-grandfathered plans may no longer deny coverage or charge more based on a person's health status, gender, or any factors outside of age, tobacco use, family size, and geography. That provision means women can never be required to pay higher premiums just because they are women. Further, the law limits the amount these issuers can vary premiums based on tobacco use and age. This protection means that under these plans, nobody has to worry that they will lose their insurance, or have to pay more, just because they have a pre-existing condition or if they get sick.

A number of consumer protections in the Affordable Care Act were already in effect prior to 2014. For example, more than three million young adults have gained coverage by being able to stay on their parents' health plans until age 26.

The law also put a ban on lifetime benefit limits, ensuring that patients can use their insurance coverage when they are sick and need it most. In addition, 76 million Americans are receiving expanded coverage through their private insurance plan for preventive services without cost sharing such as copays or deductibles, including colonoscopy screenings, Pap smears and mammograms for women, well child visits, and flu shots for all children and adults. Moreover, the Affordable Care Act builds on the Mental Health Parity and Addiction Equity Act of 2008 to extend federal mental health parity protections to 62 million Americans.

**The Affordable Care Act is Working: Increasing Insurance Coverage**

The Affordable Care Act is making comprehensive health coverage available to millions of Americans who previously lacked access to or could not afford health insurance. As a result, the rate of uninsured adults fell by more than a quarter (26 percent) in the first full year of Affordable Care Act implementation - from 20.3 percent to 15.1 percent.[1] This means that 10.3 million more Americans gained coverage of essential health benefits, could access recommended preventive care with no cost sharing, and enjoyed the financial protections of health insurance, all due to the Affordable Care Act.

[1] Source: HHS Assistant Secretary for Planning and Evaluation Issue Brief, "Survey Data on Health Insurance Coverage for 2013 and 2014," October 31, 2014.

### Improving Value

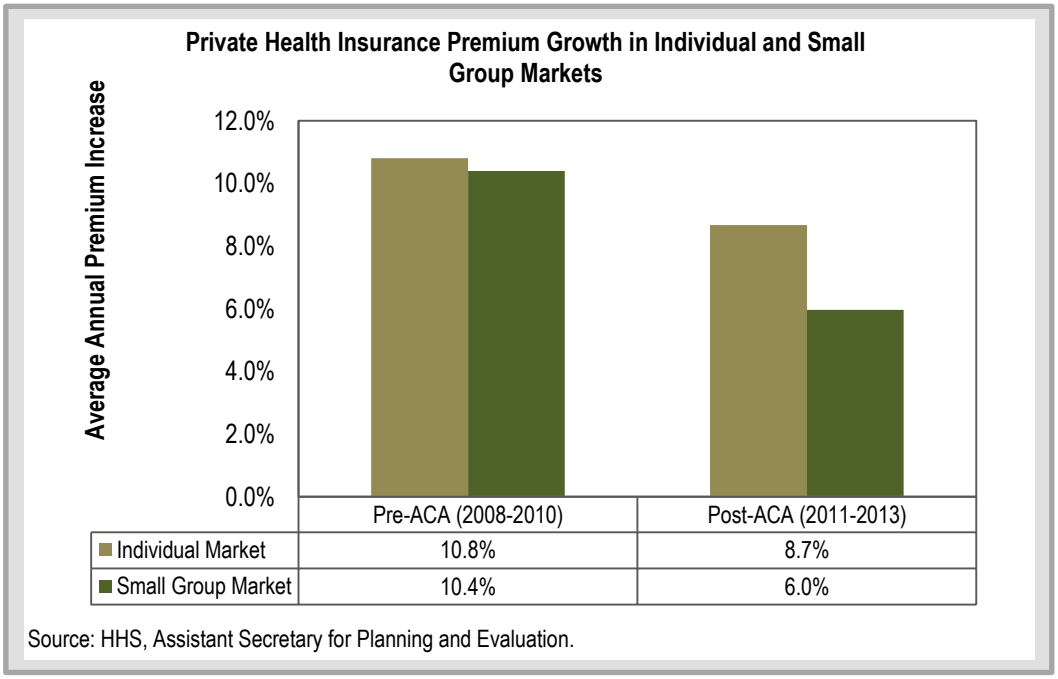
***Medical Loss Ratio:*** The Affordable Care Act required private insurers in the individual and small group market to spend at least 80 percent of collected premium revenue on clinical expenses and activities that improve consumers' health. This requirement is 85 percent for the large group market. Insurers who do not abide by this requirement must issue rebates to consumers. In 2013, consumers received $250 million in rebates through this provision, and consumers received additional value through lower premiums overall.

***Insurance Premium Rate Review:*** Private insurers must submit to relevant state offices or HHS justification for any premium increase greater than ten percent prior to implementation of the increase. This information is then made publicly available, increasing transparency for consumers. Since the enactment of the Affordable Care Act, consumers have saved approximately $9 billion in unnecessary healthcare costs due in part to the premium rate review and the medical loss ratio provisions, and received $2.8 billion in rebates in 2011 and 2012.

Through the end of 2014, HHS has awarded nearly $250 million to states and the District of Columbia to support their premium rate review programs. These grants support the hiring of new staff, improved communication with consumers about rate review, the creation of data centers that analyze health costs, and the enhancement of existing infrastructure required to operate an effective rate review program. In FY 2015, HHS may use remaining funds to support state

implementation of consumer protections and insurance reforms.

***Premium Stabilization Programs:*** The Affordable Care Act included two temporary and one permanent program to mitigate volatility of insurance premiums in the individual and small group markets beginning in 2014 when Marketplaces and new market rules take effect. The transitional reinsurance program provides protection to plans in the individual market when enrollees experience high claims costs for plan years 2014 through 2016. The temporary risk corridors program protects qualified health plans from uncertainty in rate setting from 2014 through 2016 through shared risk in losses and gains. The permanent risk adjustment program transfers funds from plans with relatively lower risk enrollees to plans with relatively higher risk enrollees to protect against the potential effects of adverse selection inside and outside the Marketplaces. The Notice of Benefit and Payment Parameters published each year outlines specifications for these programs, and transfers resulting from these programs first occur in FY 2015 for the 2014 plan year.



Source: HHS, Assistant Secretary for Planning and Evaluation.

# Center for Medicare & Medicaid Innovation

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Obligations and Outlays** | | | | |
| Innovation Activities | 991 | 1,501 | 1,298 | -203 |
| Innovation Supports | 101 | 202 | 187 | -15 |
| Administrative Expenses | 89 | 138 | 161 | +23 |
| **Total, Innovation Center Obligations** | **1,181** | **1,842** | **1,646** | **-195** |
| **Total, Outlays** | **997** | **1,291** | **1,590** | **+299** |

The Center for Medicare and Medicaid Innovation ("Innovation Center") was established by Section 3021 of the Affordable Care Act. The Innovation Center is tasked with testing innovative health care payment and service delivery models with the potential to improve the quality of care and reduce Medicare, Medicaid, and the Children Health Insurance Program expenditures. The Affordable Care Act appropriated $10 billion to support Innovation Center activities initiated from FY 2011 to FY 2019.

Since its launch in November 2010, the Innovation Center has embarked on an ambitious research agenda. Models currently being developed and tested include Medicare payment reforms that encourage efficient and high quality care, new approaches to better coordinate care for beneficiaries who are enrolled in both Medicare and Medicaid, and new mechanisms to promote patient safety in hospitals. Additional models are currently under development and will be tested in the coming months and years.

The Innovation Center's portfolio of models has attracted participation from a broad array of health care providers, states, payers, and other stakeholders, and serves Medicare, Medicaid, and CHIP beneficiaries in all 50 states, the District of Columbia, and Puerto Rico. Over 2.5 million Medicare, Medicaid, and CHIP beneficiaries are or soon will be receiving care furnished by the more than 60,000 providers participating in Innovation Center payment and service delivery models.

In its first four plus years of operation, from FY 2010 through FY 2014, the Innovation Center obligated approximately $3.0 billion. Cumulative obligations are projected to increase to $4.8 billion by the end of FY 2015 and to nearly $6.5 billion by the end of FY 2016 as the portfolio of models being tested continues to expand. CMMI is on track to obligating the full $10 billion appropriation by 2019. In FY 2015 and FY 2016, over 90 percent of spending is projected to be on specific models and initiatives, as well as necessary innovation supports, with the remainder dedicated to administrative expenses. While model spending is projected to slightly decrease in FY 2016 (as compared to FY 2015), this reduction primarily reflects the estimated timing of major awards, and not a contraction in the Innovation Center's portfolio.

## Innovation Center Models

As of January 2015, the Innovation Center is testing 24 major payment and service delivery models under the authority of Section 1115A of the Social Security Act. The Innovation Center also administers over 20 other Medicare demonstrations that are authorized and funded by other statutory authorities. Each of the models below will be comprehensively evaluated with the potential for expansion if they are certified to be effective at improving quality without increasing spending or reducing spending while maintaining quality.

## Primary Care Transformation

***Federally Qualified Health Center Advanced Primary Care Demonstration:*** In 2011, the Innovation Center selected 500 federally qualified health centers to participate in a three year demonstration to evaluate the effect of an advanced primary care practice model, also known as a patient centered medical home, on the quality and cost of care provided to Medicare beneficiaries. Participating health centers that pursued level three status as a patient centered medical home

as defined by the National Committee for Quality Assurance were eligible for additional Medicare care management payments. This model ended on October 31, 2014, at which point 434 federally qualified health centers remained in the model, serving 207,000 Medicare beneficiaries. The evaluation for this model is underway.

***Comprehensive Primary Care Initiative:*** In October 2011, the Innovation Center announced the Comprehensive Primary Care Initiative. In this initiative, private payers and state Medicaid programs partner with Medicare to invest in primary care. The Initiative was rolled out in two phases. The Innovation Center first selected seven markets with significant payer interest to participate in this demonstration. The markets include Arkansas, Colorado, New Jersey, Oregon, New York's Capital District Hudson Valley region, Ohio and Kentucky's Cincinnati Dayton region, and the Greater Tulsa region of Oklahoma. Through this initiative, approximately 2,500 providers are serving an estimated 396,000 Medicare beneficiaries at over 480 practice sites. The selected practices receive additional care coordination or similar payments from all participating payers, allowing them to transform their practices and make expanded services available to all patients. In years two through four of the initiative, practices have an opportunity to earn shared savings. The distribution of shared savings is adjusted based on patient acuity, the number of attributed beneficiaries, and performance on quality metrics.

### Accountable Care Models

As part of CMS's effort to promote accountable care, the Innovation Center has launched four initiatives. These initiatives build upon the Medicare Shared Savings Program established by the Affordable Care Act.

***Pioneer Accountable Care Organization (ACO) Model:*** This model allows health care organizations and providers that are already experienced in coordinating care for patients across care settings to move more rapidly to a population based Medicare payment model. Pioneer ACOs assume more risk than participants in the Shared Savings Program and must commit to having the majority of their revenues across all payers come from performance-based contracts (in which payment depends on quality of care) by the end of the second performance year. Nineteen organizations are currently participating in the model.

**Preliminary Second Year Results from the Pioneer ACO Model**

Preliminary results for the second performance year of the Pioneer ACO Model were released on September 16, 2014. The mean quality score among Pioneer ACOs increased by 19 percent, from 71.8 percent in 2012 to 85.2 percent in 2013. Pioneer ACOs generated estimated total model savings of over $96 million and savings to the Medicare Trust Funds of approximately $41 million. Model savings and other financial results are based on preliminary results and are subject to revision. The mean quality score among ACOs increased by 19 percent and organizations showed improvements in 28 of the 33 measures compared to year 1. Pioneer ACOs achieved lower per capita growth in spending for the Medicare program at 1.4 percent, which is about 0.45 percent lower than Medicare fee-for-service per capita growth. Eleven Pioneer ACOs earned shared savings, three generated shared losses, and three elected to defer reconciliation until after the completion of performance year three. The remaining six Pioneer ACOs did not earn shared savings or generate losses.

***Advance Payment ACO Model:*** This model tests whether pre-paying a portion of future shared savings can increase participation in the Medicare Shared Savings Program. Providing up-front payments to certain physician-led and rural organizations in the Shared Savings Program will allow these ACOs to make investments in infrastructure and staff in order to improve patient care and reduce costs. Advance payments will be recouped from the actual shared savings payments that ACOs earn. There are currently 35 ACOs participating in the Advance Payment Model, although the last advance payments were made in June 2014. Ten ACOs that started in 2012 generated shared savings in the first year of the program.

***ACO Investment Model:*** In October 2014, the Innovation Center announced a new model that builds on the experience with the Advance Payment Model to encourage new ACOs to form in rural and underserved areas and to assist current Medicare Shared Savings Program ACOs in transitioning to arrangements with greater financial risk. The Model will be available to two cohorts of ACOs: those that plan to join the Medicare Shared Savings Program in 2016 and those that started participating in the Program in 2012, 2013, or 2014. Current Advance Payment ACOs are not eligible to participate.

***Comprehensive End-Stage Renal Disease (ESRD) Care Initiative:*** In February 2013, the Innovation Center announced the Comprehensive ESRD Care Initiative, which will incentivize the provision of high quality, efficient, and coordinated care to Medicare beneficiaries who require dialysis. In order to participate, groups of providers (including dialysis facilities, nephrologists, and others) must form Seamless Care Organizations, which assume full clinical and financial accountability for assigned beneficiaries. These organizations will be eligible to share in any model savings with Medicare. Initial applications from providers to participate in this model have been received.

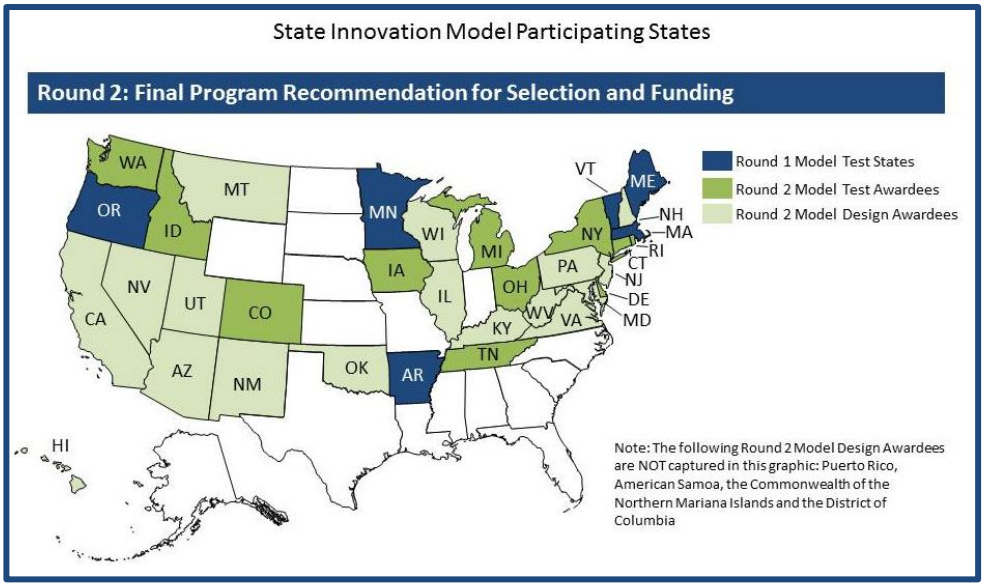
### Bundles for Care Improvement

***Bundled Payments:*** The Bundled Payments for Care Improvement Initiative seeks to better coordinate care by providing a bundled Medicare payment for an episode of care involving one or more providers. Providers paid through the bundle may include (among others) hospitals, physicians, and skilled nursing facilities. The Innovation Center has begun testing four initial models as part of the broader Bundled Payments Initiative – each model incorporates a different set of services and payment arrangements. In each model, providers or other risk-bearing organizations must offer a discount to Medicare as a condition of participating in the initiative. As of October 2013, providers were participating in all four of the bundled payment models. Awardees that entered into agreements with the CMS Innovation Center between October 2013 and January 2014 have begun the risk-bearing phase for some or all of their episodes. The initiative is projected to serve 130,000 Medicare beneficiaries. There are 48 episodes of care that participants can choose from, such as acute myocardial infarction and urinary tract infection.

### Initiatives to Speed the Adoption of Best Practices

***Partnership for Patients:*** The Partnership for Patients is a collaborative effort by CMS and more than 8,400 stakeholders across the nation, including over 3,700 hospitals, to improve patient safety. The Partnership set ambitious targets of reducing hospital acquired conditions by 40 percent and hospital readmissions by 20 percent (compared to a 2010 baseline) over four years. While a final evaluation is not yet complete, early indicators suggest the Partnership has helped lead to significant decrease in hospital-acquired conditions. A cumulative total of 1.3 million fewer hospital-acquired conditions were experienced by hospital patients in 2011, 2012, and 2013 relative to the number of hospital-acquired conditions that would have occurred if rates had remained steady at the 2010 level. Approximately 50,000 fewer patients died in the hospital as a result of the reduction in hospital-acquired conditions.

***Transforming Clinical Practice Initiative:*** In October 2014, the Secretary announced a new initiative, totaling $800 million in Innovation Center funding and another $40 million in Quality Improvement Organization funding, designed to help clinicians achieve large-scale health transformation. The Initiative will support 150,000 clinicians over the next four years in sharing, adapting and further developing their comprehensive quality improvement strategies. CMS will award cooperative agreement funding for two types of network systems under this initiative: Practice Transformation Networks and Support and Alignment Networks. The Practice Transformation Networks are peer-based learning networks designed to coach, mentor, and assist clinicians in developing core competencies specific to practice transformation. The Support



and Alignment Networks will utilize national and regional professional associations and public-private partnerships that are currently working in practice transformation efforts to provide a system for workforce development aligned with the goals of the model.

### Initiatives to Accelerate New Service Delivery and Payment Model Testing

***Health Care Innovation Awards:*** In 2012, the Innovation Center announced 107 recipients of Health Care Innovation Awards. These awardees, which include providers, payers, local governments, and other partners, were chosen based on the strength of their proposals to implement or expand compelling new models to improve care and reduce costs, with a particular focus on high need populations and workforce development. Awards span a three year time period.

In May 2013, the Innovation Center announced a second round of Health Care Innovation Award grants, focused on several key areas, including outpatient and post-acute care, populations with specialized needs, practice transformation, and population health. A total of 39 awards awardees for this second round of funding were announced in two groups in May 2014 and June 2014. The performance period for round two began in September 2014 and extends through June 2017.

***State Innovation Models:*** Round two of the State Innovation Model initiative provides more than $665 million to support states in transforming their health care payment and delivery systems. In order to qualify for awards, states proposed reforms that incorporated multiple payers and are expected to improve quality of care and the health of the state population, while reducing costs. Some states are receiving funding to support the testing of such models. Round two awardees were announced in December 2014. A total of 28 states, 3 territories and the District of Columbia will receive funding through round two.

***Innovation Accelerator Program:*** CMS launched the Medicaid Innovation Accelerator Program in July 2014 with the goal of improving health and health care for Medicaid beneficiaries by supporting states' efforts to accelerate new payment and service delivery reforms. While complementing other federal-state delivery system reform efforts such as the State Innovation Models initiative, the Innovation Accelerator Program will provide additional federal tools and resources to support states in advancing Medicaid-specific delivery system reform and by sharing lessons and best practices. For example, through the Innovation Accelerator Program, CMS will provide technical assistance and other types of technical support to states interested in accelerating the development and testing of Substance Use Disorder service delivery innovations.

***Maryland All-Payer Model:*** In 2014, the Innovation Center began collaborating with the State of Maryland on a new model testing the impact of all-payer hospital rate-setting on the quality and cost of care. While Maryland has utilized all-payer rate setting for over three decades, this new model will allow the State to focus more directly on the challenges currently facing Maryland's hospitals. In particular, the new model will require limited overall cost growth, measurable savings for Medicare, and improvement on critical quality and outcome measures. If this model meets key goals over its initial five-year testing period, Maryland will have the opportunity to propose approaches to expand the model to other provider types, in addition to hospitals.

***Medicare Care Choices Model:*** This model provides a new option for Medicare beneficiaries with certain conditions to receive palliative care services from participating hospice providers while concurrently receiving certain curative services. Currently, Medicare beneficiaries are required to forgo curative care in order to receive access to palliative care services offered by hospices. This initiative represents a fundamental change in the delivery of care for persons with terminal illness. CMS will evaluate whether providing palliative services can improve quality of life and care, increase patient satisfaction, and reduce Medicare expenditures. Thirty thousand beneficiaries are estimated to be enrolled in this model throughout the three-year period of performance.

***Prior Authorization Models:*** In 2014, the Innovation Center announced that it will begin testing two prior authorization models for repetitive scheduled non-emergent ambulance transport and non-emergent hyperbaric oxygen therapy. The objective of the models is to test whether prior authorization helps reduce improper payments and thereby lowers Medicare costs, while maintaining or improving quality of care. The models will not create additional documentation requirements; rather, they will require

reporting the same information that is currently necessary to support Medicare payment, only earlier in the process. This effort will help ensure that all relevant coverage, coding, and clinical documentation requirements are met before the service is rendered to the beneficiary and before the claim is submitted for payment.

### Initiatives Focused on the Medicaid Population

***Strong Start for Mothers and Newborns:*** The Strong Start initiative, which began in February 2012, supports reducing the risk of significant complications and long-term health problems for both expectant mothers and newborns. The Innovation Center has worked with experts at the Centers for Disease Control and Prevention, National Institutes of Health, Administration for Children and Families, and the Health Resources and Services Administration to identify the goals and shape the direction of Strong Start.

Strong Start contains two strategies: 1) a public-private partnership, building on the work of Partnership for Patients to test ways to encourage best practices and support providers in reducing early elective deliveries prior to 39 weeks; and 2) a four-year initiative to test the effectiveness of specific enhanced prenatal care approaches to reduce the frequency of premature births in pregnant Medicaid or CHIP beneficiaries. In February 2013, CMS awarded $41.4 million to 27 recipients under this initiative in 32 states, the District of Columbia, and Puerto Rico, projected to reach 80,000 women enrolled in Medicaid and CHIP over the life of the demonstration.

***Initiatives Supporting Medicare-Medicaid Enrollees***

More than 10 million Americans are dually enrolled in the Medicare and Medicaid programs. Section 2602 of the Affordable Care Act established the Federal Coordinated Health Care Office, also known as the Medicare-Medicaid Coordination Office, to promote access to care, improve the overall beneficiary experience, and coordinate services for Medicare-Medicaid enrollees. This office also provides technical assistance to support states' efforts toward innovative service delivery for Medicare-Medicaid beneficiaries.

***Medicare-Medicaid Financial Alignment Initiative:*** To incentivize high-quality, coordinated care, CMS has partnered with states to design person-centered approaches to aligning care across primary, acute, and behavioral health and long-term supports and services. States participating in the initiative have designed models to improve quality and achieve savings using either a capitated payment system or the current fee for service structure. Implementation of the first financial alignment models began in 2013. As of December 2014, CMS has approved capitated models in nine states, a fee-for-service model in one state, and has allowed one state to implement both models. Additionally, Minnesota has implemented an alternative model to integrate care for Medicare-Medicaid enrollees, building on the state's current Dual Eligible Special Needs Plans infrastructure.

***Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents:*** Nursing facility residents often experience potentially avoidable inpatient hospitalizations, which are expensive, disruptive, and disorienting for the frail elderly and people with disabilities. Through this initiative, CMS partnered with seven organizations in 2012 to implement evidence-based interventions that both improve care and lower costs, focusing on reducing preventable inpatient hospitalizations among long-term residents of nursing facilities. This initiative has served an estimated 24,000 Medicare-Medicaid enrollees each year and has enhanced care for many others served by these nursing facilities. This initiative supports the Partnership for Patients' goal of reducing hospital readmission rates by 20 percent.

# Program Management

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Discretionary Administration** | | | | |
| Program Operations | 2,943 | 2,825 | 3,024 | +199 |
| Federal Administration | 733 | 733 | 784 | +51 |
| Survey and Certification | 375 | 397 | 437 | +40 |
| Research | 20 | 20 | — | -20 |
| State High-Risk Pools | 20 | — | — | — |
| **Total, Discretionary Budget Authority** /1 /2 | **4,092** | **3,975** | **4,245** | **+270** |
| **Mandatory Administration** | | | | |
| Affordable Care Act | 126 | 52 | 1 | -51 |
| American Recovery and Investment Act | 130 | 130 | 65 | -65 |
| Medicare Improvements for Patients and Providers Act | 3 | 3 | 3 | — |
| Protecting Access to Medicare Act (2014) | 49 | 25 | 6 | -17 |
| Improving Access to Medicare Post-Acute Care Transformation (2014) | — | 107 | 21 | -86 |
| **Total, Mandatory Administration** | **307** | **317** | **96** | **-220** |
| **Reimbursable Administration** | | | | |
| Medicare and Medicaid Reimbursable Administration /3 | 1,108 | 621 | 955 | +334 |
| Marketplace-Related Reimbursable Administration/4 | 252 | 869 | 1,535 | +666 |
| **Subtotal, Current Law** | **5,759** | **5,781** | **6,831** | **+1,050** |
| **Proposed Law (Mandatory)** | | | | |
| Program Management (mandatory) | — | — | 400 | +400 |
| Sustainable Growth Rate Reform (mandatory) | — | — | 600 | +600 |
| Offsetting Collections /5 | — | — | 30 | +30 |
| Extend Funding for CMS Quality Measurement Development | — | — | 30 | +30 |
| **Subtotal, Proposed Law** | **—** | **—** | **1,060** | **+1,060** |
| **Program Level, Proposed Law Budget Authority** | **5,759** | **5,781** | **7,891** | **+2,110** |
| | | | | |
| Risk Corridors | — | 5,450 | 6,390 | +940 |
| **Program Management Program Level with Risk Corridors** | **5,759** | **11,231** | **14,281** | **+3,050** |
| | | | | |
| **Full-time Equivalents** /6 | **5,820** | **6,080** | **6,327** | **+247** |

1/ Includes $119 million from the Secretary's one percent transfer authority in FY 2014. Totals may not add due to rounding.

2/ State High Risk Pools are classified as a mandatory activity in FY 2014, but are included above.

3/ Includes user fees and reimbursables supporting CMS program management.

4/ Includes the following user fees: Marketplaces, and risk adjustment (FY 2015 and FY 2016).

5/ Includes proposals for six new offsetting collections. Please see Legislative Proposals section for more information.

6/ FTE totals include FTE from other funding sources: HCFAC, state grants, reimbursables, and mandatory appropriations. CMS will fund the following FTE from other sources: FY 2014 = 1,325; FY 2015 =1,610; and FY 2016=1,656.

The FY 2016 CMS Program Management request is $4.2 billion, an increase of $270 million above FY 2015. This request will enable CMS to enhance and continue to effectively administer Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), as well as new health insurance reforms contained in the Affordable Care Act.

***Program Operations:*** The Program Operations request is $3 billion, an increase of $199 million above the FY 2015 level. The FY 2015 level includes $305 million for Medicare operations, and the Budget requests this funding as part of the Program Operations request. The Program Operations account funds essential contractor, information technology (IT), and outreach activities necessary to administer Medicare, Medicaid, CHIP, and private health insurance reforms and other programs instituted by the Affordable Care Act. Top priority activities for FY 2016 include:

- Ongoing Medicare Contractor Operations: Approximately 30 percent, or $899 million, of the FY 2016 Program Operations request supports ongoing contractor operations such as Medicare claims processing.
- Medicare Appeals: The Budget includes $159 million to enhance the processing of provider and beneficiary claim appeals. This amount includes $36 million in new initiatives to improve the efficiency of the Medicare appeals process at the first two levels and limit appeals that escalate to the Office of Medicare Hearings and Appeals.
- Marketplaces: The Budget includes $544 million in requested budget authority to support the continued enhancement and operations of Marketplace activities such as eligibility, plan management, and quality improvement. In addition, CMS anticipates collecting approximately $1.6 billion in user fee revenues to support Marketplace activities. See the Crosscutting Accounts section below for additional information.
- IT Systems and Support: The Budget includes $340 million for non-Marketplace IT systems and other support, including enterprise-wide software and hardware development and support, and CMS's data center and telecommunications infrastructure. These investments enable secured data to be accessible to CMS staff and stakeholders. This amount includes a $52 million investment in CMS's IT shared services initiative, which achieves efficiencies by leveraging key IT resources to serve multiple CMS programs.
- Medicaid and CHIP Operations: The Budget requests $41.5 million to fund administrative activities to improve Medicaid and CHIP program operations and implement new responsibilities under the Affordable Care Act. Some of these activities include initiatives to improve enrollment of eligible individuals into Medicaid and CHIP and modernize data systems.

**Protecting Beneficiaries' Identities**

Protecting against identity theft is a top priority for the Administration. The Budget proposes a $50 million investment for a multiyear process of removing Social Security Numbers from Medicare Cards, which will strengthen the security of millions of beneficiaries' personal information.

- Removing Social Security Numbers from the Medicare card reduces the risk of identity theft from a lost or stolen card that contains the beneficiary's number and would allow CMS to more easily terminate and replace beneficiary identifiers suspected of being associated with fraudulent billing.
- HHS is committed to working with the Social Security Administration, the Railroad Retirement Board, states and other stakeholders to update the Medicare cards to protect beneficiaries.

***Federal Administration:*** For FY 2016, the Budget requests $784 million for CMS federal administrative costs, $51 million above the FY 2015 enacted level. Of this total, $686 million will support a full-time equivalent (FTE) level of 4,671, an increase of 201 FTEs over FY 2015. This staffing increase will enable CMS to address the needs of a growing Medicare population, as well as oversee expanded responsibilities resulting from the Affordable Care Act and other legislation passed in recent years.

***Survey and Certification:*** The FY 2016 Survey and Certification request is $437 million, a $40 million increase over FY 2015. The increased funding level supports survey frequency levels in response to increasing numbers of participating facilities and improved quality and safety standards. This increase also provides targeted funding for the most serious quality of care concerns by increasing nursing home special focus facility work and enhancing quality monitoring and oversight in the states, territories, islands, and IHS facilities within tribal nations. CMS expects states to complete over 25,000 initial surveys

**Survey and Certification Frequencies**

| Type of Facility | 2015 | 2016 |
|---|---|---|
| Long-Term Care Facilities *(statutory)* | Every Year (100%) | Every Year (100%) |
| Home Health Agencies *(statutory)* | Every 3 Years (33.3%) | Every 3 Years (33.3%) |
| Non-Accredited Hospitals | Every 3.3 Years (30.3%) | Every 3 Years (33.3%) |
| Accredited Hospitals | 1.6% Per Year | 2.5% Per Year |
| Organ Transplant Facilities *(contract performed)* | Every 5 Years (20%) | Every 4.5 Years (22.2%) |
| ESRD Facilities | Every 3.5 Years (28.6%) | Every 3 Years (33.3%) |
| Ambulatory Surgical Centers | Every 4 Years (25%) | Every 4 Years (25%) |
| Community Mental Health Centers | Every 6 Years (16.7%) | Every 6 Years (16.7%) |
| Hospice (Funding from P.L. 113-185) | Every 3 Years (33.3%) | Every 3 Years (33.3%) |
| Outpatient Physical Therapy, Outpatient Rehabilitation, Rural Health Clinics, Portable X-Ray | Every 6 Years (16.7%) | Every 6 Years (16.7%) |

and re-certifications and over 52,000 visits in response to complaints in FY 2016.

The Improving Medicare Post-Acute Care Transformation Act of 2014 increases hospice survey frequencies to no less than once every three years.

Approximately 87 percent of the request will go to state survey agencies. Surveys include mandated federal inspections of long-term care facilities (i.e., nursing homes) and home health agencies, as well as federal inspections of other key facilities. All facilities participating in the Medicare and Medicaid programs must undergo inspection when entering the program and on a regular basis thereafter. In addition, CMS is currently engaged in an effectiveness and efficiency strategy aimed at quality improvement while identifying risk-based approaches to surveying.

The Budget proposes a discretionary survey and certification revisit user fee which provides CMS with an increased ability to revisit poor performers, while creating an incentive for facilities to correct deficiencies and ensure quality of care. The Budget assumes that no revenue will be realized in FY 2016, the year of establishment.

***Research:*** Beginning in FY 2016, ongoing research activities will be funded from Program Operations.

## Crosscutting Summaries

***Health Insurance Marketplaces (Marketplaces):*** The discretionary budget includes $629 million for CMS activities and administrative expenses to support Marketplace operations in FY 2016, including $85 million in Federal Administration.

In addition to the Budget request, CMS will collect an estimated $1.6 billion in user fees from issuers in the Federally-facilitated Marketplace, as well as reinsurance and risk adjustment administrative collections, for a total estimated program level of $2.2 billion.

Marketplaces provide affordable, quality health insurance options to individuals and small businesses, and CMS operates some or all Marketplace functions in over 30 states through the Federally-facilitated Marketplaces. Specifically, CMS performs eligibility and appeals work, certification and oversight of qualified health plans, payment and financial management functions, and operates the Small Business Health Options Program (SHOP). Some states in the Federally-facilitated Marketplaces assist

**Health Insurance Marketplaces**
**FY 2016 Program Level Request**
*(dollars in millions)*

| Activity | 2016 |
|---|---|
| Marketplace Operations | 639 |
| *Eligibility and Enrollment (non-add)* | *417* |
| Consumer Information and Outreach | 808 |
| Marketplace Information Technology | 657 |
| Federal Administration | 85 |
| **Total, Marketplace Program Level/1** | **$2,189** |

1/ Marketplace Program Level includes $1.56 billion in user fees, including $25 million in reinsurance administrative contributions, and $629 million in requested budget authority. Numbers may not add due to rounding.

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

The CMS survey and certification budget aims to improve dementia care in nursing homes by decreasing the percentage of long-stay nursing home residents receiving an antipsychotic medication. Antipsychotic medications have common and dangerous side effects when misused, especially when used to treat the behavioral and psychological symptoms of dementia. In FY 2011 23.9 percent of long-stay nursing home residents received an antipsychotic medication. In FY 2013 that rate fell to 20.3 percent, and CMS has targeted a FY 2016 rate of 16.7 percent.

with plan management functions or operate their own SHOP. Additionally, CMS oversees operations of State-based Marketplaces and provides technical assistance as needed.

CMS provides Marketplace consumer assistance through a call center and website, as well as in-person support through Navigator grants. Additionally, CMS conducts an outreach campaign during the open enrollment season to inform consumers of their insurance options.

Finally, CMS operates a number of IT systems to support the Marketplaces, such as the system that operates core Marketplace functions including eligibility, plan management, and payment functions. The data services hub provides eligibility verification services to all Marketplaces through interfaces with trusted data sources in other federal departments. Other IT costs include hosting services and data management systems.

***National Medicare Education Program:*** Total FY 2016 budget authority for the National Medicare Education Program is $355.1 million. The program level includes an additional $81.6 million in funding from Program Management, and Medicare Advantage/Prescription Drug Program user fees allocated to the call center and beneficiary materials. In order to ensure that beneficiaries have accurate and up-to-date information on their coverage options and covered benefits, beneficiary education remains a top priority for CMS.

Of the total budget authority, $248.9 million, or 70 percent, supports the 1-800-MEDICARE call center which provides beneficiaries with access to customer service representatives who are trained to answer questions regarding the Medicare program. The request will support approximately 26 million calls with an average-speed-to-answer of 5 minutes. Beneficiaries can also use 1-800-MEDICARE to report fraud allegations. CMS is using information from beneficiary fraud allegations in new ways to compile provider-specific complaints, flag providers who have been the subject of multiple fraud complaints, and map shifts and trends in fraud allegations over time.

The request also includes $65.2 million for beneficiary materials, the majority of which will fund the *Medicare & You* handbook. It will also provide funding for CMS to mail notices of minimum essential coverage to all Medicare enrollees, as required by the Affordable Care Act.

### 2016 Legislative Proposals

***Provide Mandatory Administrative Resources for Implementation:*** The Budget includes $400 million in no-year mandatory Program Management funds to implement the mandatory health care proposals accompanying this submission. These health care proposals will allow CMS to realize additional cost efficiencies, and further root out waste and abuse in Medicare and Medicaid, and save as much as $423 billion over the next ten years. The Budget also includes $600 million to reform Medicare physician payments and accelerate physician participation in high-quality and efficient healthcare delivery systems. [$1.0 billion in costs over 10 years]

***Invest in CMS Quality Measurement:*** The Budget proposes to extend funding for a consensus-based entity focused on performance measurement through 2018. The duties for a consensus-based entity are divided between those originally authorized by the Medicare Improvements for Patients and Providers Act of 2008 and those that were added by the Affordable Care Act. Under current law, no additional funding will be provided after 2015. The Budget includes $30 million yearly through 2018, available until expended. This funding is essential as CMS continues to implement valued-based purchasing initiatives and other models which focus on performance-based payments. [$90 million in costs over 10 years]

***Allow CMS to Reinvest Civil Monetary Penalties Recovered from Home Health Agencies:*** This proposal allows CMS to retain and invest civil monetary penalties assessed on home health agencies for activities to improve the quality of care of patients receiving home health services. The Affordable Care

Act provided this authority for skilled nursing facilities. [$10 million in costs over ten years]

***Allow CMS to Assess a Fee on Medicare Providers for Payments Subject to the Federal Levy Program:*** This activity electronically matches Medicare provider payments between delinquent tax and non-tax debts and federal payments disbursed by the government. It allows the Treasury Department to levy up to 15 percent of a provider's Medicare reimbursement against an outstanding debt. This proposal will allow CMS to recoup its transaction administrative costs from the provider, estimated to be $2 million each year. [No budget impact]

***Other User Fee Proposals:*** The Budget also includes several mandatory proposals that establish new user fees for: Medicare appeals, registering clearinghouses and billing agents that act on behalf of Medicare providers and suppliers, and submitting provider applications for individual provider applications to participate in Medicare.

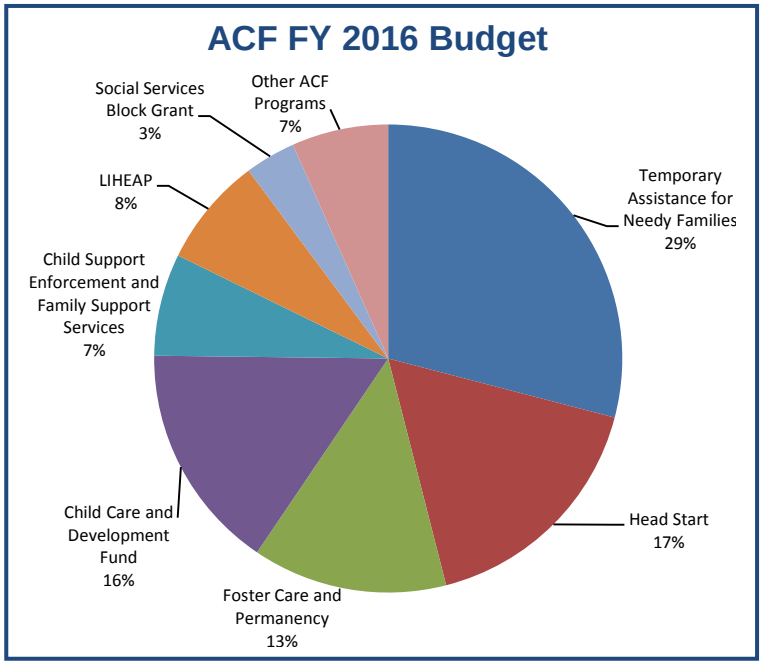
# Administration for Children and Families

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 |
|---|---|---|---|
| **Mandatory** | | | |
| Budget Authority | 33,981 | 33,808 | 39,852* |
| **Discretionary** | | | |
| Budget Authority | 17,678 | 17,791 | 19,825 |
| **Total** | | | |
| **Total, ACF Budget Authority** | **51,659** | **51,599** | **59,676** |
| *Includes $15 million in mandatory funds transferred from the TANF Contingency Fund for Welfare Research in FY 2016. | | | |

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

The FY 2016 Budget request for the Administration for Children and Families (ACF) is $59.7 billion. ACF works in partnership with states and communities to provide critical assistance to vulnerable families while helping families and children achieve a path to success. ACF's Budget supports enabling more parents to work or pursue education and training to better support their families while at the same time promoting the school readiness of their children. This effort includes significant new investments to provide working families with access to quality child care, as well as continued reforms in Head Start and Child Support. Funds are also included for programs that serve the most vulnerable children and families, including victims of domestic violence, dating violence, and human trafficking; children in the child welfare system; and unaccompanied children and runaway and homeless youth.




The Budget invests in the well-being of children known to the child welfare system by increasing federal investment on the front-end of the child welfare service delivery system for evidence-based and evidence-informed prevention and post-permanency for children and youth likely to enter the foster care system, and promoting family-based care as an alternative to congregate care settings.

# Administration for Children and Families: Discretionary

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Early Childhood Programs** | | | | |
| Head Start | 8,598 | 8,598 | 10,118 | +1,520 |
| Child Care & Development Block Grant (discretionary) | 2,358 | 2,435 | 2,805 | +370 |
| **Refugee Programs** | | | | |
| Transitional and Medical Services | 391 | 383 | 427 | +43 |
| Unaccompanied Children | 912 | 948 | 967 | +19 |
| Victims of Trafficking | 14 | 16 | 22 | +6 |
| Other Refugee Programs | 213 | 213 | 213 | -- |
| **Subtotal, Refugee Programs** | **1,530** | **1,560** | **1,629** | **+69** |
| **Programs for Vulnerable Populations** | | | | |
| Chafee Education & Training for Foster Youth | 43 | 43 | 43 | -- |
| Family Violence Prevention | 138 | 140 | 162 | +23 |
| Adoption Incentives | 38 | 38 | 38 | -- |
| Runaway and Homeless Youth Programs | 114 | 114 | 123 | +9 |
| Child Abuse Prevention | 93 | 94 | 114 | +20 |
| Child Welfare Programs | 345 | 335 | 338 | +4 |
| Promoting Safe and Stable Families (discretionary) | 60 | 60 | 90 | +30 |
| Administration for Native Americans | 47 | 47 | 50 | +3 |
| **LIHEAP** | | | | |
| Formula Grants | 3,390 | 3,390 | 3,190 | -200 |
| Contingency Fund | -- | -- | -- | -- |
| Energy Assistance Innovation Fund | -- | -- | 200 | +200 |
| **Subtotal, LIHEAP Budget Authority** | **3,390** | **3,390** | **3,390** | **--** |
| **Community Service Programs** | | | | |
| Community Services Block Grant | 668 | 674 | 674 | -- |
| Other Community Services Programs | 54 | 55 | 19 | -36 |
| **Subtotal, Community Service Programs** | **722** | **729** | **693** | **-36** |
| **Other ACF Programs** | | | | |
| Disaster Human Services Case Management | 2 | 2 | 2 | -- |
| Social Services Research & Demonstration | 6 | 6 | 18 | +12 |
| *National Survey, Child & Adolescent Well-Being (non-add)* | -- | -- | *6* | *+6* |
| *Early Childhood Evaluation (non-add)* | -- | -- | *3* | *+3* |
| *LIHEAP Evaluation (non-add)* | -- | -- | *3* | *+3* |
| *PHS Evaluation Fund Appropriation (non-add)* | *6* | -- | -- | -- |
| Federal Administration | 199 | 201 | 212 | +11 |
| *Center, Faith Based/Community Partnerships (non-add)* | 1 | 1 | -- | -1 |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Totals and Less Funds from Other Sources** | | | | |
| **Total, Program Level** | **17,684** | **17,791** | **19,825** | **+2,034** |
| PHS Evaluation Fund Appropriation | 6 | -- | -- | -- |
| **Total, Discretionary Budget Authority** | **17,678** | **17,791** | **19,825** | **+2,034** |
| | | | | |
| Full-time Equivalents | 1,222 | 1,401 | 1,441 | +40 |

The Administration for Children and Families (ACF) plays a critical role in protecting the most vulnerable Americans, especially children, and providing them opportunities to fulfill their potential. The FY 2016 Budget requests $19.8 billion, an increase of $2 billion above FY 2015. This includes significant new resources to expand access to high-quality early care and education for young children as part of the President's plan to help America's children succeed in school and in life. The Budget also supports other important programs that serve our nation's most vulnerable children and families, including refugees, unaccompanied children, victims of domestic trafficking and family violence, as well as runaway and homeless youth.

### Serving Americans at Key Stages of Life

The beginning years of a child's life are critical for building the early foundation needed for success in school and in life. The evidence from the field is clear -- children who attend high-quality early learning programs are more likely to do well in school, find good jobs, and succeed in their careers than those who do not.

The Budget renews an ambitious plan to create a continuum of early learning opportunities from birth through age five by providing high-quality preschool for every child, building the supply of high quality early learning opportunities for young children, and expanding investments in voluntary, evidence-based home visiting programs.

***Head Start:*** Since FY 2008, Head Start funding has increased by more than $3.5 billion, and the FY 2016 Budget continues these historic gains by including an additional $1.5 billion above FY 2015 to strengthen Head Start services and expand access to Early Head Start, including through Early Head Start – Child Care Partnerships.

Research shows that full-day, full-year early learning programs produce stronger outcomes for the children. To that end, the FY 2016 request includes an additional $1.1 billion to ensure that all Head Start programs provide services for a full day and a full-school year, which more closely aligns with programs that demonstrate strong outcomes.

The FY 2016 request also includes an additional $150 million over FY 2015 to further expand access to high-quality early learning programs for infants and toddlers through Early Head Start and Early Head Start-Child Care Partnerships. The number of infants and toddlers served by Early Head Start has nearly doubled since FY 2008. The Budget supports further expansion of these Partnerships, which provide funding to Early Head Start programs to expand and work with child care providers to deliver high-quality full day services for tens of thousands of children.

In FY 2016, ACF will continue to require grantees that do not meet rigorous quality benchmarks to compete for ongoing federal funding. The Budget includes $25 million, the same as FY 2015, to minimize the potential for service disruptions for children as incumbent and new grantees make transitions through this process.

***Child Care:*** The FY 2016 request for the Child Care and Development Fund is $9.4 billion, including $6.6 billion in mandatory funding and $2.8 billion in discretionary funding. The Budget includes $82 billion in mandatory funding above current law over ten years to ensure that all low-income working families with young children have access to high-quality child care.

Of the $2.8 billion available in discretionary funds for child care, $266 million is targeted to help states implement new provisions of the Child Care and Development Block Grant Act reauthorization that will increase quality, ensure continuity of services, and provide parents clear information about child care providers so they can make informed choices. This

funding level also includes $100 million for new Child Care Pilots for Working Families that will test innovative strategies to better serve working families by addressing gaps in the delivery of child care.

### Serving Vulnerable Children

The FY 2016 Budget includes critical investments to better serve children in state child welfare systems, and runaway and homeless youth.

***Promoting Safe and Stable Families:*** The Budget requests an additional $30 million in discretionary funding to support states and tribes in operating a coordinated program of family preservation services, community-based family support services, time-limited reunification services, and adoption promotion and support services. Of the additional funding proposed, $20 million will be targeted to increase child welfare services capacity for tribes, $7 million will support service delivery in rural communities, and $3 million will enhance research, evaluation, and technical assistance.

***Child Abuse Prevention***: The Budget requests an additional $15 million to prevent traffickers from luring children and youth in the child welfare system into prostitution and other forms of criminal activity. Young people receiving child welfare services can be vulnerable to trafficking, and these funds will identify and better serve victims and those at risk of being victimized. Funds will also be used to conduct a robust evaluation to develop a research base of promising practices. In addition, the Budget includes $5 million for new competitive grants to identify and evaluate best practices for child protection investigations.

***Runaway and Homeless Youth:*** In FY 2016, the Budget requests an additional $9 million. Of this total, $5 million will expand services in the Transitional Living Program, including services for the lesbian, gay, bisexual, transgender, and questioning youth; $2 million will support the Prevalence, Needs, and Characteristics of Homeless Youth study; and $2 million will enhance on-site monitoring. These investments align with the Opening Doors: Federal Strategic Plan to Prevent and End Homelessness by better serving homeless youth.

### Protecting Vulnerable Individuals

***Refugees and Unaccompanied Children:*** ACF is a key partner in Administration-wide efforts to support refugee arrivals and help them begin new lives. ACF provides refugees with time-limited cash and medical assistance, as well as social services including job training and English instruction so refugees, asylees, and other new humanitarian arrivals eligible for refugee benefits can become self-sufficient as quickly as possible. The Budget will support 143,000 new arrivals, an increase of 37 percent since FY 2008.

ACF has long provided assistance to victims of international human trafficking, identifying foreign-born persons victimized in the United States and making them eligible for refugee assistance. The Budget continues service levels for foreign victims of human trafficking and includes an increase of $6 million to expand services for domestic victims of human trafficking. Competitive grants will be awarded to organizations working with at-risk populations, including runaway youth and victims of domestic violence, and used to identify victims and connect them to the full range of services they need to restore their lives. Funds will also be used to train professionals most likely to encounter victims, including health care workers, criminal justice personnel, and teachers, to better align the trafficking hotline with hotlines maintained by the Departments of Justice and Homeland Security, and to demonstrate effective housing solutions for young victims of domestic trafficking.

***Unaccompanied Children:*** ACF provides shelter to unaccompanied children who are apprehended by immigration authorities. By law, ACF must take custody of most unaccompanied children within 72 hours. These children remain in ACF's care until they can be placed with sponsors, usually parents or other relatives, who assume responsibility for their care while their immigration cases are processed.

In the summer of 2014, the Administration responded to a significant increase in the number of unaccompanied children who were apprehended on the southwest border with an aggressive, coordinated federal response focused on providing humanitarian care for the children as well as on stronger deterrence, enforcement, foreign cooperation, and capacity for federal agencies to ensure our border remains secure. ACF utilized temporary bed space at military bases to provide temporary care for the increased number of children. By August, ACF was able to resume caring for all children in permanent standard facilities, closing the temporary beds established on military

bases. In part due to actions taken by the Administration over the past six months, including increased border security and assistance to Central American governments to curb the flow of unaccompanied children, the rate of apprehensions at the border in FY 2015 is below the FY 2014 rate. In light of these efforts and the recent fall in the number of children placed in ACF's custody, DHS, HHS, and the other agencies responsible for monitoring and serving unaccompanied children expect arrivals to remain stable.

Given the range of external factors that may impact the migration of these children, there is inherent uncertainty in this area. The Budget includes level base funding from FY 2015 at $948 million and creates a contingency fund that would trigger additional funds if caseloads exceed levels that could be supported with base funding and any carryover funds from the prior year.

***Family Violence Prevention and Services:*** The Budget includes $162 million, an increase of $23 million, for Family Violence Prevention and Services, the primary federal funding stream that provides shelter and supportive services for victims of family violence, domestic violence, and dating violence, and their dependents. Of the additional funds requested in FY 2016, $15 million will help address the unmet need for emergency shelter and for supportive services such as legal advocacy, counseling, and safety planning. A portion of these funds will also be used to develop and test comprehensive service models for children and youth who have been exposed to domestic violence. This effort will assist in responding to the most requested service for parents receiving domestic violence services. The Budget also provides an additional $8 million to expand the capacity of the National Domestic Violence Hotline, to ensure timely response to calls, increase bilingual services, and expand online chatting and texting services.

***Low Income Home Energy Assistance Program (LIHEAP):*** The Budget includes $3.4 billion in discretionary funding for LIHEAP, the same as FY 2015. A new mechanism will provide additional mandatory funds triggered by significant increases in the number of eligible low-income households, the price of fuel, or extreme cold at the beginning of winter.

To better address both the short and long-term needs of low-income households, the budget proposes increased emphasis on activities that increase energy efficiency, such as weatherization. LIHEAP households often live in housing that is less energy-efficient than the homes of higher income families and are more likely to rely on more expensive fuels such as oil and propane. In some cases, energy efficiency investments, including switching to less expensive fuels, can significantly reduce families' energy bills over the long-term. Despite the potential benefits of improving energy efficiency in low income households, only a few states spend more than 15 percent of their LIHEAP formula funds on energy efficiency measures. To promote greater investment in these longer term strategies, the Budget requires states to dedicate at least 10 percent of their LIHEAP allocations to weatherization and other energy efficiency activities to give states the flexibility to spend up to 40 percent of their allocation on energy efficiency if they choose to do so.

The Budget also includes $200 million to test innovative strategies to serve LIHEAP households, including reducing energy use, supporting fuel switching, reducing energy bills, and smoothing energy costs to avoid large spikes during some parts of the year. Funds would be competitively awarded to states to support partnerships between utilities and local community-based organizations.

### Strengthening Communities

***Native Americans:*** Generation Indigenous is an Administration-wide initiative to better coordinate demonstration results from efforts across the Federal government to serve Native youth. The Administration for Native Americans in ACF promotes cultural preservation and economic self-sufficiency for tribes and native organizations.

Along with the Indian Health Service, and the Substance Abuse and Mental Health Services Administration, the Administration for Native Americans will support this initiative with an additional $3 million for a special program to increase and improve Native American language instruction across the educational continuum.

***Community Services Programs:*** The Budget includes $674 million for the Community Services Block Grant, the same as FY 2015, and supports ongoing reforms that strengthen accountability and performance management at the federal, state and local levels. ACF will establish a set of national organizational standards that states will use to ensure local agencies have the

appropriate organizational capacity to successfully meet community needs. This investment is also part of a new Upward Mobility Project proposed in the Budget, which will allow ten states, localities or consortia of the two to blend funding across all or some of four programs – the Social Services Block Grant, Community Services Block Grant, Community Development Block Grant, and HOME within the Department of Housing and Urban Development – in exchange for more accountability for results. Pilot projects will implement evidence-based or promising strategies for helping individuals succeed in the labor market and improving economic mobility, children's outcomes, and the ability of communities to expand opportunity. Funding is not requested for the Rural Community Facilities program or the Community Economic Development program. ACF will collaborate on the Healthy Food Financing Initiative funded through the Department of Treasury.

### Ensuring Program Effectiveness

ACF ensures that its programs are effective and strives for continuous improvement in program implementation.

***Evaluation and Innovation:*** This Budget dedicates resources for research and evaluation across a range of programs. Taken together with existing authorities and funding for research, these proposals will help ACF advance toward a vision in which every ACF program will continually create and use evidence to innovate, learn, and improve. Increased funding of $12 million within the Social Service Research and Demonstration program includes $6 million to support the National Survey of Child and Adolescent Wellbeing, which provides critical information that is foundational to ACF's efforts to improve the social and emotional welfare of children in and out of foster care. In addition, $3 million is requested to help identify the features of early child care and education that are most important in supporting early childhood development. The remaining $3 million is for an evaluation of LIHEAP. The Budget also increases the child care research and evaluation set-aside from $10 million to $14 million, and allows up to 1 percent of the Head Start funding for full-day, full-year programming to be used for research and evaluation.

***Federal Administration:*** The Budget includes $212 million, $11 million above FY 2015, to cover the cost of administering programs across ACF, including staffing and office space. The Budget will support ACF's participation in government-wide efforts to reduce square footage, improve energy efficiency, and reduce utility costs over the long-term. Specifically, additional funds will support the consolidation of ACF's headquarters staff in Washington, DC, and the moves in the regions. The Budget aligns funding for the Center for Faith Based and Neighborhood Partnerships within the Office of the Secretary, where the Center is administered.

# Administration for Children and Families: Mandatory

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Current Law Budget Authority** | | | | |
| Child Care Entitlement to States | 2,917 | 2,917 | 2,917 | — |
| *Child Care and Development Fund (non-add)* /1 | *5,275* | *5,352* | *5,352* | — |
| Child Support Enforcement and Family Support | 4,131 | 4,038 | 4,105 | +67 |
| Children's Research and Technical Assistance /2 | 48 | 34 | 37 | +3 |
| Foster Care and Permanency | 7,429 | 7,343 | 7,601 | +258 |
| LIHEAP Contingency Fund | — | — | — | — |
| Promoting Safe and Stable Families (mandatory only) /3 | 451 | 470 | 345 | -125 |
| Social Services Block Grant | 1,656 | 1,661 | 1,700 | +39 |
| Temporary Assistance for Needy Families (TANF) | 16,737 | 16,737 | 16,739 | +2 |
| TANF Contingency Fund /4 | 612 | 608 | 608 | — |
| *Subtotal, TANF (non-add)* | *17,349* | *17,345* | *17,347* | *+2* |
| **Total, Current Law Budget Authority** | **33,981** | **33,808** | **34,052** | **+244** |
| **Proposed Law Budget Authority** | | | | |
| Child Care Entitlement to States | 2,917 | 2,917 | 6,582 | +3,665 |
| *Child Care and Development Fund (non-add)* | *5,275* | *5,352* | *9,387* | *+4,035* |
| Child Support Enforcement and Family Support | 4,131 | 4,038 | 4,215 | +177 |
| Children's Research and Technical Assistance | 48 | 34 | 37 | +3 |
| Foster Care and Permanency | 7,429 | 7,343 | 8,301 | +688 |
| LIHEAP Contingency Fund | — | — | 1,130 | +1,130 |
| Promoting Safe and Stable Families (mandatory only) | 451 | 470 | 435 | -35 |
| Social Services Block Grant /5 | 1,656 | 1,661 | 2,085 | +424 |
| TANF | 16,737 | 16,737 | 16,739 | +2 |
| TANF Contingency Fund | 612 | 608 | — | *-608* |
| TANF Program Improvement | — | — | 10 | +10 |
| Pathways to Jobs /6 | — | — | 598 | *+598* |
| *Subtotal, TANF (non-add)* | *17,349* | *17,345* | *17,347* | *+2* |
| **Total, Proposed Law Budget Authority** | **33,981** | **33,808** | **39,852** | **+6,054** |

1/ The Child Care and Development Fund includes mandatory funding from the Child Care Entitlement to States and discretionary funding from the Child Care and Development Block Grant.

2/ Includes $15 million in mandatory funds transferred from the TANF Contingency Fund for Welfare Research in FY 2016.

3/ The total for Promoting Safe and Stable Families (PSSF) includes Abstinence Education, the Personal Responsibility Education Program, and PSSF mandatory funding. In addition, there is a discretionary appropriation of $59.8 million for PSSF in FY 2014 and FY 2015 and $89.8 million in FY 2016.

4/ The Protect Our Kids Act of 2012 (P.L. 112-275) extended the Contingency Fund through the end of FY 2014, and targeted $2 million of the $612 million for the Contingency Fund for each of fiscal years 2013 and 2014 to establish the Commission to Eliminate Child Abuse and Neglect Fatalities. The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235), appropriated $608 million for the Contingency Fund in fiscal years 2015 and 2016, reserving in FY 2015 $15 million for welfare research funds and $10 million for a U.S. Census Bureau study.

5/ The proposed law reflects the reauthorization of the Health Profession Opportunity Grants and a new Upward Mobility proposal.

6/ Of the $598 million for the Pathways to Jobs initiative, the proposed law would reserve $15 million for Welfare Research and $10 million for a U.S. Census Bureau study in FY 2016.

The FY 2016 Budget request for ACF mandatory programs is $39.9 billion. ACF serves the nation's most vulnerable populations through mandatory programs including Temporary Assistance for Needy Families (TANF), Child Care Entitlement to States, Child Support Enforcement, Foster Care, Adoption Assistance, Guardianship Assistance, Independent Living, and Promoting Safe and Stable Families.

The Budget guarantees access to high-quality child care for low income working families with young children; encourages the use of evidence-based interventions to improve outcomes for children in foster care and to decrease the over-prescription of psychotropic medications; focuses on preventing the removal of children from their families; limits the use of institutional settings and group homes for foster care placements; increases the child support that is paid directly to families; promotes fathers' involvement in the lives of their children; and proposes to repurpose the TANF Contingency Fund into a fund for subsidized employment.

**Guaranteeing Access to Child Care to Support Working Families and Children**

A continually growing body of evidence suggests early and continuous exposure to high-quality child care is beneficial for child development and is most impactful for children from disadvantaged backgrounds. High-quality, stable, and reliable child care can improve children's cognitive and social outcomes and reduce later costs to society. In addition to increasing the likelihood children will be in safe nurturing learning environments, access to high quality child care also benefits children by helping parents increase their employment and earnings, thereby reducing financial hardship and possibly parental stress. The FY 2016 Budget makes an unprecedented and historic commitment to improving access to high-quality, affordable child care for low income children and addressing prohibitively high child care costs for working families by investing $82 billion in mandatory funds in the Child Care Development Fund over 10 years. The Budget commits to providing child care assistance to more than 2.6 million children by 2025, nearly tripling the number of infants and toddlers to 1.8 million. In creating a child care guarantee for children ages 0 through 3 years old in families with incomes up to 200 percent of the federal poverty level, this historic investment will pay off by drawing into the labor force primary caregivers of young children, in particular young mothers, who have seen disproportionate declines in labor force participation since 2008.

### Child Care Entitlement to States

The Budget proposes a historic investment in child care, to close the gap between the cost of high quality care and what families can afford while insisting that child care is not only safe, but supports children's healthy development and their future academic achievement and success.

The Budget provides funding to expand child care assistance to all eligible families with children under age four by 2025. An additional $82 billion investment will ensure that all low-income families with incomes below 200 percent of the poverty line with children ages three and under have access to high-quality child care so that parents can work, attend school, or participate in training.

With the Child Care Development Fund caseload currently at the lowest point in 15 years, this investment will expand access to high-quality care for approximately 1.15 million additional infants and toddlers at the end of 10 years. In 2025, over 2.6 million children will be served by the Child Care and Development Fund, including nearly 1.8 million infants and toddlers. This investment complements a major investment in preschool through the Department of Education, $1.1 billion in discretionary funding to increase the amount of time that children spend in Head Start services, and $650 million in discretionary funds to expand Early Head Start and increase the supply of high-quality care through Early Head Start-Child Care Partnerships (both described in the ACF Discretionary chapter). Together, these are key elements of the Administration's broader education agenda, designed to ensure a cohesive and well-aligned continuum of early learning for children from birth to age five that supports continuity, healthy development, learning, and stability for children in the critical years before preschool.

Total funding for the Child Care and Development Fund is $9.4 billion in FY 2016, which includes $266 million in additional discretionary funding to help states raise the bar on quality by implementing the new requirements of the recent Child Care and Development Block Grant Reauthorization, as well as $100 million for demonstrations to test child care models that better serve working families including the unique needs of families with non-traditional schedules

### Child Support Enforcement and Family Support Programs

Child Support is a joint federal, state, tribal, and local partnership that seeks to ensure financial and emotional support for children from both parents by locating non-custodial parents, establishing paternity, and establishing and enforcing child support orders. The Budget request is $4.2 billion in budget authority in FY 2016 for Child Support Enforcement and Family Support Programs.

Over the past year, the ACF issued a notice of proposed rulemaking to update child support regulations within current law. HHS intends to fully consider any comments received on the rule before proceeding with a final rulemaking. Notwithstanding the rule, HHS recognizes a number of areas where additional legislative reforms could further improve the child support program.

The Budget promotes strong families and responsible fatherhood by ensuring that children benefit when parents pay support, promoting parenting time arrangements, and improving enforcement tools. The Budget includes $2.8 billion over 10 years for an initiative to modernize the Child Support program and to promote responsible fatherhood. Of those net 10 year costs, $2.3 billion affects the Child Support program; the Supplemental Security Income and the Supplemental Nutrition Assistance Program realize savings of $585 million, $130 million affects Medicaid, and $476 million affects Foster Care. This Budget also includes funding specifically to encourage states to pass through child support payments to families, making sure more child support collections reach children rather than being retained by the federal and state governments, and a child support research fund to encourage state programs to implement family-centered services.

The Budget provides $10 million annually for grants to states to facilitate non-custodial parents' access to and visitation with their children.

Other family support programs funded in this account include Payments to Territories and the Repatriation program. Payments to Territories fund approximately $33 million in assistance for eligible aged, blind, and disabled residents of Guam, Puerto Rico, and the Virgin Islands.

**Child Support Highlights**

The Child Support program continues to make strong gains in establishing child support orders and increasing child support collections. In FY 2013, the last year for which final data are available:

- Child support collections increased by 1 percent from FY 2012 to $28 billion.
- 1.6 million paternities were established and acknowledged.
- Paternity was established for 96 percent of Title IV-D out-of-wedlock births, exceeding the target of 93 percent.
- Child support orders were established for 83 percent of child support cases, which surpassed the target of 77 percent.
- For every dollar invested in the program, $5.31 in child support was collected, which exceeded the performance target of $4.88.
- Six tribal programs became comprehensive, fully operational program service providers, bringing the total number of comprehensive Tribal Child Support Programs to 51.

### Children's Research and Technical Assistance

The Budget request includes $37 million for activities in two areas: child support training and technical assistance and the operation of the Federal Parent Locator Service, which assists states in locating absent parents. Of the total, $12 million will fund child support training and technical assistance and $25 million will support the Federal Parent Locator Service.

Funding for Welfare Research, which was previously funded in this account at $15 million, is requested as part of the TANF Contingency Fund. Support for the National Survey of Child and Adolescent Well-Being, previously funded in this account, is requested in ACF's discretionary budget.

### Foster Care and Permanency

The Budget request for the Foster Care, Adoption Assistance, Guardianship Assistance, and Independent Living programs is $8.0 billion in FY 2016 budget authority. These programs, authorized by title IV-E of the Social Security Act, support safe living environments for vulnerable children and prepare older foster youth for independence.

The Budget requests $586 million over 10 years in matching funds for prevention and post-permanency services included as part of the child's case plan. Most of the services funded must be evidence-based or evidence-informed. Prevention and permanency interventions can reduce the likelihood that a child will have to be removed from a family and can increase the likelihood that recently established permanency

**Demonstration to Address the Over-Prescription of Psychotropic Medications for Children in Foster Care**

The FY 2016 Budget includes a five-year collaborative demonstration project between ACF and CMS to encourage states to provide evidence-based psychosocial interventions to children and youth in the foster care system in order to reduce the over-prescription of psychotropic medications and to improve outcomes for these young people.

The need for action in this area is evident. ACF data from 2009 to 2011 show that 18 percent of the approximately 400,000 children in foster care were taking one or more psychotropic medications at the time they were surveyed. The Government Accountability Office has estimated an even higher range of 21 to 39 percent. Children in foster care are prescribed psychotropic medications at far higher rates than other children served by Medicaid, and often in amounts that often exceed the Food and Drug Administration's guidelines.

The existing evidence-base in the area of trauma-informed psychosocial interventions warrants a large initial investment to expand access to effective interventions. The ACF investment of $250 million over five years would fund infrastructure and capacity building, while the Medicaid investment of $500 million over five years would provide incentive payments to states that demonstrate measured improvement.

arrangements can be sustained. The Budget also includes savings of $69 million over ten years to promote family-based foster care for children with behavioral and mental health needs, as an alternative to congregate care, and provides increased oversight of congregate care when such placements are determined to be necessary. An additional $114 million over 10 years is included in the Budget to provide enhanced start-up funding for tribes seeking to implement their own child welfare programs.

The Budget includes mandatory funding in ACF to support a collaborative demonstration project with the Centers for Medicare & Medicaid Services (CMS) to address the over-prescription of psychotropic medications for children in foster care. This investment includes $250 million over five years in ACF, paired with $500 million in new performance based incentive funds in CMS, to improve outcomes for these children.

The Budget also includes $45 million in FY 2016 and $476 million over 10 years to require that child support payments made on behalf of children in foster care are used in the best interests of the child.

The FY 2016 Budget includes $5.0 billion in budget authority to support the Foster Care program, including maintenance payments to children. This amount is a $371 million increase above FY 2015. The proposed level of funding will provide assistance and support to an estimated 168,900 children each month, which is approximately 6,600 more children than in FY 2015. States have made important reforms in response to changes in Federal laws over the past 15 years that have focused on prevention and permanency. The proportion of all children in foster care who are title IV-E eligible continues to decline, in large part because eligibility for federal foster care is tied to the income eligibility standards effective in 1996 for Aid to Families with Dependent Children, which have declined in real dollar terms since then. The federal title IV-E participation rate for maintenance payments stood at approximately 51.8 percent of all children in foster care in FY 2000, while in FY 2014, the federal title IV-E participation rate was approximately 41 percent of all children in foster care nationally. This funding will also support implementation of new requirements for IV-E agencies from the Preventing Sex Trafficking and Strengthening Families Act of 2014, which was signed into law on September 29, 2014. See the ACF Discretionary Chapter for information on additional proposals to address human trafficking.

The Budget includes $2.5 billion in budget authority for the Adoption Assistance program, an increase of $53 million above FY 2015. An estimated average of 444,000 children per month, an increase of 7,000 over FY 2015, will qualify for this assistance in FY 2016.

The Budget includes $123 million for the Guardianship Assistance program, an increase of $24 million above the FY 2015 enacted level of $99 million and an increase of $15 million above the updated FY 2015 current law estimate. The increase is due to a higher take-up rate in this program. The program is continuing to grow, and we expect there will be an increase in the number of children participating in the Guardianship Assistance program as new states and tribes begin programs, and established states expand the implementation of their programs. Under this program, state title IV-E agencies provide a subsidy on behalf of a child to a relative who has been granted legal guardianship of that child. The goal of the program is to keep children with relatives – rather than in foster care – when the relative's home is a safe and appropriate placement for them. An estimated average of 25,100 children per month, an increase of 3,000 over FY 2015, will participate in FY 2016.

The Budget also includes $140 million for the Chafee Foster Care Independence Program, the same level as in FY 2015. This program funds services for youth who

are likely to remain in foster care until they turn 18 and current or former foster children between the ages of 18 and 21. The Budget proposes to allow those states that provide foster care up to age 21 to use Chafee program funds for current or former foster children through age 23 to prevent an abrupt end to services when children age out of foster care in those states.

The Foster Care, Adoption Assistance, Guardianship Assistance, and Independent Living programs demonstrated success in improving safety, permanency, and well-being of children in FY 2013, the latest year for which complete performance data are available. Working with the states, these programs support the goal of minimizing disruptions to the continuity of family and other relationships for children in foster care by decreasing the number of placement settings per year for a child in care. In FY 2013, over 85 percent of children who had been in care less than 12 months had 2 or fewer placement settings, which exceeded ACF's target of 80 percent. Research shows that placement stability is necessary for children and youth to be able to form and maintain consistent relationships with caretakers and other adults, which is a core skill for life long success.

### LIHEAP Contingency Fund

The Budget includes $1.1 billion in FY 2016 and $8.1 billion over 10 years to establish a contingency fund, which will provide additional mandatory funds triggered by significant increases in the number of eligible low-income households, the price of fuel, or extreme cold at the beginning of winter.

### Promoting Safe and Stable Families

The Budget includes $435 million for the mandatory portion of the Promoting Safe and Stable Families account. Of this amount, $345 million supports the Promoting Safe and Stable Families program, $75 million supports the Personal Responsibility Education Program, and $15 million supports the reauthorization of the Family Connection Grants. The Budget proposes to reauthorize the Personal Responsibility Education Program and the Family Connection Grants through FY 2016.

The Child and Family Services Improvement and Innovation Act of 2011 (P.L. 112-34) reauthorized the Promoting Safe and Stable Families program through FY 2016. This funding will continue support for a variety of state child welfare activities, including family preservation services; community based family support services; time-limited reunification services; and adoption promotion and support services. Under the reauthorization, states are required to address trauma that children in the child welfare system have experienced during their lives and to have explicit protocols for oversight and monitoring of psychotropic medications. These efforts and the evidence base developed from them have helped build the foundation for the collaborative demonstration to address the over-prescription of psychotropic medications for children in foster care proposed in the Budget, in partnership with CMS.

In FY 2013, the adoption placement rate for children from foster care moving into permanent homes was 12 percent (50,608 children adopted), exceeding the target of 10.5 percent. By monitoring the adoption rate, ACF is helping to ensure that there is a focus on moving children from foster care to a permanent home. Since many children are best served by returning to their homes, the target for the adoption rate is not set very high.

### Social Services Block Grant (SSBG)

The Social Services Block Grant is a capped entitlement which provides flexible grants to states according to population size for the provision of social services ranging from child care to residential treatment. States have broad discretion over the use of these funds. Social Services Block Grant funds support a variety of initiatives to support services for low-income and vulnerable individuals such as protective services, special services to persons with disabilities, adoption services, case management, health-related services, transportation support, foster care, substance abuse services, home-delivered meals, independent and transitional living, and employment-related services.

The Social Services Block Grant, including funding for the Health Professions Opportunity Grants, is funded at $2.1 billion for FY 2016. The Budget supports a reauthorization of the Health Professions Opportunity Grants and proposes to consolidate the authority to operate this program in ACF, expand the list of partners to consult, and allow funds to be used for subsidized employment. Reauthorization would provide $85 million per year for these grants.
The Budget also includes $1.5 billion in additional funding for the Social Services Block Grant, over five years, to support the Upward Mobility Project. The Project will allow up to 10 states, localities, or consortia of states and communities more flexibility to use funds from up to four federal block grants – ACF's Social Services Block Grant and Community Services Block

Grant and the Department of Housing and Urban Development's Community Development Block Grant and HOME Investment Partnerships Program – for efforts designed to promote self-sufficiency, improve educational and other outcomes for children, and enhance communities' ability to provide opportunities for families. Projects will have to rely on evidence-based programs or be designed to test new ideas and will have a significant evaluation component. The $1.5 billion in additional funding will be awarded competitively by ACF, in consultation with the Department of Housing and Urban Development to support Upward Mobility Projects.

### Temporary Assistance for Needy Families (TANF)

TANF provides $17.3 billion annually to states, territories, and eligible tribes to assist low-income families and improve employment and other outcomes. For FY 2015, The Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) extended all TANF grants through September 30, 2015 and provided $608 million annually for the TANF Contingency Fund in FY 2015 and FY 2016. In FY 2015, this amount includes a transfer of $15 million for Welfare Research, previously funded through Children's Research and Technical Assistance, as well as a $10 million transfer for the Census Bureau's Survey of Income and Program Participation.

When Congress takes up reauthorization, the Administration will be prepared to work with lawmakers to strengthen the program's effectiveness in accomplishing its goals. This effort should include using performance indicators to drive program improvement and ensuring that states have the flexibility to engage recipients in the most effective activities to promote success in the workforce, including families with serious barriers to employment.

The Budget includes a proposal to redirect $10 million from the $608 million TANF Contingency Fund for program improvements, including technical assistance for state programs, monitoring, research, and evaluation. The Budget also proposes prohibiting the use of nongovernmental third party expenditures to meet state Maintenance of Effort requirements and a provision to ensure that states use TANF funds for benefits and services for needy families. The Budget also includes a general provision to transfer $15 million from the Contingency Fund to Welfare Research and $10 million to the Census Bureau to support the Survey of Income and Program Participation, consistent with the FY 2015 appropriations funding.

The Budget also re-proposes the Pathways to Jobs initiative within TANF, which would repurpose the balance of the Contingency Fund to support work opportunities through subsidized employment for low-income parents and guardians, and youth, including summer jobs for youth. Building on the successes of the expired TANF Emergency Contingency Fund, Pathways to Jobs will target individuals who are either eligible for TANF cash assistance (including custodial and noncustodial parents with a child eligible for TANF cash assistance) or who are below 200 percent of federal poverty level and face other barriers to employment. The program would permit up to 100 percent coverage for wages, workplace benefits, training, and administrative costs through the first 90 days of employment for eligible individuals, including eligible summer employment. Partial subsidies are also allowable after the first 90 days. State subsidized employment efforts through Pathways to Jobs would be required to satisfy one or more of the four statutory proposes of the TANF program and to comply with requirements prohibiting displacement of other workers. The proposal also includes statutory changes necessary to give ACF the authority to collect data necessary to evaluate and oversee this program, and the Budget recommends setting aside up to one percent for national evaluation of the program. Additionally, the Budget proposes to allow states the option to use an alternative approach to the Income and Eligibility Verification System (IEVS) if the state can show that the alternative meets the purposes of the IEVS requirements and is equally or more cost effective.

# ACF Mandatory Legislative Proposals

| *dollars in millions* | 2016 | 2016-2020 | 2016-2025 |
|---|---|---|---|
| **Proposed Law Outlays** | | | |
| Child Care Entitlement | 2,969 | 23,728 | 78,327 |
| Child Support Enforcement and Family Support Programs /1 | 110 | 916 | 2,287 |
| Foster Care and Permanency | 182 | 870 | 1,358 |
| Promoting Safe and Stable Families | 2 | 246 | 389 |
| Social Services Block Grant /2 | 304 | 1,795 | 1,841 |
| Temporary Assistance for Needy Families (TANF) | - | - | - |
| **Total Outlays, ACF Legislative Proposals** | **4,392** | **25,936** | **73,161** |

1/ The Child Support outlays in this table are net of estimated savings in the Supplemental Nutrition Assistance Program ($534 million) and the Supplemental Security Income program ($51 million), which would result from this proposal. These outlays include the impact on federal offsetting collections. The impact on Medicaid ($130 million over ten years) is displayed in the Medicaid table.

2/ The Health Profession Opportunity Grants and new Upward Mobility proposal are within the Social Services Block Grant account.

# Administration for Community Living

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Health and Independence Services** | | | | |
| Home & Community-Based Supportive Services | 348 | 348 | 386 | +38 |
| Nutrition Services | 811 | 815 | 875 | +60 |
| Native American Nutrition & Supportive Services | 26 | 26 | 29 | +3 |
| Preventive Health Services | 20 | 20 | 20 | -- |
| Chronic Disease Self-Management | 8 | 8 | 8 | -- |
| Falls Prevention | 5 | 5 | 5 | -- |
| Aging Network Support Activities | 7 | 10 | 10 | -- |
| **Subtotal, Health and Independence** | **1,225** | **1,231** | **1,333** | **+101** |
| **Caregiver Services** | | | | |
| Family Caregiver Support Services | 146 | 146 | 151 | +5 |
| Family Support Initiative | -- | -- | 15 | +15 |
| Native American Caregiver Support Services | 6 | 6 | 7 | +1 |
| Alzheimer's Disease Demonstration Grants | 4 | 4 | 4 | -- |
| Alzheimer's Disease Initiative – Services | 11 | 11 | 11 | -- |
| Lifespan Respite Care | 2 | 2 | 5 | +3 |
| **Subtotal, Caregiver Services** | **168** | **168** | **192** | **+23** |
| **Protection of Vulnerable Older Adults** | | | | |
| Long-Term Care Ombudsman Program | 16 | 16 | 16 | -- |
| Prevention of Elder Abuse & Neglect | 5 | 5 | 5 | -- |
| Senior Medicare Patrol Program | 9 | 9 | 9 | -- |
| Elder Rights Support Activities | 4 | 8 | 29 | +21 |
| **Subtotal, Protection of Vulnerable Older Adults** | **33** | **37** | **58** | **+21** |
| **Developmental Disabilities Programs** | | | | |
| State Councils on Developmental Disabilities | 71 | 72 | 72 | -- |
| Developmental Disabilities Protection and Advocacy | 39 | 39 | 39 | -- |
| Projects of National Significance | 9 | 9 | 15 | +6 |
| University Centers for Excellence in Developmental Disabilities | 37 | 38 | 39 | +1 |
| National Institute on Disability, Indep. Living, & Rehab. Research /1 | 104 | 104 | 108 | +4 |
| Independent Living /1 | 101 | 101 | 106 | +5 |
| **Subtotal, Developmental Disabilities** | **360** | **362** | **378** | **+16** |

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/-2015 |
|---|---|---|---|---|
| **Consumer Information, Access and Outreach** | | | | |
| Voting Access for People With Disabilities | 5 | 5 | 5 | -- |
| Aging and Disability Resource Centers | 15 | 6 | 20 | +14 |
| National Clearinghouse for Long-Term Care Information | -- | -- | 1 | +1 |
| State Health Insurance and Assistance Programs | 52 | 52 | 52 | -- |
| Alzheimer's Disease Initiative – Outreach | 4 | 4 | 4 | -- |
| Paralysis Resource Center | 7 | 7 | 7 | -- |
| Limb Loss /2 | 3 | 3 | 3 | -- |
| Assistive Technology /1 | 33 | 33 | 31 | -2 |
| MIPPA Extensions | 18 | 9 | -- | -9 |
| **Subtotal, Consumer Information, Access and Outreach** | **137** | **119** | **123** | **+4** |
| **Other Programs, Total, and Less Funds From Other Sources** | | | | |
| Program Administration | 37 | 38 | 40 | +2 |
| **Total, Program Level** | **1,961** | **1,956** | **2,123** | **+168** |
| Less Funds from Other Sources | -54 | -36 | -28 | -- |
| **Total, Budget Authority** | **1,907** | **1,919** | **2,096** | **+177** |
| | | | | |
| Full-time Equivalents | 195 | 212 | 221 | +9 |

1/ These programs were transferred to ACL from the Department of Education by the Workforce Innovation and Opportunity Act. FY 2014 and FY 2015 program funding, administrative funding, and FTE for these programs are displayed comparably.

2/ The Limb Loss program transferred to ACL from CDC in FY 2015. FY 2014 funding for this program is displayed comparably.

*The Administration for Community Living works to maximize the independence, well-being, and health of older adults, people with disabilities across their lifespan, and their families and caregivers.*

The FY 2016 Budget requests $2.1 billion for the Administration for Community Living (ACL), an increase of $177 million over FY 2015. ACL focuses on ensuring that older adults and people with disabilities are able to live independently with the support they need while participating in communities that value their contributions. In FY 2016, the Budget prioritizes efforts to bolster nutrition assistance and other key services that help seniors remain independent, assist and support family caregivers, and increase ACL's capacity to empower and support individuals with disabilities to live independent lives, fully integrated into all aspects of society.

### Helping Seniors Stay Healthy and Independent

The Budget requests a total of $1.3 billion for services that help older adults remain independent and in the community, including $36 million to support these services in Tribal communities. These efforts will build upon the momentum created by the decennial 2015 White House Conference on Aging, which seeks to recognize the importance of these key programs while also looking ahead to the issues that will help shape the landscape for older Americans for the next decade.

Within this total, the Budget requests $875 million for nutrition services, an increase of $60 million over FY 2015, to ensure that millions of older Americans remain healthy and independent by providing reliable access to nutritious meals and supporting evidence-based innovation that will help improve service quality and efficiency.

The Budget also includes $386 million, $38 million more than in FY 2015, to fund in-home and community-based services to help older Americans live independently and with dignity. These services include transportation; case management; information and referral; help with personal care, including eating, dressing, and bathing; and adult day care and physical fitness programs. In combination with state and local funding, the Budget will support over 28 million hours of assistance to seniors unable to perform daily activities; more than 23 million rides for critical activities such as visiting the doctor, pharmacy, or grocery stores; and nearly 8 million hours of adult day

**Nutrition Services**

The Budget includes $875 million for Nutrition Services, $60 million more than FY 2015. Of this increase, $40 million will allow ACL, in combination with state and local funding, to continue to serve 208 million meals to over 2 million older individuals nation-wide, halting the decline in service levels for the first time since 2010, when these programs received a one-time funding increase due to the American Recovery and Reinvestment Act. The number of meals served by Nutrition Services has declined in recent years due to a combination of factors, including flat federal funding that has not kept pace with the rising costs of inputs such as food and fuel, as well as tightened state and local funding that has made leveraging additional non-federal dollars more difficult.

In addition to the $40 million invested in core Nutrition Services, the Budget also invests $20 million in an initiative to support evidence-based innovations that will help make future funding for Nutrition Services more impactful through improved quality and efficiency. This funding will be awarded as competitive grants to increase the knowledge of states and nutrition providers, drive improved health outcomes for program recipients by promoting higher service quality, and increase program efficiency through innovative service delivery models.

care. These direct services assist older individuals as well as the caregiving friends and family members of these seniors by providing caregivers with relief and flexibility to attend to other demands in their lives, while also continuing to support their friends or loved ones. The Budget also includes $10 million for Aging Network Support Activities that assist seniors to access the resources and services they need to remain in the community, including $2.5 million that is specifically targeted to assist nonprofit service providers that work with the Holocaust survivor community.

The Budget includes $20 million for Preventive Health Services, a program that provides grants to states and territories that help educate older adults about the importance of healthy lifestyles and promote healthy behaviors, which can help to prevent or delay chronic disease and disability, thereby reducing the need for more costly medical interventions. The Budget also includes $8 million for Chronic Disease Self-Management Education and $5 million for Falls Prevention, which both support programs designed to help seniors improve their health status, with the ultimate goal of reducing hospital stays and emergency room visits.

### Protecting Older Americans from Abuse

Fighting the rising scourge of adult abuse, neglect, and exploitation in America remains one of ACL's top priorities. The Budget, as part of the $29 million request for Elder Rights Support Activities, continues to request $25 million—an increase of $21 million—for ACL's Elder Justice initiative to address the damaging impact of abuse, neglect, and exploitation on the health and independence of seniors by making strategic investments in Adult Protective Services, research, and evaluation activities.

With this funding, ACL will continue to develop of a national Adult Protective Services data system, including grants to states to test and develop infrastructure, while also providing funding for key research. Research in the area of Adult Protective Services is essential to the future development of evidence-based interventions that will effectively prevent, identify, report, and respond to abuse of adults of all ages. ACL will become the federal home for Adult Protective Services and will develop national standards to assist all states in improving the quality and consistency of their Adult Protective Services programs.

This investment in addressing elder abuse builds on ACL's existing consumer rights programs, which are already helping to protect seniors and people with disabilities in a number of ways. The Budget requests $16 million for the Long-Term Care Ombudsman Program, which provides support for ombudsmen who advocate on behalf of residents of long-term care facilities to ensure the protection of their rights and welfare. The Budget also includes $5 million for the Prevention of Elder Abuse and Neglect program and $9 million for the Senior Medicare Patrol Program. These programs seek to protect seniors from abuse and equip them with knowledge to prevent fraud and abuse.

### Providing Assistance to Individuals with Disabilities while Conducting Innovative Research

ACL is dedicated to ensuring that individuals with disabilities, as well as their families, have the supports they need to live, work, learn, and play as contributing members of their local communities. ACL works toward accomplishing this goal in FY 2016 through a variety of programs, services, and research efforts.

Ongoing partnerships with states and territories include $72 million for State Councils on Developmental Disabilities, $39 million for Developmental Disabilities Protection and Advocacy programs, and $39 million for University Centers for Excellence in Developmental Disabilities.

The Budget also includes, for the first time, three programs transferred to ACL from the Department of Education by the Workforce Innovation and Opportunity Act of 2014, including the National Institute on Disability, Independent Living, and Rehabilitation Research; the Independent Living programs; and the Assistive Technology programs. The addition of these programs to ACL bolsters its capacity to help Americans with disabilities live independently and participate fully in their communities.

The National Institute on Disability, Independent Living, and Rehabilitation Research—which the Budget funds at $108 million, $4 million over FY 2015—generates knowledge and promotes its use to assist people with disabilities in performing activities of their choice in the community, while also seeking to expand society's capacity to provide full opportunities and accommodations for its citizens with disabilities. This program focuses on research in areas such as employment, health and function, technology for access and function, independent living and community integration, and other associated disability research areas for individuals with disabilities of all ages.

The Budget provides $106 million for the Independent Living program, an increase of $5 million over FY 2015, which supports states and consumer-controlled nonprofit organizations to assist individuals with significant disabilities in their achievement of self-determined independent living goals, as well as fostering working relationships between various entities to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities. The programs transferred by the Workforce Innovation and Opportunity Act share ACL's vision that all people, regardless of age and disability, live with dignity, make their own choices, and participate fully in society.

#### Supporting Family Caregivers

The Family Support Initiative aims to identify and expand innovative state and local strategies to assist the many millions of family caregivers who support older adults and people with disabilities in their efforts to live independently.

Research published by RAND in October 2014 estimated the value of informal family care for just the elderly population to be $522 billion per year, which is more than all Medicaid expenditures in 2013. Less than nine percent of in-home supports for older adults are provided exclusively through paid services. Additionally, among the estimated five million Americans with developmental disabilities, over 75 percent live with family members, with the vast majority requiring decades of care and less than 25 percent receiving funded services. For all populations, waitlists for services continue to grow, and the number of Americans needing these services is expected to double by 2050. Families are in dire need of assistance, as "caregiver burnout" is a major contributor to placement in institutional care.

The $15 million request for this initiative will provide funds for the development and expansion of promising and evidence-based state and local approaches to supporting the largest provider of our nation's long-term care: families. This initiative complements the FY 2016 request for $151 million for ACL's Family Caregiver Support Services, $5 million for Lifespan Respite, $19 million to support the needs of families caring for people with Alzheimer's disease and dementia, and investments in family support made under the DD Act. These investments will help to build the rigorous research and evidence base needed to build comprehensive, sustainable systems of family support across the lifespan.

The Budget also provides $15 million for Projects of National Significance, including an additional $5 million in FY 2016 for a Youth Transitions initiative as part of a broader HHS effort to help young Americans with disabilities in the midst of difficult transitions and provide them with the tools and supports they need to enter adulthood. This initiative will help youth with intellectual or developmental disabilities transition successfully from adolescence and the supportive environment of school into an adulthood that offers them post-secondary education and work opportunities, ultimately reducing the likelihood that they become solely dependent on Social Security, Medicaid, or other similar benefits.

The Budget also includes $7 million for the Paralysis Resource Center and $3 million for the Limb Loss program, the latter program having transferred to ACL in FY 2015 from the Centers for Disease Control and Prevention.

### Assisting Americans and Promoting Efficiency in Community Based Service Delivery

The Budget requests $20 million in new discretionary funding for the Aging and Disability Resource Centers program, which has a proven track record of success in supporting state efforts to develop more efficient, cost-effective, and consumer-responsive systems of information and integrated access by creating consumer-friendly entry points into long-term care at the community level. Aging and Disability Resource Centers make it easier for Americans nation-wide to learn about and access their health and long-term services and support options.

The Budget also requests $52 million to fund the State Health Insurance Assistance Program, which supports 12,000 counselors in more than 1,300 community-based organizations across the country. These individuals and organizations provide Medicare beneficiaries who have a disability and/or are elderly, as well as those nearing Medicare eligibility, with one-on-one outreach and counseling on the health insurance options available to them.

The FY 2016 request also includes $31 million for the Assistive Technology programs, which were transferred to ACL under the Workforce Innovation and Opportunity Act. Assistive Technology programs support state efforts to improve opportunities for individuals with disabilities of all ages to obtain assistive technology that fosters greater independence, productivity, as well as integration and inclusion within the community and workforce.

### Federal Administration

The Budget includes $40 million in funding for program management and support activities. This funding supports rent, staff, and other administrative costs, and is also used to support staff in ACL's regional offices.

# Office of the Secretary, General Departmental Management

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Budget Authority | 457 | 448 | 493 | +45 |
| PHS Evaluation Fund Appropriation | 69 | 65 | 66 | +1 |
| Pregnancy Assistance Fund | 23 | 23 | 25 | +2 |
| Proposed Law, RAC Collections | - | - | 2 | **+2** |
| **Total, Program Level** | **549** | **536** | **586** | **+50** |
| | | | | |
| Full-time Equivalents | 1,493 | 1,581 | 1,656 | +75 |

*General Departmental Management supports the Secretary in her role as chief policy officer and general manager of the Department.*

The FY 2016 Budget for General Departmental Management is $586 million in program level funding, an increase of $50 million above FY 2015. The Budget supports grant programs and the Secretary's roles in administering and overseeing the organization, programs, and activities of the Department. These efforts are carried out through 11 Staff Divisions and Offices.

***Teen Pregnancy Prevention:*** The Budget includes $105 million to support community efforts to reduce teen pregnancy and collaborate on abstinence education projects. In addition, $7 million in Public Health Service Act evaluation funding is included for the evaluation of teen pregnancy prevention activities. Teen pregnancy prevention funding will be used for replicating programs that have proven effective through rigorous evaluation to reduce teenage pregnancy; for research and demonstration grants to develop, replicate, refine and test additional models and innovative strategies; and for training, technical assistance, and outreach. Collaborative efforts in teen pregnancy prevention will support innovative strategies which are medically accurate and age appropriate.

***Office of Minority Health:*** The Budget includes $57 million for the Office of Minority Health, the same as FY 2015. The Office of Minority Health will lead, coordinate and collaborate on minority health activities in HHS, with emphasis on program development. This funding will enable the Office of Minority Health to continue targeted grants and health promotion, service demonstration, and educational efforts to prevent disease, reduce and ultimately eliminate disparities in racial and ethnic minority populations across the country.

***Minority HIV/AIDS:*** The FY 2016 Budget includes $54 million, an increase of $2 million above FY 2015 to support innovative approaches to HIV/AIDS prevention and treatment in minority communities disproportionately impacted by this disease. These funds will allow the Department to continue priority investments and public health strategies targeted to

reduce the disparate burden of HIV/AIDS in racial and ethnic minority populations.

***Office on Women's Health:*** The Budget includes $32 million for the Office on Women's Health, the same as FY 2015. The Office on Women's Health will lead, coordinate, and collaborate on women's health activities and program development in HHS. This funding will allow the Office on Women's Health to continue targeted grants and support the advancement of women's health programs through promoting and coordinating research, service delivery, and education. These programs are also carried out throughout the divisions and offices of HHS, with other government organizations, and with consumer and health professional groups.

***Acquisition Reform:*** The Budget continues $2 million for the HHS portion of a government-wide initiative in contract and acquisition reform. Funding will be used to increase the capacity and capabilities of the Department's acquisition workforce.

***Other General Departmental Management:*** The Budget includes $327 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 HHS components and also includes funding to continue ongoing programmatic activities. The Budget will support strengthening program integrity by reducing fraud, waste, and abuse and increasing accountability. Additionally, the FY 2016 Budget will develop and expand on three new data and innovation initiatives.

***DATA Act:*** The Budget includes $10 million to implement the Digital Accountability and Transparency Act of 2014 as well as the Federal Funding Accountability and Transparency Act of 2006 to improve transparency of Federal spending and Government-wide financial data standards. HHS plays a crucial role in the implementation of the Digital Accountability and Transparency Act of 2014 and has been designated as the leader for grants standardization. The Department will focus on improvements to Grants.gov as well as data standardization efforts that will include both financial and non-financial data.

***Agency Digital Service Team:*** The Budget also includes $10 million for the Department to establish and staff an agency Digital Services team. The request will enable HHS to focus on the implementation of milestones to build capacity and support the development of a Digital Services team and drive the efficiency and effectiveness of the agency's highest-impact digital services.

The success rate of government digital services is improved when agencies have digital service experts on staff with modern design, software engineering, and product management skills. To ensure the agency can effectively build and deliver important digital services, the FY 2016 Budget includes funding for staffing costs to build a Digital Service team that will focus on transforming the agency's digital services with the greatest impact to citizens and businesses so they are easier to use and more cost-effective to build and maintain.

***IDEA Lab:*** The Budget supports the growth of the HHS Idea Lab and includes $3 million to expand initial activities. Resources will allow HHS to pilot new programmatic activities to support innovative ideas that increase efficiency and effectiveness.

# Office of the Secretary, Office of Medicare Hearings and Appeals

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Budget Authority | 82 | 87 | 140 | +53 |
| **Proposed Law** | | | | |
| Recovery Audit Collections | 0 | 0 | 125 | +125 |
| Refundable Filing Fee | 0 | 0 | 5 | +5 |
| **Total Program Level, OMHA** | **82** | **87** | **270** | **+183** |
| Full-time Equivalents | 468 | 564 | 1,475 | +911 |

*The Office of Medicare Hearings and Appeals provides an independent forum for the fair and efficient adjudication of Medicare appeals for beneficiaries and other parties. This mission is carried out by a cadre of knowledgeable Administrative Law Judges (ALJ) exercising judicial and decisional independence under the Administrative Procedures Act, with the support of a professional, legal, and administrative staff.*

The FY 2016 Budget request for the Office of Medicare Hearings and Appeals (OMHA) is $140 million, an increase of $53 million over FY 2015. The Budget request also includes a legislative package to address the growing backlog of Medicare appeals. HHS estimates that enactment of this package would provide an additional $125 million in Recovery Audit collections, and $5 million from a proposed refundable filing fee. OMHA administers hearings and appeals nationwide for the Medicare program. By statute, these Medicare appeals are to be heard within 90 days after receipt of a request for a hearing from a Medicare appellant.

Due to the overwhelming growth in its workload, OMHA has not been able to meet the required 90 day timeframe for case adjudication. It currently takes over 400 days for OMHA to adjudicate an appeal. At current resource levels, OMHA's backlog of appeals is projected to reach 1,000,000 by the end of FY 2016. To address these challenges, OMHA has taken a number of administrative actions to reduce the pending appeals workload. For example, OMHA recently began to pilot settlement conference facilitations which offer alternative dispute resolution as a way to resolve pending cases without an Administrative Law Judge hearing. In addition, OMHA has made statistical sampling available to appellants, which has the potential to resolve large numbers of cases based on representative samples. While helpful, these steps taken alone are insufficient to keep up with the dramatic growth in claims.

The Budget request includes a comprehensive legislative package aimed at both helping HHS process a greater number of appeals and reducing the number of appeals filed. Please refer to the Centers for Medicare & Medicaid Services narrative for a comprehensive discussion of the appeals proposals.

With a funding level of $270 million, OMHA will open new field offices and hire additional adjudicators and support staff. OMHA will continue to utilize technology to offer appellants access to multiple hearing venues and services. These additional resources are critical for OMHA to respond to the increasing number of appeals

while maintaining the quality and accuracy of its decisions, and ultimately, to restore the agency's ability to provide timely hearings for Medicare appellants.

OMHA administers appeals in five field offices: Miami, Florida; Cleveland, Ohio; Irvine, California; Arlington, Virginia; and the recently opened Kansas City office. OMHA extensively utilizes hearings held via video teleconference and telephone in order to provide appellants with accessible hearings at low cost.

OMHA began processing cases on July 1, 2005; since then, it has received approximately 3 million claims nationwide for Medicare Parts A, B, C, and D appeals, as well as for Medicare entitlement and eligibility appeals. In FY 2011, OMHA began receiving additional claims resulting from the permanent nationwide expansion of the Recovery Audit program, administered by CMS. These claims, in addition to the more traditional Part A and B claims, have contributed to OMHA's significant workload increase. OMHA received a total of 655,000 claims in FY 2013, and close to 1,000,000 claims in FY 2014. OMHA projects that its FY 2015 caseload will increase to approximately 1,200,000 claims (an 83 percent increase over FY 2013).

**HHS Three-Pronged Medicare Appeals Process Improvement Strategy**

- Invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog
- Take administrative actions to reduce the number of pending appeals and prevent new cases from entering the system
- Propose legislative reforms that provide additional funding and new authorities to increase efficiency and address the volume of incoming appeals.

# Office of the Secretary, Office of the National Coordinator for Health Information Technology

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Budget Authority | 16 | 60 | 0 | -60 |
| PHS Evaluation Fund Appropriation | 45 | -- | 92 | +92 |
| **Program Level** | **60** | **60** | **92** | **+32** |
| | | | | |
| Full-time Equivalents | 171 | 185 | 200 | +15 |

*The Office of the National Coordinator for Health Information Technology advances an interoperable health care delivery system where the collection, sharing, and use of health information ensures that critical information is accessible when and where it is needed to improve and protect people's health and well-being.*

The FY 2016 Budget for the Office of the National Coordinator for Health Information Technology (ONC) is $92 million, $32 million above FY 2015. The Budget reflects the need for continued progress towards greater optimization of health information technology (IT) to further care transformation and increase interoperability through policies, standards, and programs that will assist both providers and consumers. It will foster greater collaboration in support of health IT across the government by building federal and national consensus around implementing the Federal Health IT Strategic Plan.

In FY 2016, ONC's investments will reflect a greater focus on interoperability through standards development, certification, and governance structures to support the requirements of Meaningful Use Stage 3. Meaningful Use Stage 3 seeks to support data exchange in a safe and secure manner utilizing standards that support interoperability and patient engagement for an enhanced care delivery system and patient experience.

### Standards, Interoperability, and Certification

ONC will continue to make strategic investments in standards development, harmonization, and pilots in order to accelerate industry progress in specific areas that require interoperability. This investment will support development and testing of standards to ensure interoperability and an expanded certification program to meet the requirements of Stage 3 Meaningful Use and the new Department-wide Precision Medicine initiative.

Supporting the Standards and Interoperability Framework will enable ONC to further coordinate critical data standards in support of interoperability for summary health care records, laboratory data exchange, and diagnostic results areas, which are high priorities for health care providers.

### Policy Development and Coordination

As the federal entity responsible for developing the framework and leading on federal health IT policy, ONC seeks to provide policy solutions for health IT issues regarding the use and exchange of electronic health information. In FY 2016, ONC will continue working on the expansion of the Certification Program's regulatory guidance for health care providers – such as mental and behavioral health and long-term care facilities – that are ineligible under the Meaningful Use Program. This approach includes publishing annual, voluntary certification regulations and guidance documents. These voluntary certification documents will help ineligible providers be interoperable with other providers.

Through federal advisory committees and the Federal Health IT Strategic Plan, ONC will continue to ensure that federal health IT policies promote interoperability, patient safety, health IT usability, and clinical quality improvement by integrating a clinical perspective.

In FY 2016, ONC will continue the analysis of health IT-related adverse events tracking benchmarks to inform the development of interventions and usability of standards for widespread implementation. The Health IT Safety Center will become operational in FY 2017.

### Governance of Health Information Exchange

ONC will transition to a governance approach in FY 2016 for health information exchange that will involve both policy collaboration and development across industry and government. Governance will be required to ensure providers can effectively meet the Meaningful Use Program Stage 3 objectives in the 2017 edition of health IT certification. ONC's governance approach will ensure that a common set of policies, standards, and practices are set forth to facilitate safe and secure exchange of patient's health data. This model, which consists of states, health information entities, and other governance entities, will enable information to be readily available to patients when and where they access care.

### Adoption, Utilization, and Meaningful Use

In FY 2016, ONC will pivot from providing technical assistance to providers through the Regional Extension Center program to educating providers through HealthIT.gov, a federal resource dedicated to health IT for both consumers and health care professionals. This site will provide solutions and best practices on common challenges providers face in achieving meaningful use and interoperability.

**Federal Health IT Strategic Plan 2015-2020**

The Federal Health IT Strategic Plan utilizes policy levers to build a national consensus for promotion and achievement of interoperability across the country. The 2015-2020 Plan embodies a mission to improve health, health care, and reduce costs through the use of information and technology. Five goals have been identified to collect, share, and use electronic health information to advance the nation's health and health care goals.

- Expand Adoption of Health IT
- Advance Secure and Interoperable Health Information
- Strengthen Health Care Delivery
- Advance the Health and Well-Being of Individuals and Communities
- Advance Research, Scientific Knowledge, and Innovation

ONC will engage state and local governments, public health stakeholders, payers, and other interested parties to build consensus around and implement key outcomes included in the plan.

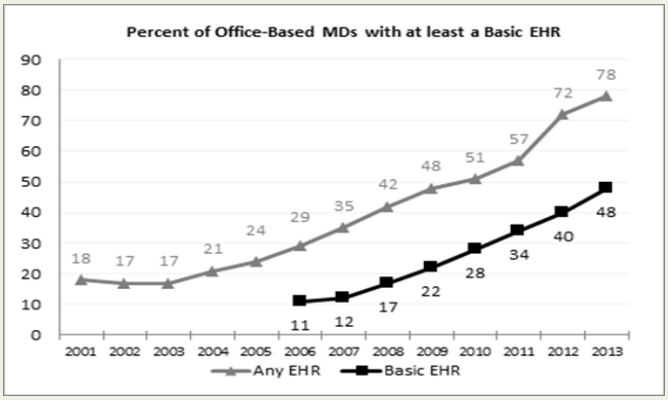
### Consumer eHealth

ONC will convene stakeholders, identify barriers, and develop strategies so consumers can electronically send, receive, find and use their health information. ONC will focus on supporting consumer access to electronic health information, enabling the development of interoperable mobile and other tools that help consumers to use their health information effectively, and increasing consumer awareness of and demand for digital health information and tools. More specifically, ONC will support providers in their efforts to engage and share data with patients as required by the Meaningful Use Program, and, via the Blue Button Pledge Program, support other organizations such as pharmacies, labs, and health insurance companies in data sharing.

ONC will continue to develop a portfolio of recommended national standards for structured health data sharing in order to encourage the technology development community to build useful tools, and will work with federal partners and the private sector on an ongoing consumer education and awareness campaign. ONC will also continue to enhance the resources it has created to help consumers better locate their health data electronically, and articulate policies that make it easier for patients to share their own health data with their doctors.

**Accelerated Health IT adoption**

Medical information is the lifeblood of the healthcare delivery system. Electronic Health Records are the key vehicles for transporting this information, making it accessible to both patient and provider. In 2008, EHR adoption rate for providers using a "basic" electronic health record was 17 percent. Since the establishment of the Meaningful Use Program and Electronic Health Record implementation assistance programs such as the Regional Extension Centers, that rate has grown to over 48 percent in 2013.Surpassing the Department's goal to assist 100,000 providers with the adoption of Electronic Health Records, ONC, through the 62 Regional Extension Centers, has helped over 150,000 providers implement electronic health record systems and achieve meaningful use of health information technology. The Department continues to provide assistance as new requirements are identified for the Meaningful Use Electronic Health Records Incentive program. This support has resulted in over 100 million patients having access to electronic prescriptions, resulting in reduced medication related errors; patient visit summaries, allowing patients to more fully understand and participate in their health care; and evidence-based care recommendations based on quality measures and indicators.




Source: Health and Human Services. Report to Congress: Update on the Adoption of Health Information Technology and Related Efforts to Facilitate the Electronic Use and Exchange of Health Information. October 2014.

# Office of the Secretary, Office for Civil Rights


## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Program Level** | **39** | **39** | **43** | **+4** |
| | | | | |
| Full-time Equivalents | 202 | 195 | 199 | +4 |

*The Office for Civil Rights ensures equal, nondiscriminatory access to and receipt of all HHS services and the protection of privacy and security of health information, thereby contributing to HHS's overall mission of improving the health and well-being of all Americans affected by its many programs.*

The FY 2016 Budget for the Office for Civil Rights (OCR) is $43 million, an increase of $4 million over FY 2015. The increase will support OCR's audit program which was mandated by the Health Information Technology for Economic and Clinical Health Act. The audit program will offer an invaluable new tool to help ensure Health Insurance Portability and Accountability Act (HIPAA) compliance by covered entities and business associates, while also informing OCR on areas in which to direct its enforcement and technical assistance. In addition, the increase will support OCR's continued expansion and improvement of its Centralized Case Management Operations unit, which has significantly improved its efficiency by receiving, recording, triaging, and distributing complaints for evaluation and resolution.

### Civil Rights

***General Authorities:*** OCR resolves over 4,000 discrimination complaints annually, conducts compliance reviews, and enforces various federal civil rights laws and regulations. These include protections against discrimination on the basis of race, color, national origin, disability, age, and sex in HHS-funded programs and certain federal, state, and local government programs. In addition, under Section 1557 of the Affordable Care Act, OCR has enforcement authority with respect to race, color, national origin, disability, age, and sex discrimination in health programs that receive financial assistance or are administered by HHS or any entity established under Title I of the Affordable Care Act.

***Other Compliance Activities:*** In addition to its direct enforcement responsibilities under federal anti-discrimination laws, OCR reviews nearly 2,500 Medicare provider applicants per year to assess compliance with federal civil rights requirements. Through its current formal agreements with 54 health care corporations, OCR ensures ongoing compliance in more than 4,600 facilities that serve over 11 million patients annually.

OCR also works with its federal agency partners to ensure that language assistance services are available to limited English proficient individuals, including with regard to services under the Affordable Care Act and other activities conducted by the Department.

In addition, OCR provides technical assistance and education to states and federal agency partners to ensure compliance with the Americans with

Disabilities Act. OCR disseminates information, creates virtual learning communities, works on guidance documents, and provides webinars on topics such as housing and Medicaid services that provide individuals with disabilities opportunities to live in their communities.

### Health Information Privacy and Security

***General Authorities:*** OCR administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules. OCR is responsible for policy development through the issuance of regulations and guidance. OCR also provides outreach and technical assistance to the regulated community to ensure covered entities and business associates understand their compliance obligations and to the public to increase individuals' awareness of their HIPAA rights and protections. OCR enforces the HIPAA Rules by investigating complaints and conducting compliance reviews of alleged violations of the HIPAA Rules, providing technical assistance and obtaining corrective actions, as well as entering into resolution agreements or issuing civil monetary penalties, where appropriate. OCR resolved more than 15,000 complaints of alleged HIPAA violations in FY 2014.

***Settlements and Civil Monetary Penalties:*** OCR has authority to enter into resolution agreements that include payment of a resolution amount and corrective action plans, as well as imposing civil monetary penalties for violations of the HIPAA Rules. OCR collected $8 million in settlements in FY 2014 – an amount based on several unusually large agreements – and anticipates collecting $5.5 million in settlements in FY 2015. OCR retains and expends these collections to support overall HIPAA enforcement activities.

***HIPAA Audit Program:*** The HITECH Act mandates that OCR conduct periodic audits to assess entity compliance with HIPAA. OCR conducted a pilot program to ensure that its audit functions could be performed in the most efficient and effective way, and in FY 2015 will continue designing, testing, and implementing its audit function to measure compliance with privacy, security, and breach notification requirements. OCR plans to conduct comprehensive and desk audits of covered entities and business associates. Audits are a proactive approach to evaluating and ensuring HIPAA privacy and security compliance.

# Office of the Secretary, Office of Inspector General


## Budget Overview

*(dollars in millions)*

| *Funds* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| Discretionary Appropriation | 71 | 73 | 83 | +11 |
| HCFAC Collections | 11 | 11 | 12 | +1 |
| Discretionary HCFAC | 28 | 67 | 119 | +52 |
| Mandatory HCFAC | 185 | 186 | 203 | +17 |
| **Total Funding, All Sources** | **295** | **337** | **417** | **+80** |
| | | | | |
| Full-time Equivalents | 1,574 | 1,591 | 1,821 | +230 |

*The Office of Inspector General's mission 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 FY 2016 Budget request for the Office of Inspector General (OIG) is $417 million, an increase of $80 million above FY 2015. The request includes $83 million for OIG oversight of HHS's more than 100 non-Medicare/Medicaid programs, some of which are new or have grown in scope and complexity during the last decade. These funds will enable OIG to target oversight efforts of HHS public health and human services programs and the Health Insurance Marketplaces (Marketplaces).

Moreover, OIG is a key partner in the joint HHS and Department of Justice Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, and the President's Budget includes $334 million in support of HEAT and other program integrity efforts aimed at reducing fraud, waste and abuse in the Medicare and Medicaid programs. In addition to maintaining the efforts and success of the Medicare Fraud Strike Forces, HEAT activities in FY 2016 include protecting the integrity of the expanding Medicaid program and recommending solutions to reduce improper payments in Medicare and Medicaid.

While specific oversight activities in FY 2016 will be determined through OIG's work planning process, the following are OIG's focus areas based on its assessment of the top management and performance challenges facing HHS.

### Implementing, Operating, and Overseeing the Marketplaces

The Marketplaces add a substantial new dimension to the Department. They include state, federal, and partnership marketplaces, each of which must implement and successfully operate a complex set of program requirements. Individuals use the Marketplaces to get information about their health insurance options, be assessed for eligibility (for qualified health plans, premium tax credits, and cost sharing reductions), and enroll in the health plan of their choice.

OIG's oversight of the Marketplaces focuses on payments, eligibility, management and administration, and security. By focusing on these key areas OIG hopes to ensure that taxpayer dollars are spent for their intended purposes in a secure system that operates efficiently.

### Integrity of the Department's Public Health and Human Services Programs

***Grants Management and Administration of Contract Funds:*** HHS is the largest grant-making organization in the federal government, awarding over 79,000 grants totaling $389 billion in FY 2014. HHS is also the third largest contracting agency in the federal government. The size and scope of departmental awards make vigilant oversight crucial to the success of programs designed to improve the health and well-being of the public. In FY 2016, OIG will continue to examine the Department's grants management and contracting practices and its oversight of grantees and contractors. OIG will also identify misused grant and contract funds for recovery and investigate suspected grant fraud. OIG will provide the Department with vital information that will help hold accountable grantees and contractors that manage large grant awards and contracts, and ensure the integrity of these significant expenditures.

***Protecting Consumers of Food, Drugs, and Medical Devices:*** HHS is responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, medical devices, biologics, and much of our nation's food supply. Additionally, HHS must ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. Furthermore, during a food emergency, HHS must find the contamination source and oversee the removal by manufacturers of these products from the market. In FY 2016, OIG will continue to evaluate the Department's management of food, drug, and device safety issues. Furthermore, OIG continues to work closely with the Food and Drug Administration and the Department of Justice to investigate illegal marketing practices by drug and device manufacturers.

### Integrity of Medicare and Medicaid

***Addressing Prescription Drug Vulnerabilities on a National Scale:*** In both the Medicare Part D and Medicaid programs, OIG has uncovered improper and potentially harmful prescribing practices, pharmacies billing for drugs not dispensed, and diversion of prescription drugs. OIG has also identified waste related to payments for prescription drugs under HHS programs, which increase costs to taxpayers and beneficiaries. The need to invest additional resources in this area is clear, and additional FY 2016 funding would support the integrity of these two programs and ensure patient safety.

***Overseeing Changes in Medicaid:*** The number of individuals covered by Medicaid is continuing to grow. The Congressional Budget Office projects the number of individuals covered by Medicaid to grow approximately 37 percent by 2024. As enrollment and spending increase, there is heightened urgency to address the program integrity challenges that Medicaid already faces. These include improving the effectiveness of Medicaid data, avoiding or recovering Medicaid improper payments and payments for which a third party is liable, preventing waste and fraud in Medicaid managed care programs, and reducing waste associated with excessive payment rates to public providers.

OIG's work in this area will focus on ensuring that the federal government pays the appropriate share of costs; improper payments are identified and recovered; eligibility is correctly determined; managed care programs, in which approximately a third of all Medicaid beneficiaries are enrolled, maintain sufficient program integrity efforts; and payment rates to health care providers are economical.

***Fighting Fraud and Waste, and Promoting Value in Medicare Parts A & B:*** Fraud and waste in Medicare Fee-for-Service programs continue to be significant challenges. Improper payments and payment inefficiencies waste Medicare dollars and divert finite resources away from beneficiary care and services. In FY 2014, CMS reported an improper payment rate of 12.7 percent for Medicare Fee-for-Service. OIG investigations continue to uncover durable medical equipment suppliers, home health agencies, community mental health centers, ambulance operators, and outpatient therapy providers that are defrauding the Medicare program. In national assessments, OIG has identified questionable billing patterns by home health agencies and community mental health centers and is conducting similar analysis of questionable billing by ambulance providers. Additionally, OIG work spotlights various types of waste including hospital billing error, improper payments to Skilled Nursing Facilities and misaligned payment rates. OIG will continue its work in these areas in FY 2016.

# Public Health and Social Services Emergency Fund

## Budget Overview

| *dollars in millions* | 2014 | 2015 | 2016 | 2016 +/- 2015 |
|---|---|---|---|---|
| **Assistant Secretary for Preparedness and Response (ASPR)** | | | | |
| Preparedness and Emergency Operations | 28 | 25 | 25 | -- |
| National Disaster Medical System | 50 | 50 | 50 | -- |
| Hospital Preparedness | 255 | 255 | 255 | -- |
| *ESAR-VHP (non-add)* | 1 | -- | -- | -- |
| Medical Countermeasure Dispensing | 5 | -- | -- | -- |
| Medical Reserve Corps /1 | 9 | 9 | 6 | -3 |
| Biomedical Advanced Research and Development Authority /2 | 413 | 473 | 522 | +49 |
| Project BioShield | 254 | 255 | 646 | +391 |
| Policy and Planning | 15 | 15 | 15 | -- |
| Operations | 31 | 31 | 31 | -- |
| **Subtotal, ASPR Program Level** | **1,061** | **1,113** | **1,549** | **+437** |
| **Other Office of the Secretary** | | | | |
| Office of Security and Strategic Information | 6 | 7 | 7 | -- |
| Cybersecurity | 53 | 41 | 73 | +32 |
| HHS Lease Replacement | 16 | -- | -- | -- |
| **Subtotal, Other Office of the Secretary** | **76** | **49** | **81** | **+32** |
| **Pandemic Influenza** | | | | |
| ASPR Pandemic Influenza | 111 | 68 | 166 | +98 |
| Office of Global Affairs Pandemic Influenza | 4 | 4 | 4 | -- |
| **Subtotal, Pandemic Influenza** | **115** | **72** | **170** | **+98** |
| **Other PHSSEF** | | | | |
| Emergency Response Initiative | -- | -- | 110 | +110 |
| Health Insurance Evidence Initiative (PHS Evaluation funds) /3 | -- | -- | 30 | +30 |
| **Subtotal, Other PHSSEF** | **--** | **--** | **140** | **+140** |
| **Total and Less Funds from Other Sources** | | | | |
| **Total Program Level, PHSSEF** | **1,251** | **1,233** | **1,940** | **+707** |
| Use of PHS Evaluation Fund Appropriation | -- | -- | 30 | -30 |
| **Total Discretionary Budget Authority, PHSSEF** | **1,251** | **1,233** | **1,910** | **+677** |
| | | | | |
| **Full-time Equivalents** | **696** | **757** | **773** | **+16** |

1/ Prior to FY 2015, MRC was administered by OASH. The FY 2014 total is added for comparability.

2/ Includes $58 million for Ebola Response from PL 113-164. Does not include $733 million for Emergency Ebola Response (PL 113-235).

3/ For details on the specifics of this initiative, please reference the Overview section.

*The Public Health and Social Services Emergency Fund directly supports the nation's ability to prepare for, respond to, and recover from the health consequences of naturally occurring and man-made threats.*

The FY 2016 Budget includes $1.9 billion, an increase of $677 million above FY 2015 for the Public Health and Social Services Emergency Fund (PHSSEF) in the Office of the Secretary. This funding will support the Department's cross-cutting efforts to improve the nation's preparedness against naturally occurring and man-made health threats. The Budget continues to support the Administration's priority to combat these threats with coordinated efforts domestically and internationally. The activities supported by the PHSSEF, including advanced development of medical countermeasures, pandemic influenza preparedness activities, and emergency preparedness, contribute to the Department's overall emergency and response strategy.

### Bioterrorism and Emergency Preparedness

PHSSEF activities supported by the FY 2016 Budget include bioterrorism preparedness and response activities within the Office of the Secretary, and the coordination of programs across HHS to make improvements in the nation's ability to prepare for, respond to, and recover from public health emergencies and disasters. Specific activities include advanced development and procurement of medical countermeasures, improvements in state and local emergency preparedness, and immediate emergency response efforts.

***Assistant Secretary for Preparedness and Response:*** Supported by the PHSSEF, the Assistant Secretary for Preparedness and Response (ASPR) serves as the principal advisor to the Secretary of HHS on public health and medical emergency preparedness and response. ASPR's efforts focus on promoting community preparedness and resiliency; strengthening the nation's health and response systems; building research and development partnerships with federal agencies, academic institutions, and private industry; and enhancing national health security. The FY 2016 Budget includes $1.5 billion for ASPR, an increase of $437 million over FY 2015.

**Ebola Outbreak Response in West Africa**

The 2014 Ebola outbreak is the largest in history and the first Ebola epidemic the world has ever known — affecting multiple countries in and around West Africa. ASPR contributes to the support of the Ebola response through:

- Accelerating development of promising vaccine and therapeutics candidates;
- Providing hospitals and healthcare coalitions with funding for personal protective equipment and training; and enhancing healthcare infrastructure for improved screening and assessment.

ASPR's efforts have contributed significantly to the government-wide domestic response to elevate preparedness and protect the nation from any further spread.

Since its inception in 2007, ASPR's Biomedical Advanced Research and Development Authority (BARDA) has support advanced research of more than 85 chemical, biological, radiological, and nuclear medical countermeasure product candidates. Because of the Administration's commitment to medical countermeasure development, BARDA expects a dozen more medical countermeasures to be sufficiently mature for procurement through Project BioShield by FY 2018. The Budget includes $522 million for medical countermeasure advanced development, an increase of $49 million over FY 2015. This funding includes support for the advanced development of: devices to measure an individual's exposure to biological agents; antidotes for chemical agents; and antiviral and vaccine candidates against Ebola and Marburg viruses.

Funding for Project BioShield supports the late development and procurements of novel medical countermeasures for the Strategic National Stockpile. Since 2003, Project BioShield has procured a total of 12 novel medical countermeasures, which have improved preparedness against threats such as anthrax, botulism, smallpox, and chemical, radiological, and nuclear agents. Two of these products, an anthrax antitoxin and a botulism antitoxin, were approved by the Food and Drug Administration in 2013 under the Animal Efficacy Rule. The FY 2016 Budget includes $646 million to support ongoing late-stage development and procurement through Project BioShield, an increase of $391 million over FY 2015. This funding would specifically support the procurement of eight medical countermeasures, including a new adjuvanted anthrax vaccine, new anthrax antitoxin and smallpox vaccine with improve shelf life, and new skin replacement therapies. In order to support necessary product maintenance, storage, and replenishment, this Project BioShield's increase is in conjunction with increased funding for the Strategic National Stockpile. Through the Centers of Disease

Control and Prevention, the FY 2016 Budget includes $571 million to support the Strategic National Stockpile, $37 million above FY 2015.

Within its previous advanced development funding, BARDA has partnered with industry in the development of nine new broad spectrum antibiotics in an effort to combat antibiotic-resistant bacteria. The FY 2016 Budget includes $192 million for the continued support of these activities within BARDA, an increase of $108 million over FY 2015. This funding aligns with the Administration's high priority goals as outlined in the *National Strategy for Combating Antibiotic-Resistant Bacteria.*

The PHSSEF has supported emergency response efforts through investments in ASPR's Hospital Preparedness Program, which provides grant support to hospitals and healthcare coalitions to bolster emergency preparedness through planning and infrastructure. Investments in coalitions have resulted in the development of improved response systems, realistic exercises, collaborative partnerships, and information sharing that has proven valuable throughout numerous disaster responses. The FY 2016 Budget includes $255 million to support ASPR's Hospital Preparedness Program, which is flat with FY 2015.

The Hospital Preparedness Program closely aligns with the Centers of Disease Control and Prevention's Public Health Emergency Preparedness program. Between FY 2008 and FY 2015, the two programs have provided a combined total of nearly $12 billion to support flexible and adaptable community preparedness planning and to encourage close coordination among a variety of stakeholders across the health spectrum.

In addition to the hospital and public health capacity support programs, the FY 2016 Budget provides $75 million to support the Department's emergency preparedness and response efforts. This funding supports the National Disaster Medical System, which is a federally-coordinated system that augments state and local medical response capabilities during public health emergencies. State and local medical preparedness is supported by this program through real-world training exercises, including those executed through the partnership with the Department of Homeland Security's Center for Domestic Preparedness in Alabama. In FY 2016, ASPR will formally take over the administration of the Medical Reserve Corps, previously administered by the Office of the Assistant Secretary for Health. ASPR will be able to achieve administrative and programmatic efficiencies for the administration of the Medical Reserve Corps because of its alignment with existing program objectives. The Budget includes $6 million to support the Medical Reserve Corps within ASPR.

This funding also supports ASPR's Office of Emergency Management, which is in place to support communities as they prepare for, respond to, and recover from the public health and medical impact of emergencies and disasters. This office also specifically supports the Secretary's Operation Center, which monitors information across multiple sources to identify potential or emerging threats to public health. The FY 2016 Budget includes $25 million for emergency management programs, which is flat with FY 2015.

The Budget includes $110 million to provide immediate response to an unanticipated public health emergency in which rapid action would be critical to mitigate these threats. This new request was informed by lessons learned from the Department's Ebola response and other recent response efforts. This proposal aims to strengthen the nation's capability to plan for and

**Pandemic Influenza: Applied Lessons Learned**

Since the 2009 outbreak of the influenza strain, H1N1, in 2009, the Department has assessed opportunities for improvement and implemented new and improved preparedness initiatives. The changes made as a result of the lessons learned from H1N1 have proven instrumental to more recent responses. These improvements include: the advanced development of high throughput rapid diagnostics; the development and production of H5N1 and H7N9 vaccine seed strains; antigen and new antigen-sparing adjuvants; and the expansion and increased flexibility of domestic vaccine manufacturing surge capacity.

The Department's lessons learned were particularly important to the H7N9 response. For example, new cell- and recombinant-based influenza vaccines, generated by the need identified in the H1N1 response have been licensed for use. Technology improvements in vaccine development and manufacturing have streamlined vaccine seed production, which has provided the ability to develop influenza vaccines quicker. Partnerships with private industry, such as the Centers of Innovation and for Advanced Development and Manufacturing, allowed the Department to quickly pivot and expand capacity for the development and manufacturing of H7N9 vaccines for stockpiling.

manage the response to public health emergencies, particularly outbreaks of infectious disease that may require both domestic and international response capabilities. Of this amount, $20 million will be used for preparedness activities, including training for potential responders and equipment.

The Budget proposes continuation of the Department-wide emergency transfer authority included in the FY 2015 Omnibus. This authority will augment HHS' capability to respond rapidly to public health emergencies, especially to states and local communities in the case of a catastrophic event.

### Pandemic Influenza

Within the past two years, the emergence of novel influenza viruses, have clearly demonstrated the critical need for ongoing influenza preparedness activities. Influenza and other emerging diseases with pandemic potential continue to mutate and evolve, posing significant risks to global public health. Previous investments have successfully increased pandemic influenza preparedness, including the retrofitting of domestic manufacturing facilities to nearly double vaccine manufacturing surge capacity. To continue these efforts, the FY 2016 Budget includes $170 million for ongoing pandemic influenza activities. This funding includes support for diagnostics advanced development, vaccine stockpiling, international preparedness, and the advanced development of immunotherapeutics.

### Department-wide Information Security

***Cybersecurity:*** The FY 2016 Budget includes $73 million for HHS' Cybersecurity Program, $32 million above FY 2015. This program works to ensure that all automated information systems throughout the Department are designed, operated, and maintained with appropriate information technology security and privacy data protections. A significant portion of this increase is necessary to upgrade bandwidth capacity within the existing Trusted Internet Connections to preserve the increased security that these functionalities have provided through prior-year investments. As cyberthreats become more frequent and more sophisticated, additional funding in the FY 2016 Budget will better enable the Department to identify and respond swiftly to mitigate cybersecurity risks.

***Security and Strategic Information:*** The Budget includes $7.5 million for the Office of Security and Strategic Information, which is the same as FY 2015. Office of Security and Strategic Information coordinates the sharing and safeguarding of classified national security information across the Department with the Director of National Intelligence and its component agencies within the intelligence community. Funding for FY 2016 will support the Office of Security and Strategic Information's efforts to adhere to increased counterintelligence requirements.

# ABBREVIATIONS AND ACRONYMS

## A

| | |
|---|---|
| ACA | Patient Protection and Affordable Care Act |
| ACF | Administration for Children and Families |
| ACL | Administration for Community Living |
| AHRQ | Agency for Healthcare Research and Quality |
| AIDS | Acquired Immune Deficiency Syndrome |
| ASPR | Assistant Secretary for Preparedness and Response |
| ATSDR | Agency for Toxic Substances and Disease Registry |

## B

| | |
|---|---|
| BA | Budget Authority |
| BARDA | Biomedical Advanced Research and Development Authority |
| BRAIN | Brain Research through Advancing Innovative Neurotechnologies |

## C

| | |
|---|---|
| CCDBG | Child Care and Development Block Grant |
| CCE | Child Care Entitlement |
| CDC | Centers for Disease Control and Prevention |
| CHIP | Children's Health Insurance Program |
| CHIPRA | Children's Health Insurance Program Reauthorization Act |
| CMHC | Community Mental Health Centers |
| CMS | Centers for Medicare & Medicaid Services |
| CO-OP | Consumer Operated and Oriented Plan |
| CPI-U | Consumer Price Index for All Urban Consumers |
| CSE | Child Support Enforcement |

## D

| | |
|---|---|
| DOJ | Department of Justice |

## E

| | |
|---|---|
| EHR | Electronic Health Record |
| ESRD | End Stage Renal Disease |

## F

| | |
|---|---|
| FDA | Food and Drug Administration |
| FSMA | Food Safety Modernization Act |
| FTE | Full-Time Equivalent |
| FY | Fiscal Year |

## G

| | |
|---|---|
| GDM | General Departmental Management |

## H

| | |
|---|---|
| HCFAC | Health Care Fraud and Abuse Control |
| HCQO | Health Costs, Quality and Outcomes Research |
| HHS | Department of Health and Human Services |
| HIPAA | Health Insurance Portability and Accountability Act |
| HITECH | Health Information Technology for Economic and Clinical Health Act |
| HIV | Human Immunodeficiency Virus |
| HIV/AIDS | Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome |

## I

| | |
|---|---|
| IHS | Indian Health Service |
| IPAB | Independent Payment Advisory Board |
| IT | Information Technology |

## L

| | |
|---|---|
| LIHEAP | Low Income Home Energy Assistance Program |

## M

| | |
|---|---|
| MedPAC | Medicare Payment Advisory Commission |

## N

| | |
|---|---|
| NIDDK | National Institute of Diabetes and Digestive and Kidney Diseases |
| NIEHS | National Institute of Environmental Health Sciences |
| NIH | National Institutes of Health |
| NLM | National Library of Medicine |

## O

| | |
|---|---|
| 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 |
| OpDiv | Operating Division |
| OS | Office of the Secretary |

## P

| | |
|---|---|
| PAYGO | Pay-As-You-Go Act of 2010 |
| PCORTF | Patient-Centered Outcomes Research Trust Fund |
| PHS | Public Health Service |

## Q

| | |
|---|---|
| QI | Qualified Individual |
| QIO | Quality Improvement Organization |

## R

| | |
|---|---|
| RAC | Recovery Audit Contractor |

## S

| | |
|---|---|
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SSBG | Social Services Block Grant |
| SSI | Supplemental Security Income |
| StaffDiv | Staff Division |

## T

| | |
|---|---|
| TANF | Temporary Assistance for Needy Families |