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Public Health Service Agencies: Overview and Funding (FY2016-FY2018)

Updated August 16, 2017

Congressional Research Service
https://crsreports.congress.gov
R44916

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

Within the Department of Health and Human Services (HHS), eight agencies are designated components of the U.S. Public Health Service (PHS). The PHS agencies are funded primarily with annual discretionary appropriations. They also receive significant amounts of funding from other sources, including mandatory funds from the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended), user fees, and third-party reimbursements (collections).

- The **Agency for Healthcare Research and Quality (AHRQ)** funds research on improving the quality and delivery of health care. For more than a decade prior to FY2015, AHRQ did not receive its own annual appropriation. Instead, it relied on redistributed ("set-aside") discretionary funds from other PHS agencies for most of its funding, with supplemental amounts from the ACA's mandatory Patient-Centered Outcomes Research Trust Fund (PCORTF). Since FY2015, AHRQ has received an annual appropriation in lieu of any set-aside funds. The agency's FY2017 funding level of $417 million was $11 million less than the FY2016 level of $428 million.
- The **Centers for Disease Control and Prevention (CDC)** is the federal government's lead public health agency. CDC obtains its funding from multiple sources besides discretionary appropriations. The **Agency for Toxic Substances and Disease Registry (ATSDR)** investigates the public health impact of exposure to hazardous substances. ATSDR is headed by the CDC director and included in the discussion of CDC in this report. The CDC/ATSDR funding level decreased from $12.2 billion in FY2016 to $12.1 billion in FY2017.
- The **Food and Drug Administration (FDA)** regulates drugs, medical devices, food, and tobacco products, among other consumer products. The agency is funded with annual discretionary appropriations and industry user fees. The agency's funding levels for FY2016 and FY2017 remained constant at about $4.7 billion, with user fees accounting for 41% of FDA's total FY2017 funding.
- The **Health Resources and Services Administration (HRSA)** funds programs and systems that provide health care services to the uninsured and medically underserved. HRSA, like CDC, relies on funding from several different sources. The agency's funding decreased from $10.8 billion in FY2016 to $10.7 billion in FY2017.
- The **Indian Health Service (IHS)** supports a health care delivery system for Native Americans. IHS's funding, which includes discretionary appropriations and collections from third-party payers of health care, increased between FY2016 and FY2017 from $6.2 billion to $6.4 billion. Appropriations increased during that period, while collections stayed the same in both fiscal years.
- The **National Institutes of Health (NIH)** funds basic, clinical, and translational biomedical and behavioral research. NIH gets more than 99% of its funding from discretionary appropriations. Recent increases in NIH's annual appropriations have boosted its funding level to a new high of $34.1 billion in FY2017, compared with $32.3 billion in FY2016.
- The **Substance Abuse and Mental Health Services Administration (SAMHSA)** funds mental health and substance abuse prevention and treatment services. SAMHSA's funding, about 95% of which comes from discretionary

appropriations, was approximately $3.8 billion in FY2016 and $4.3 billion in FY2017.

This report supersedes two earlier products, both of which remain available: CRS Report R43304, *Public Health Service Agencies: Overview and Funding (FY2010-FY2016)*, and CRS Report R44505, *Public Health Service Agencies: Overview and Funding (FY2015-FY2017)*.

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Introduction to the PHS Agencies

The Department of Health and Human Services (HHS) has designated 8 of its 11 operating divisions (agencies) as components of the U.S. Public Health Service (PHS). The PHS agencies are (1) the Agency for Healthcare Research and Quality (AHRQ), (2) the Agency for Toxic Substances and Disease Registry (ATSDR), (3) the Centers for Disease Control and Prevention (CDC), (4) the Food and Drug Administration (FDA), (5) the Health Resources and Services Administration (HRSA), (6) the Indian Health Service (IHS), (7) the National Institutes of Health (NIH), and (8) the Substance Abuse and Mental Health Services Administration (SAMHSA).[1]

The PHS agencies all provide and support essential public health services; however, their specific missions vary. With the exception of FDA, the agencies have limited regulatory responsibilities. Two of them—NIH and AHRQ—are primarily research agencies. NIH conducts and supports basic, clinical, and translational medical research. AHRQ conducts and supports research on the quality and effectiveness of health care services and systems.

Three of the agencies—IHS, HRSA, and SAMHSA—provide health care services or help support systems that deliver such services. IHS supports a health care delivery system for American Indians and Alaska Natives. Health services are provided directly by the IHS, as well as through tribally contracted and operated health programs, and through services purchased from private providers. HRSA funds programs and systems to improve access to health care among low-income populations, pregnant women and children, persons living with Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS), rural and frontier populations, and others who are medically underserved. SAMHSA funds community-based mental health and substance abuse prevention and treatment services.

CDC is a public health agency that develops and supports community-based and population-wide programs and systems to promote quality of life and prevent the leading causes of disease, injury, disability, and death. ATSDR, which is headed by the CDC director and included in the CDC section of this report, is tasked with identifying potential public health effects from exposure to hazardous substances.

Finally, FDA is primarily a regulatory agency, whose mission is to ensure the safety of foods, dietary supplements, and cosmetics, and the safety and effectiveness of drugs, vaccines, medical devices, and other health products. In addition, FDA has authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health.

The programs and activities of five of the PHS agencies—AHRQ, CDC, HRSA, NIH, and SAMHSA—are mostly authorized under the Public Health Service Act (PHSA).[2] While some of FDA's regulatory activities are also authorized under the PHSA, the agency and its programs derive most of their statutory authority from the Federal Food, Drug, and Cosmetic Act

[1] HHS also includes three human services agencies that are not part of the Public Health Service: (1) the Administration for Children and Families (ACF); (2) the Administration for Community Living (ACL), which was created in April 2012 by consolidating the Administration on Aging (AoA), the HHS Office on Disability, and ACF's Administration on Developmental Disability; and (3) the Centers for Medicare & Medicaid Services (CMS). Departmental leadership is provided by the Office of the Secretary (OS), which comprises various staff divisions, including the Assistant Secretary for Preparedness and Response (ASPR), the Assistant Secretary for Health (ASH), the Office of the Surgeon General, the Office for Civil Rights (OCR), the Office of Inspector General (OIG), and the Office of the National Coordinator for Health Information Technology (ONC). For more information on HHS and links to the PHS agency websites, see http://www.hhs.gov/.

[2] 42 U.S.C. §§201 et seq.

(FFDCA).[3] HRSA's maternal and child health programs are authorized by the Social Security Act (SSA),[4] and many of the IHS programs and services are authorized by the Indian Health Care Improvement Act.[5] ATSDR was created by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA, the "Superfund" law).[6]

Discretionary Funding

The primary source of funding for each PHS agency is the discretionary budget authority it receives through the annual appropriations process.[7] AHRQ, CDC, HRSA, NIH, and SAMHSA are funded by the Departments of Labor, Health and Human Services, and Education, and Related Agencies (LHHS) appropriations act. Funding for ATSDR and IHS is provided by the Department of the Interior, Environment, and Related Agencies (Interior/Environment) appropriations act. FDA gets its funding through the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Agriculture) appropriations act.[8]

HHS Secretary's Transfer Authority

The annual LHHS appropriations act gives the HHS Secretary limited authority to transfer funds from one budget account to another within the department. The Secretary may transfer up to 1% of the funds in any given account. However, a recipient account may not be increased by more than 3%. Congressional appropriators must be notified in advance of any transfer.[9]

The HHS Secretary used this transfer authority in FY2013 and again in FY2014 as part of a broader effort to provide the Centers for Medicare & Medicaid Services (CMS) with additional funding to implement the Affordable Care Act (ACA).[10] In FY2013, for example, NIH was the primary source of transfers both to CMS for ACA implementation and to CDC and SAMHSA to help offset a loss of funding for those two agencies from the ACA's Prevention and Public Health Fund (PPHF, discussed below). That year, a significant portion of the PPHF funds originally allocated to CDC and SAMHSA were instead redirected to CMS, also for ACA implementation.

[3] 21 U.S.C. §§301 et seq.

[4] SSA Title V, 42 U.S.C. §§701 et seq.

[5] 25 U.S.C. §§1601 et seq.

[6] 42 U.S.C. §9604(i).

[7] Budget authority is the authority provided in federal law to incur financial obligations that will result in expenditures, or outlays, of federal funds. Such obligations include contracts for the purchase of supplies and services, liabilities for salaries and wages, and grant awards. Appropriations are the most common form of budget authority. Discretionary budget authority represents funding that is provided in and controlled by the annual appropriations acts.

[8] For an overview of each of these three appropriations acts, see CRS Report R44478, *FY2017 Labor-HHS-Education Appropriations: Status and Issues*; CRS Report R44470, *Interior, Environment, and Related Agencies: FY2017 Appropriations*; and CRS Report R44588, *Agriculture and Related Agencies: FY2017 Appropriations*.

[9] The HHS Secretary's FY2017 transfer authority was provided in Section 205 of the FY2017 LHHS appropriations act (P.L. 115-31, Division H).

[10] The ACA was signed into law on March 23, 2010 (P.L. 111-148, 124 Stat. 119). On March 30, 2010, President Obama signed the Health Care and Education Reconciliation Act (HCERA; P.L. 111-152, 124 Stat. 1029), which included several new health reform provisions and amended numerous provisions in the ACA. Several subsequently enacted bills made additional changes to selected ACA provisions. All references to the ACA in this report refer collectively to the law and to the changes made by HCERA and subsequent legislation.

In FY2014, NIH was again the primary source of transfers to CMS to support ACA implementation.[11]

PHS Evaluation Set-Aside

In addition to the transfer authority provided in the annual LHHS appropriations act, Section 241 of the PHSA authorizes the HHS Secretary, with the approval of congressional appropriators, to use a portion of the funds appropriated for programs authorized by the PHSA to evaluate their implementation and effectiveness.[12] This long-standing transfer authority is known as the Public Health Service Evaluation Set-Aside (set-aside), or PHS budget "tap."

Under this authority, the appropriations of numerous HHS programs are subject to an assessment. Although the PHSA limits the set-aside to no more than 1% of program appropriations, in recent years the annual LHHS appropriations act has specified a higher amount. The FY2017 LHHS appropriations act capped the set-aside at 2.5%, the same percentage that has been in place since FY2010.[13]

Following passage of the annual LHHS appropriations act, the HHS Budget Office calculates the assessment on each of the donor agencies and offices. These funds are then transferred to various recipient agencies and offices within the department for evaluation and other specified purposes, based on the amounts provided in the appropriations act.[14]

Table 1 shows the total assessments and transfers for FY2013, by HHS agency and office, and indicates whether the entity was a net donor or recipient of set-aside funds that year. These figures are broadly representative of the distribution of set-aside funds that occurred each fiscal year over a period of several years prior to FY2015, when the appropriators decided to make major changes to the allocation of such funds.[15]

NIH, whose annual discretionary appropriation exceeds that of all the other PHS agencies combined, is subject to the largest assessment of set-aside funds. NIH contributed almost $710 million (69%) of the $1.026 billion in set-aside funds in FY2013. However, the agency received $8 million in set-aside funding, making it a significant net donor of set-aside funds. Similarly, HRSA contributed more set-aside funds than it received in FY2013. On the other hand, AHRQ, CDC, and SAMHSA were net recipients of set-aside funding in FY2013. While not PHS

[11] Since 2014, the HHS Secretary has continued to exercise this transfer authority, but CRS has not been provided with any details about these transfers.

[12] Since FY2014, annual appropriations acts have included a provision instructing the HHS Secretary to use the PHS set-aside funds for the "evaluation ... *and* the implementation and effectiveness" of programs funded in the HHS title of the LHHS appropriations act. Previously such provisions had restricted tap funds to the "evaluation ... *of* the implementation and effectiveness" of programs authorized under the PHSA [emphasis added]. The current provision can be found in P.L. 115-31, Division H, Section 204.

[13] P.L. 115-31, Division H, Section 204.

[14] Only funds appropriated for activities and programs authorized by the PHSA are subject to an assessment. Thus, most of the funds appropriated for CDC, HRSA, NIH, and SAMHSA are assessed. The annual LHHS appropriations act excludes some funding from the set-aside; still other funding is excluded by convention. For example, funds appropriated for HHS block grants targeting prevention, substance abuse, and mental health, as well as funds for program management activities and for buildings and facilities, are typically excluded from the set-aside. Funding for agencies (e.g., ATSDR, FDA, IHS) and programs (e.g., HRSA's maternal and child health block grant) that are not authorized by the PHSA are also excluded.

[15] In **Table 1**, FY2013 and FY2016 were selected to serve as examples of how the set-aside funds were distributed before and after the appropriators made changes to the allocation of funds in FY2015. CRS does not have complete information on transfers and assessments for FY2014, FY2015, or FY2017.

agencies, the Administration for Children and Families (ACF) and various offices within the Office of the Secretary (OS) also received set-aside funds.

Table 1 also shows the set-aside assessments and transfers for FY2016. These figures reflect the significant changes that the appropriators first made in FY2015 by returning most of the set-aside funding to NIH and eliminating any transfers to AHRQ, CDC, and HRSA. As a result, NIH has gone from being by far the largest net donor of set-aside funds to a net recipient of such funding. Meanwhile, AHRQ and CDC have experienced a significant loss of set-aside funding and are now both net donors of these funds.

Table 1. PHS Evaluation Set-Aside Fund Assessments and Transfers

Dollars in Thousands

	FY2013			FY2016		
Agency/ Office	**Total Assessments**	**Total Transfers**	**Net Gain (Loss)**	**Total Assessments**	**Total Transfers**	**Net Gain (Loss)**
NIH	709,536	8,200	(701,336)	733,198	780,000	46,802
HRSA	126,340	25,000	(101,340)	209,399	—	(209,399)
CDC	116,170	375,048	258,878	156,003	—	(156,003)
SAMHSA	53,867	129,667	75,800	29,661	133,667	104,006
AHRQ	78	365,362	365,284	6,555	—	(6,555)
CMS	—	—	—	—	184,000	184,000
ACF	—	5,762	5762	—	—	—
ACL	158	—	(158)	898	—	(898)
OS	19,412	116,522	97,110	29,281	67,328	38,047
Total	**1,025,561**	**1,025,561**		**1,164,995**	**1,164,995**	

Sources: Department of Health and Human Services, "Use of Public Health Service Set-Aside Authority for Fiscal Year 2013," Report to Congress; and Department of Health and Human Services, "Use of Public Health Services Set-Aside Authority for Fiscal Year 2016," Report to Congress.

Notes: NIH = National Institutes of Health; HRSA = Health Resources and Services Administration; CDC = Centers for Disease Control and Prevention; SAMHSA = Substance Abuse and Mental Health Services Administration; AHRQ = Agency for Healthcare Research and Quality; CMS = Centers for Medicare and Medicaid Services; ACF = Administration for Children and Families; ACL = Administration for Community Living; OS = Office of the Secretary. CMS, ACF, ACL, and OS are not PHS agencies.

FY2013 and FY2016 were selected to serve as examples of how the set-aside funds were distributed before and after the appropriators made changes to the allocation of funds in FY2015. CRS does not have complete information on transfers and assessments for FY2014, FY2015, or FY2017.

The situation with AHRQ is of particular interest. From FY2003 through FY2014, AHRQ did not receive a regular annual discretionary appropriation.[16] The agency was supported by set-aside funds and, in recent years, by amounts from other sources. Since FY2015, however, AHRQ has received a discretionary appropriation in lieu of any set-aside funding.[17]

[16] The 2009 economic stimulus bill—the American Recovery and Reinvestment Act (P.L. 111-5)—provided AHRQ with a supplemental appropriation of $1.1 billion. Of that total amount, $400 million was transferred to NIH and $400 million was allocated at the discretion of the HHS Secretary. The remaining $300 million was administered by AHRQ.

[17] For more information see CRS Report R44136, *The Agency for Healthcare Research and Quality (AHRQ) Budget: Fact Sheet*.

21st Century Cures Act

Enacted in December 2016, the 21st Century Cures Act (Division A of P.L. 114-255) established three new accounts and authorizes annual transfers to the accounts to help support PHS agency programs and activities.[18] The availability of funds each year in the accounts—described in more detail below—is controlled through the annual appropriations process. In other words, the funds in the accounts are not available until appropriated. Moreover, these appropriations are to be subtracted from any cost estimates provided for purposes of budget controls. Thus, these appropriations are not to be counted against any spending limits, such as the statutory discretionary spending limits. Amounts appropriated from the accounts are considered outside those limits.

- **NIH Innovation Account.** The 21st Century Cures Act authorizes annual transfers to this account over the 10-year period FY2017-FY2026 totaling $4.796 billion. These funds are available for appropriation to NIH to help support the Precision Medicine Initiative, the BRAIN initiative, cancer research, and the use of adult stem cells in regenerative medicine (see line "NIH Innovation Account" in **Table 9**; individual amounts for each of the four activities are not listed in the table).
- **FDA Innovation Account.** The 21st Century Cures Act authorizes annual transfers to this account over the nine-year period FY2017-FY2025 totaling $500 million. These funds are available for appropriation to FDA to help support the agency's new regulatory authorities under the act (see line "FDA Innovation Account" in **Table 6**).
- **Account for the State Response to the Opioid Abuse Crisis.** The 21st Century Cures Act authorizes the transfer of $500 million to this account for each of FY2017 and FY2018. These funds are available for appropriation for state grants to address the opioid abuse crisis (see line "State Targeted Response to the Opioid Crisis" in **Table 10** (SAMHSA)).[19]

Supplemental Appropriations

HHS, and the PHS agencies in particular, have received a number of one-time supplemental appropriations in recent years to address specific circumstances. To ensure comparable presentations from year to year, the agency budget tables in this report generally do not include these amounts. Instead, they are summarized in **Appendix A**.

Mandatory Funding, User Fees, and Collections

Although the bulk of PHS agency funding is provided through annual discretionary appropriations, agencies also receive mandatory funding, user fees, and third-party collections. As discussed below, these additional sources of funding are a substantial component of the budgets of several PHS agencies.

[18] P.L. 114-255, 130 Stat. 1033, Sections 1001-1003.

[19] For additional information about these three accounts, see CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255).*

Mandatory Appropriations

The ACA included numerous appropriations that together provided billions of dollars in mandatory spending[20] to support specified grant programs and activities within HHS.[21] A few PHS agencies continue to receive these funds, which are itemized in the funding tables in this report.

The ACA also established and funds three multibillion dollar trust funds to help support PHS agency programs and activities:

- **Community Health Center Fund (CHCF).** The ACA provided the CHCF a total of $11 billion in annual appropriations over the five-year period FY2011-FY2015.[22] These funds helped support the federal health centers program and the National Health Service Corps (NHSC), both administered by HRSA. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[23] appropriated two more years of funding for the CHCF—a total of $3.910 billion for each of FY2016 and FY2017. A table summarizing each fiscal year's CHCF appropriation and the allocation of funds appears in **Appendix B**.
- **Prevention and Public Health Fund (PPHF).** The ACA provided the PPHF with a permanent annual appropriation. These funds are intended to support prevention, wellness, and other public health programs and activities authorized by the PHSA.[24] For example, the HHS Secretary transferred almost half of the FY2013 PPHF funds to CMS to support ACA implementation. To date, CDC has received the majority of PPHF funds, while AHRQ, HRSA, and SAMHSA have received smaller amounts. A table showing the allocation of annual PPHF funding by agency since FY2010 is provided in **Appendix C**.
- **Patient-Centered Outcomes Research Trust Fund (PCORTF).** This fund is supporting comparative effectiveness research over a 10-year period (FY2010-FY2019) with a mix of appropriations—some of which are offset by revenue from a fee imposed on health insurance policies and self-insured health plans—and transfers from the Medicare Part A and Part B trust funds.[25] A portion of the PCORTF funding is allocated to AHRQ. More information on the PCORTF, including the appropriation and transfer formulas, is provided in **Appendix D**.

In addition to the ACA funding, HRSA, CDC, and IHS each receive mandatory funds from other sources. HRSA's Family-to-Family Health Information Centers Program has been funded by a series of mandatory appropriations since FY2007; CDC receives Medicaid funding to support the Vaccines for Children program; and both IHS and NIH receive mandatory funds for diabetes

[20] Mandatory spending, also known as direct spending, refers to spending that is controlled by laws other than annual appropriations acts, and includes spending on entitlement programs. Most mandatory spending is budget authority that is both provided and controlled by the program's authorizing statute (e.g., Social Security, 42 U.S.C. §401 et seq.). However, for some mandatory spending—referred to as appropriated entitlement spending—the authorizing statute controls the program parameters (e.g., the eligibility rules, benefit levels) that entitle certain recipients to payments. The amounts necessary to finance those entitlements, however, are provided by appropriations acts each fiscal year.

[21] For a complete list and discussion of all the appropriations in the ACA, including details of the obligation of these funds, see CRS Report R41301, *Appropriations and Fund Transfers in the Affordable Care Act (ACA)*.

[22] ACA Section 10503(a)-(b).

[23] P.L. 114-10, 129 Stat. 87.

[24] ACA Section 4002, as amended; 42 U.S.C. §300u-11.

[25] ACA Section 6301(d)-(e).

programs. These and other mandatory appropriations are itemized in the agency funding tables in this report.

The use of mandatory funding, including amounts provided by the ACA, has become an important component of PHS agency budgeting in recent years. Mandatory funds are not controlled by the annual appropriations process and generally do not count toward the discretionary spending caps, discussed below.

User Fees

Several PHS agencies assess user fees on third parties to help fund their programs and activities. User fees collected by CDC, HRSA, and SAMHSA represent a relatively small portion of each agency's overall budget.[26] In comparison, the industry user fees that FDA collects help finance a broad range of the agency's regulatory activities and account for a substantial and growing share of the agency's budget.

In 1992, the Prescription Drug User Fee Act (PDUFA)[27] established the first user fee program at FDA. Since PDUFA's enactment, Congress has created several other FDA user fee programs. These programs provide FDA with additional resources that allow it to hire more personnel and expedite the process of reviewing new product applications. Some user fees also pay for information technology infrastructure and postmarket surveillance of FDA-approved products. FDA's user fee programs now support the agency's regulation of prescription drugs, animal drugs, medical devices, tobacco products, and some foods, among other activities. The amount of user fees that FDA collects under these programs has increased steadily since PDUFA was enacted, both in absolute terms and as a share of FDA's overall budget. In FY2017, user fees account for 41% of the agency's funding. More discussion of user fees is provided in the FDA section of this report and in **Appendix E**.

IHS Third-Party Collections

IHS supplements its annual discretionary appropriation with third-party collections from public and private payers. Most of these funds come from Medicare and Medicaid, which reimburse IHS for services provided to American Indians and Alaska Natives enrolled in these programs at facilities operated by IHS and the tribes. IHS also collects reimbursements from private health insurers. IHS collections (and reimbursements) are reflected in **Table 8** of this report.

Recent Trends in PHS Agency Funding

Congress has taken a number of recent steps through both the annual appropriations process and the enactment of deficit-reduction legislation to reduce the growth in federal spending. These actions, briefly discussed below, have had an impact on the level of discretionary funding for several PHS agencies since FY2010.

Among the five PHS agencies funded through the LHHS appropriations act, AHRQ has seen a reduction in discretionary funding over the past seven years. However, that reduction for the most part was offset by the agency's receipt of mandatory funding. Discretionary funding for the other four agencies—CDC, HRSA, NIH, and SAMHSA—has fluctuated in recent years, dipping in

[26] These user fees are listed in the agency-specific tables in this report.

[27] P.L. 102-571, Title I, 106 Stat. 4491.

FY2013 as a result of the sequestration of discretionary appropriations that fiscal year (see below). Both CDC and HRSA have received increasing amounts of mandatory funding since FY2010, which has raised each agency's overall funding level.

FDA and IHS, which receive their discretionary funding through the Agriculture and Interior/Environment appropriations acts, respectively, have seen their appropriations increase since FY2010. In addition, both agencies have witnessed a steady increase in funding from other sources—user fees at FDA, and third-party collections at IHS.

Impact of Budget Caps and Sequestration

In April 2011, lawmakers agreed to cuts in discretionary spending for a broad range of agencies and programs as part of negotiations to complete the FY2011 appropriations process and avert a government shutdown. Four months later, during negotiations to raise the debt ceiling, Congress and President Obama enacted the Budget Control Act of 2011 (BCA).[28] The BCA established enforceable discretionary spending limits, or caps, for defense and nondefense spending for each of FY2012 through FY2021, and provided for further annual reductions to the caps equally divided between the categories of defense and nondefense spending beginning in FY2013. All the spending summarized in this report falls within the nondefense category. Within each spending category, those further reductions are allocated proportionately to discretionary spending and mandatory spending, subject to certain exemptions and special rules.

Under the BCA, the spending reductions are achieved through two different methods: (1) sequestration (i.e., an across-the-board cancellation of budgetary resources), and (2) lowering the BCA-imposed discretionary spending caps. The Office of Management and Budget (OMB) is responsible for calculating the percentages and amounts by which mandatory and discretionary spending are required to be reduced each year, and for applying the relevant exemptions and special rules.

Mandatory Spending

The BCA requires mandatory spending reductions to be executed each year through FY2021 via a sequestration of all nonexempt accounts. Generally, the ACA and other mandatory funding discussed in this report is fully sequestrable at the applicable percentage rate for nonexempt nondefense mandatory spending for PHS agencies (see **Table 2**), with the following key exceptions. First, the funds for the CDC-administered Vaccines for Children program come from Medicaid, which is exempt from sequestration. Second, CDC funding for the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) and the World Trade Center Health Program also are exempt from sequestration. Third, under the sequestration special rules, cuts in CHCF funding for community health centers and migrant health centers and the cuts in mandatory diabetes funding for IHS are capped at 2% (see **Table 2**).

The OMB calculation for the upcoming fiscal year's mandatory spending sequestration order is announced at the same time that the President's budget is released each fiscal year. That amount is not recalculated for the subsequent enactment of additional mandatory spending. Thus, while all the nonexempt PHS programs with mandatory funding were sequestered in FY2013, FY2014, and FY2017, some programs avoided sequestration in FY2015 and/or FY2016 because budgetary

[28] P.L. 112-25, 125 Stat. 240. The BCA amended the Balance Budget and Emergency Deficit Control Act of 1985 (BBEDCA; P.L. 99-177; Title II, 99 Stat. 1038). For more information, see CRS Report R41965, *The Budget Control Act of 2011*.

resources had not yet been enacted at the time the sequestration was ordered. The Maternal, Infant, and Early Childhood Home Visiting program, administered by HRSA, is an example of one such program (see **Table 7**). The ACA authorized the home visiting program and funded it through FY2014. Subsequently, in two separate legislative actions, funding was extended for the home visiting program through FY2017. However, at the time the OMB calculation was announced for FY2015, and again for FY2016, that funding extension had not been enacted, so there were no budgetary resources for that program included in the sequestration order.[29]

Table 2. Sequestration of Funding for PHS Agency Programs

FY2013-FY2018

Program	Percentage Reduction					
	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
Mandatory Spending						
Nonexempt programs	5.1%[a]	7.2%	7.3%	6.8%	6.9%	6.6%
Community & migrant health centers, IHS	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Discretionary Spending						
Nonexempt programs	5.0%[a]	NA[b]	NA[b]	NA[b]	NA[b]	NA[b]

Sources: OMB Report to the Congress on the Joint Committee Sequestration for Fiscal Year 2013, March 1, 2013; OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2014, May 20, 2013; OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2015, March 10, 2014; OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2016, February 2, 2015; OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2017, February 9, 2016; and OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2018, May 23, 2017.

a. These percentages reflect adjustments made by the American Taxpayer Relief Act of 2012 (ATRA; P.L. 112-240), which amended the BCA by reducing the overall dollar amount that needed to be cut from FY2013 spending.

b. Not applicable.

Discretionary Spending

Under the BCA, FY2013 discretionary spending was also reduced through sequestration. However, for each of the remaining fiscal years (i.e., FY2014 through FY2021), the annual reductions in discretionary spending required under the BCA are to be achieved by lowering the discretionary spending caps by the total dollar amount of the required reduction. This means that the cuts within the lowered spending cap may be apportioned through the annual appropriations decisionmaking, rather than via an across-the-board reduction through sequestration.

FY2013 Sequestration

In general, PHS agency discretionary appropriations in FY2013 were fully sequestrable at the applicable percentage rate for nonexempt nondefense discretionary spending (see **Table 2**). As a

[29] While a full accounting of this anomaly is beyond the scope of this report, the following programs listed in the tables in the report were not sequestered in the years indicated in parentheses because there were no mandatory budgetary resources enacted at the time the sequestration was ordered: (1) CHCF – health centers, NHSC (FY2016); (2) Maternal, Infant, and Early Childhood Home Visiting program (FY2015, FY2016); (3) Family-to-Family Information Centers (FY2014, FY2015, FY2016); and (4) IHS and NIH mandatory diabetes funding (FY2015, FY2016).

result, each agency saw a dip in its discretionary funding for FY2013. OMB determined that FDA user fees for FY2013 were fully sequestrable, but it concluded that IHS's third-party collections in FY2013 were exempt from sequestration.

FY2014-FY2018 Nondefense Discretionary Spending Caps

Table 3 shows the original nondefense discretionary (NDD) spending caps for FY2014-FY2018 established by the BCA. For each of these five fiscal years, the BCA required the caps to be lowered by approximately $37 billion to achieve the necessary reduction in NDD spending.

The Bipartisan Budget Act of 2013 (BBA13)[30] amended the BCA by establishing new levels for the FY2014 and FY2015 spending caps, and by eliminating the requirement for those caps to be reduced. While the BBA13 caps were set at a level that was lower than the original BCA caps (see **Table 3**), they were higher than the BCA-lowered caps that they replaced.

The Bipartisan Budget Act of 2015 (BBA15)[31] further amended the BCA by establishing new levels for the FY2016 and FY2017 NDD spending caps, and by eliminating the requirement for those caps to be lowered. Once again, the BBA15 caps were set at a level below the original BCA caps for those two fiscal years (see **Table 3**), but higher than the BCA-lowered caps that they replace.

The revised caps allowed an additional $26 billion for nondefense programs in FY2016 compared with the previous fiscal year. However, virtually no increase in appropriations is allowed by the BBA15 revised cap level for FY2017. The revised cap for FY2017 is only $40 million above the revised cap for FY2016.

For FY2018, OMB has calculated that the NDD spending cap of $553 billion will be lowered by $37.251 billion to $515.749 billion—pursuant to the BCA—which is almost $3 billion below the FY2017 revised cap level (see **Table 3**).[32]

Table 3. Nondefense Discretionary Spending Limits

Billions of Dollars

	FY2014	FY2015	FY2016	FY2017	FY2018
Original caps under BCA	510.000	520.000	530.000	541.000	553.000
Revised caps[a]	491.773	492.356	518.491	518.531	515.749

Source: Budget Control Act of 2011 (P.L. 112-25); Bipartisan Budget Act of 2013 (P.L. 113-67, Division A); Bipartisan Budget Act of 2015 (P.L. 114-74); OMB Sequestration Preview Report to the President and Congress for Fiscal Year 2018, May 23, 2017.

a. Pursuant to BBA13 (FY2014 & FY2015), BBA15 (FY2016 & FY2017), and OMB (FY2018).

[30] P.L. 113-67, Division A; 127 Stat. 1165.

[31] P.L. 114-74, 129 Stat. 584.

[32] Office of Management and Budget, *OMB Sequestration Preview Report to the President and Congress for Fiscal Year 2018*, May 23, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/sequestration_reports/2018_preview_report_may2017_potus.pdf.

Report Roadmap

The remainder of this report consists of seven sections, one for each PHS agency, beginning with AHRQ.[33] Each section includes an overview of the agency's statutory authority and principal activities, and a brief summary of recent trends in the agency's funding. This material is accompanied by a detailed funding table showing the agency's FY2016 and FY2017 funding, as well as the requested amounts in the FY2018 budget.

The funding amounts for FY2016 and the FY2018 request are based on the FY2018 budget documents,[34] whereas the amounts for FY2017 are taken from the LHHS appropriations table in the joint explanatory statement to accompany the FY2017 LHHS appropriations act.[35] Note that the FY2017 amounts may in some instances differ from the agency's final operating levels due to transfers, reprogramming, or other adjustments.

The funding tables show the post-sequestration amounts for the accounts that were subject to sequestration, unless indicated otherwise.

The funding tables are formatted in a similar, though not identical, manner. The formatting generally matches the way in which each agency's funding is presented in the congressional budget documents. Each table shows the funding for all the agency's budget accounts and, typically, for selected programs and activities within those accounts. These amounts are summed to give the agency's total, or *program level*, funding. At the bottom of the table any user fees, set-aside funds, ACA funds, and other nondiscretionary amounts are subtracted from the program level to give the agency's *discretionary budget authority* (i.e., annual discretionary appropriations).

The tables for AHRQ, CDC, HRSA, and SAMHSA include non-add entries—italicized and in parentheses—to indicate the contribution of funding to specific accounts from sources other than the agency's discretionary appropriations. Almost all of the CDC accounts, for example, are funded with discretionary appropriations plus amounts from other sources (see **Table 5**).

The use of a dash in the funding tables generally means "not applicable." Either the activity or program was not authorized or there was no mandatory funding provided for that fiscal year. In contrast, a zero usually indicates that congressional appropriators had chosen not to appropriate any discretionary funds that year.

It is important to keep in mind that the PHS agency funding tables that appear in budget documents and appropriations committee reports, as well as the tables in this report, show only the amount of evaluation set-aside funds received. They do not reflect the amount of funding assessed on agency accounts. As a result, the funding tables for the PHS agencies subject to an assessment can give a somewhat distorted view of their available budgetary resources by not subtracting the assessment amounts. This effect has been particularly significant in the case of the three agencies—CDC, HRSA, and NIH—that are subject to a significant assessment under the evaluation set-aside authority (see **Table 1**).

[33] ATSDR and its budget are included in the discussion of CDC.

[34] The department and agency budget documents are available at http://www.hhs.gov/budget/.

[35] "Division H–Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2017," Explanatory Statement of the Consolidated Appropriations Act, 2017, *Congressional Record*, vol. 163, part III (May 3, 2017), pp. H3958-H4030.

Agency for Healthcare Research and Quality (AHRQ)[36]

Agency Overview

AHRQ supports research designed to improve the quality of health care, increase the efficiency of its delivery, and broaden access to health services.[37] Specific research efforts are aimed at reducing the costs of care, promoting patient safety, measuring the quality of health care, and improving health care services, organization, and financing. AHRQ is required to disseminate its research findings to health care providers, payers, and consumers, among others. In addition, the agency collects data on health care expenditures and utilization through the Medical Expenditure Panel Survey (MEPS) and the Healthcare Cost and Utilization Project (HCUP).

For more information

CRS Report R44136, *The Agency for Healthcare Research and Quality (AHRQ) Budget: Fact Sheet*

AHRQ has evolved from a succession of agencies concerned with fostering health services research and health care technology assessment. The Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) added a new PHSA Title IX and established the Agency for Health Care Policy and Research (AHCPR), a successor agency to the former National Center for Health Services Research and Health Care Technology Assessment (NCHSR). AHCPR was reauthorized in 1992 (P.L. 102-410). On December 6, 1999, President Clinton signed the Healthcare Research and Quality Act of 1999 (P.L. 106-129), which renamed AHCPR as AHRQ and reauthorized appropriations for its programs and activities through FY2005. Congress has yet to reauthorize the agency's funding. Despite the expired authorization of appropriations, AHRQ continues to get annual funding.

The AHRQ budget is organized according to three program areas: (1) Healthcare Costs, Quality, and Outcomes (HCQO) Research; (2) MEPS; and (3) program support. HCQO research currently focuses on four priority areas, summarized in the text box below.

Health Costs, Quality, and Outcomes (HCQO) Research Areas

Health Information Technology (HIT). Research evaluating HIT and its impact on the quality and efficiency of health care.

Patient Safety Research. Research on reducing and preventing medical errors, with a focus on health care-associated infections (HAIs).

Health Services Research, Data and Dissemination. Research on quality of health care that spans multiple priority areas, including, for example, the annual National Healthcare Quality and National Healthcare Disparities Reports.

Prevention/Care Management. AHRQ provides the U.S. Preventive Services Task Force (USPSTF) with scientific, administrative, and other types of support, although the Task Force is an independent panel of national experts.

From FY2003 through FY2014, AHRQ did not receive its own annual discretionary appropriation. Instead, the agency largely relied on the PHS evaluation set-aside to fund its activities and programs. In recent years, AHRQ has received mandatory funds from the PPHF (see **Appendix C**) and the PCORTF (see **Appendix D**). In FY2015, AHRQ received its own

[36] This section was written by Amanda K. Sarata, Specialist in Health Policy.

[37] See the AHRQ website at http://www.ahrq.gov.

discretionary appropriation for the first time in more than a decade in lieu of any set-aside funding.[38] This trend continued in FY2016 and FY2017, with the agency receiving its own discretionary appropriation and no set-aside funds.

President Trump's FY2018 budget proposes to consolidate AHRQ under NIH by adding a new institute within NIH, the National Institute for Research on Safety and Quality (NIRSQ). The request would provide NIRSQ with $272 million in budget authority, which would bring the total funding available to $379 million for FY2018 for AHRQ-related activities continued under the new institute (this amount includes the estimated PCORTF transfer of $107 million for FY2018). This would represent a decrease of $38 million from AHRQ's FY2017 program level. The request would eliminate funding for Health Information Technology (HIT) research and would decrease or keep level funding for Patient Safety research and Prevention/Care Management. It would increase funding for MEPS; exact amounts for Health Services Research, Data, and Dissemination and Program Support are not specified in the request.[39]

Recent Trends in Agency Funding

Since FY2010, AHRQ's budget has increased from $403 million to $417 million (+$14 million), with transfers from PCORTF growing from $8 million in FY2011 to an estimated $93 million in FY2017. Discretionary sources of funding shifted from set-aside transfers to the agency's own discretionary appropriation beginning in FY2015, and this trend continued through FY2017. In addition, ACA mandatory funds have been a prominent and generally increasing source of funding for the agency since FY2010. AHRQ's program level had been increasing steadily between FY2011 and FY2015, with decreases in discretionary funding being more than offset by transfers of PCORTF funds. However, in FY2016, the total program level for the agency decreased for the first time since FY2011. This decline continued in FY2017, with a decreasing PCORTF transfer estimated for the first time since the trust fund's inception (see **Table 4**). In **Table 4**, the funding presented in the 2018 request column would go to the NIH/NIRSQ to carry out the functions within AHRQ designated to be continued under the President's budget. These amounts are also listed in the NIH section (**Table 9**).

Table 4. Agency for Healthcare Research and Quality (AHRQ)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2016	2017	2018 Request
HCQO Research	**197**	**187**	**n/s[a]**
Health Information Technology Research	22	17	0
Patient Safety	74	70	70
Health Services Research, Data, and Dissemination[b]	89	89	n/s
PHS Evaluation Set-Aside (non-add)	*(0)*	*(0)*	*(0)*
Prevention/Care Management (USPSTF)	12	12	7

[38] FY2009 was the one exception. AHRQ received a supplemental discretionary appropriation that year from the American Recovery and Reinvestment Act of 2009 (P.L. 111-5).

[39] The information in this paragraph is drawn primarily from the *FY2018 HHS Budget in Brief*, National Institutes of Health, pp. 36-42. AHRQ does not have a congressional budget justification for FY2018, nor does it have its own entry in the *FY2018 Budget in Brief*, so there is limited information available to determine how the proposed FY2018 budget for NIH/NIRSQ would map to AHRQ's budget from prior years.

MEPS	**66**	**66**	**70**
Program Support	**71**	**71**	**n/s**
PCORTF (Patient-Centered Health Research)[c]	**94**	**93**	**107**
Total, Program Level	**428**	**417**	**379**
Less Funds From Other Sources			
PHS Evaluation Set-Aside	0	0	0
PCORTF Transfers	94	93	107
Total, Discretionary Budget Authority	**334**	**324**	**272**

Sources: Amounts for FY2016 and the FY2018 request are from the AHRQ FY2018 *Justification of Estimates for Appropriations Committees*, available at http://www.hhs.gov/budget/. The FY2017 amounts are from the 2017 Consolidated Appropriations Act (P.L. 115-31) and its Explanatory Statement (for H.R. 244 in the May 3, 2017 Congressional Record).

Notes: Individual amounts may not add to subtotals or totals due to rounding.

a. Where n/s appears, it denotes that the specific breakdown of funding for this category was not specified.

b. Formerly "Crosscutting Activities"; also formerly "Research Innovations."

c. AHRQ receives funds transferred from the PCORTF to carry out PHSA Section 937, which requires the dissemination of the results of patient-centered outcomes research carried out by the Patient Centered Outcomes Research Institute (PCORI) and other "government-funded research relevant to comparative clinical effectiveness research." For FY2011-FY2013, the PCORTF transfer supplemented the agency's set-aside funding for its patient-centered health research program. Since FY2014, however, AHRQ's patient-centered health research program has been entirely funded by the PCORTF transfer, which is now shown as its own separate budget line. AHRQ's budget documents no longer list patient-centered health research as a separate program area.

Centers for Disease Control and Prevention (CDC)[40]

Agency Overview

CDC's mission is to "to protect America from health, safety and security threats, both foreign and in the [United States]."[41] CDC is organized into a number of centers, institutes, and offices. Some of these focus on specific public health challenges (e.g., chronic disease prevention, injury prevention); others focus on general public health capabilities (e.g., surveillance and laboratory services).[42] In addition, the Agency for Toxic Substances and Disease Registry (ATSDR), discussed below, is headed by the CDC Director.

Many CDC activities are not specifically authorized but are based in broad, permanent statutory authorities in the PHSA.[43] Four CDC operating divisions are explicitly authorized: (1) the National Institute for Occupational Safety and Health (NIOSH) was permanently authorized by the Occupational Safety and Health Act of 1970; (2) the National Center on Birth Defects and Developmental Disabilities (NCBDDD) was established in PHSA Section 317C by the Children's Health Act of 2000; (3) the National Center for Health Statistics (NCHS) was established in

[40] This section was written by Sarah A. Lister, Specialist in Public Health and Epidemiology.

[41] See the CDC website at https://www.cdc.gov/about/organization/mission.htm.

[42] Information about CDC's organization is available at http://www.cdc.gov/about/organization/cio.htm.

[43] For example, PHSA Section 301 authorizes the Secretary of HHS to conduct research and investigations as necessary to control disease, and Section 317 authorizes the Secretary to award grants to states for preventive health programs.

PHSA Section 306 by the Health Services Research, Health Statistics, and Medical Libraries Act of 1974; and (4) ATSDR was established by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA, the "Superfund" law).[44] Authorizations of appropriations for NCBDDD, NCHS, and ATSDR have expired, but the programs continue to receive annual appropriations.

Most of CDC's spending is extramural. In FY2016, CDC provided $6.6 billion in grants for public health programs and research around the world.[45] The agency has few regulatory responsibilities.

Recent Trends in Agency Funding

Table 5 presents funding levels for CDC programs for FY2016 through the FY2018 request. In addition to annual discretionary appropriations, program level amounts for recent years include funds from the following four mandatory appropriations: (1) the Vaccines for Children (VFC) program;[46] (2) NIOSH activities to support the Energy Employees Occupational Illness Compensation Program Act (EEOICPA);[47] (3) the World Trade Center Health Program (WTCHP);[48] and (4) appropriations provided under ACA, principally through the PPHF.[49] CDC receives a small amount of funds from authorized user fees, and it may receive funds from supplemental appropriations and other transfers.

When considering funding trends for CDC/ATSDR, it is useful to consider mandatory and discretionary funds separately. For example, for FY2017, the CDC/ATSDR total operating budget, or program level, is $12.1 billion. This amount comprises

- $6.3 billion (52%) in discretionary funds (i.e., budget authority) for CDC provided in the LHHS appropriations act;
- $4.4 billion (37%) in mandatory Medicaid funds for VFC (this amount is often excluded from analyses of overall CDC budget trends);
- $847 million (7%) in mandatory PPHF funds;
- $402 million (3%) in other mandatory funds, namely EEOICPA and WTCHP;
- $75 million (<1%) in discretionary funds for ATSDR provided in Interior/Environment appropriations; and
- $17 million (<1%) from authorized user fees and other transfers.

The CDC/ATSDR program level has generally increased since FY2010, with the increase coming primarily from growth in mandatory spending (particularly VFC) rather than discretionary appropriations.[50]

The President's FY2018 request proposes to cut CDC budget authority by almost $1.2 billion from the enacted FY2017 level, to $5.1 billion. This includes a proposed $326 million reduction

[44] 29 U.S.C. §671; 42 U.S.C. §247b-4; 42 U.S.C. §242k; and 42 U.S.C. §9604(i).

[45] See CDC, "FY2016 Assistance Snapshot," https://www.cdc.gov/funding/documents/fy2016/fy-2016-ofr-assistance-snapshot.pdf.

[46] See CDC, "Vaccines for Children Program," http://www.cdc.gov/vaccines/programs/vfc/index.html.

[47] See CDC, EEOICPA, "Frequently Asked Questions," http://www.cdc.gov/niosh/ocas/faqsact.html.

[48] See CDC, "World Trade Center Health Program," http://www.cdc.gov/wtc/index.html.

[49] CRS Report R44796, *The ACA Prevention and Public Health Fund: In Brief*.

[50] See CRS Report R43304, *Public Health Service Agencies: Overview and Funding (FY2010-FY2016)*.

in budget authority for CDC chronic disease prevention programs, from the enacted FY2017 level of $778 million to $452 million. The budget proposes to consolidate several chronic disease programs (e.g., for diabetes and heart disease) into a new $500 million "America's Health Block Grant," to allow states and territories to tailor spending to their specific challenges. Similar consolidations were proposed by the Obama Administration but were not adopted in appropriations acts.

Table 5. Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2016	2017	2018 Request
Immunization and Respiratory Diseases	797	794	701
PPHF Transfer (non-add)	*(324)*	*(324)*	*(204)*
PHSSEF Influenza Transfers (non-add)	*(15)*	*(15)*	*0*
Vaccines for Children (VFC)[a]	4,400	4,437	4,598
HIV/AIDS, Viral Hepatitis, STI and TB	1,121	1,117	934
Emerging & Zoonotic Infectious Diseases	582	585	514
PPHF Transfer (non-add)	*(52)*	*(52)*	*(137)*
Chronic Disease Prevention and Health Promotion	1,177	1,116	952
PPHF Transfer; multiple programs (non-add)	*(339)*	*(338)*	*0*
PPHF Transfer; America's Health Block Grant (non-add)	*0*	*0*	*(500)*
ACA Mandatory: Childhood Obesity Research Demonstration[b]	10	—	—
Birth Defects, Developmental Disabilities, Disability and Health	136	138	100
Environmental Health	182	215	157
PPHF Transfer (non-add)	*(17)*	*(17)*	*0*
Childhood Lead Poisoning Prevention, P.L. 114-254 (non-add)	—	*(35)*	—
Injury Prevention and Control	236	286	216
Public Health Scientific Services	491	489	460
Occupational Safety and Health	339	335	200
Global Health	427	435	350
Public Health Preparedness and Response	1,413	1,405	1,266
CDC-wide Activities	411	274	105
PPHF Transfer; Prevention Block Grant (non-add)	*(160)*	*(160)*	*0*
Buildings and Facilities	10	10	20
User Fees	2	2	2
EEOICPA	50	55	55
WTCHP[c]	313	347	366
Agency for Toxic Substances and Disease Registry (ATSDR)	75	75	62
Total, CDC/ATSDR Program Level	**12,172**	**12,115**	**11,059**

Program or Activity	2016	2017	2018 Request
Less Funds From Other Sources			
VFC[a]	4,400	4,437	4,598
EEOICPA	50	55	55
PHSSEF Transfers	15	15	0
ACA Mandatory: PPHF Transfers	892[d]	891[d]	841[d]
ACA Mandatory: Childhood Obesity Research Demonstration[b]	10	—	—
WTCHP[c]	313	347	366
User Fees	2	2	2
Total, CDC/ATSDR Discretionary BA	**6,490**	**6,368**	**5,196**
Less ATSDR Discretionary BA	75	75	62
Total, CDC Discretionary BA	**6,414**	**6,293**	**5,134**

Sources: Amounts for FY2016 and the FY2018 request are from the CDC FY2018 *Justification of Estimates for Appropriations Committees*, available at http://www.hhs.gov/budget/. The FY2017 amounts are from the 2017 Consolidated Appropriations Act (P.L. 115-31) and its Explanatory Statement (for H.R. 244 in the May 3, 2017 Congressional Record).

Notes: Individual amounts may not add to subtotals or totals due to rounding. PHSSEF is Public Health and Social Services Emergency Fund, a fund used by appropriators to provide the Secretary with ongoing or one-time emergency funding, such as for the response to influenza epidemics. STI is sexually transmitted infection. TB is tuberculosis.

All PPHF amounts reflect sequestration of nondefense mandatory spending; see **Table 3**.

Amounts in this table do not include emergency supplemental Zika response funding for FY2015-FY2019 provided in P.L. 113-235. These funds are discussed in CRS Report R44460, *Zika Response Funding: Request and Congressional Action*; and at CDC, "Fighting Zika 24/7: CDC's Response to Zika," March 29, 2017, https://www.cdc.gov/zika/specific-groups/funding.html.

In addition to other ACA mandatory amounts presented, ACA Section 10323(b) appropriated $23 million for the period FY2010-FY2014 and $20 million for each five-year period thereafter, in no-year funding for the early detection of certain medical conditions related to environmental health hazards in Libby, MT.

a. The Vaccines for Children (VFC) program provides free pediatric vaccines to doctors who serve eligible (generally low-income) children. VFC is funded entirely as an entitlement through federal Medicaid appropriations and is exempt from sequestration. FY2016-FY2018 amounts are estimated transfers from Medicaid.

b. ACA Section 4306 appropriated $25 million for a childhood obesity demonstration project, http://www.cdc.gov/obesity/childhood/researchproject.html. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, P.L. 114-10) appropriated additional funding for the project ($10 million for the two-year period FY2016–FY2017).

c. FY2016-FY2018 amounts are estimated federal obligations and do not include the New York City matching contribution.

d. PPHF amounts for FY2016 and FY2017 were transferred to the Childhood Lead Poisoning Prevention Program, and are in addition to the $35 million appropriated for FY2017 in P.L. 114-254.

Food and Drug Administration (FDA)[51]

Agency Overview

FDA regulates the safety of human foods, dietary supplements, cosmetics, and animal foods, as well as the safety and effectiveness of human drugs, biological products (e.g., vaccines), medical devices, and animal drugs. FDA also regulates the manufacture of radiation-emitting products to protect the public from hazardous levels of radiation. In 2009, Congress gave FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health.

Seven centers within FDA represent the broad program areas for which the agency has responsibility: (1) the Center for Biologics Evaluation and Research (CBER), (2) the Center for Devices and Radiological Health (CDRH), (3) the Center for Drug Evaluation and Research (CDER), (4) the Center for Food Safety and Applied Nutrition (CFSAN), (5) the Center for Veterinary Medicine (CVM), (6) the National Center for Toxicological Research (NCTR), and (7) the Center for Tobacco Products (CTP). Several other offices have agency-wide responsibilities.

For more information

CRS Report R44576, *The Food and Drug Administration (FDA) Budget: Fact Sheet*

The Federal Food, Drug, and Cosmetic Act (FFDCA) is the principal source of FDA's statutory authority.[52] FDA is also responsible for administering certain provisions in other laws, most notably the PHSA.[53] Although the FDA's authorizing committees in Congress are the committees with jurisdiction over public health issues—the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce—FDA's assignment within the appropriations committees reflects its origin as part of the Department of Agriculture. The Senate and House appropriations subcommittees on Agriculture, Rural Development, FDA, and Related Agencies have jurisdiction over FDA's budget, even though the agency has been part of various federal health agencies (HHS and its predecessors) since 1940.

FDA's budget has two funding streams: annual appropriations (i.e., discretionary budget authority, or BA) and industry user fees.[54] In FDA's annual appropriation, Congress sets both the total amount of appropriated funds and the amount of user fees that the agency is authorized to collect and obligate for that fiscal year. Appropriated funds are largely for the Salaries and Expenses account, with a smaller amount for the Buildings and Facilities account. The appropriations of the several different user fees contribute only to the Salaries and Expenses account.

[51] This section was written by Agata Dabrowska, Analyst in Health Policy.

[52] 21 U.S.C. §§301 et seq.

[53] PHSA Section 351 (21 U.S.C. §262) authorizes the regulation of biological products and states that FFDCA requirements apply to biological products licensed under the PHSA. A listing of other laws containing provisions for which FDA is responsible is available at http://www.fda.gov/RegulatoryInformation/Legislation/default.htm.

[54] While both funding streams are discretionary budget authority, in keeping with the convention used in FDA's *Justification of Estimates for Appropriations Committees* and in previous iterations of this report, the term *budget authority* refers to the agency's discretionary appropriations from the General Fund, and the term *user fees* refers to dedicated collections to the federal government paid by the pharmaceutical and other industries.

The largest and oldest FDA user fee that is linked to a specific program was first authorized by the Prescription Drug User Fee Act (PDUFA, P.L. 102-571) in 1992. **Appendix E** presents the authorizing legislation for current FDA user fees, sorted by the dollar amount they contribute to the agency's FY2017 budget. After PDUFA, additional laws were enacted to provide user fee authorities regarding medical devices, animal drugs, animal generic drugs, tobacco products, priority review, food reinspection, food recall, voluntary qualified food importer, generic drugs, biosimilars, and, most recently, outsourcing facilities (related to drug compounding) and some wholesale distributors and third-party logistics providers (related to pharmaceutical supply chain security).[55] Each of the medical product fee authorities requires reauthorization every five years.[56] Several indefinite authorities, which do not need to be reauthorized, apply to fees for mammography inspection, color additive certification, export certification, and priority review vouchers.[57]

In the 114th Congress, the 21st Century Cures Act was signed into law (Division A of P.L. 114-255). Among other things, the Cures Act modified the drug and device development and approval pathways at FDA to support innovation. To help fund the activities and programs authorized in the Cures Act, the law created an FDA Innovation Account, to which a total of $500 million is authorized to be transferred over a nine-year period (FY2017-FY2025).[58] The availability of funds in the Innovation Account is controlled through the annual appropriations process.

Recent Trends in Agency Funding

Since the enactment of PDUFA in 1992, FDA revenue from user fees has generally increased, both in absolute terms and as a share of FDA's total funding, accounting for 41% of the agency's FY2017 total program level.

The Trump Administration's FY2018 request includes $3.223 billion in user fees,[59] an increase of 65% over the FY2017-enacted amount (see **Table 6**). Under the Administration's request, user fees would account for 63% of the FDA's total program level. This proposed increase in user fee revenue is accompanied by a proposed decrease in the agency's direct appropriation—about $900 million below the FY2017-enacted amount. This increase in user fee revenue and decrease in the

[55] CRS Report R42366, *Prescription Drug User Fee Act (PDUFA): 2012 Reauthorization as PDUFA V*; CRS Report R42508, *The FDA Medical Device User Fee Program*; CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*; and CRS Report R42680, *The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144)*.

[56] See CRS Report R44750, *FDA Medical Product User Fee Reauthorization: In Brief*.

[57] User fees provide varying proportions of funding for several FDA programs (see **Table E-1**). For example, the agency's tobacco regulatory activities are entirely supported through user fees paid by tobacco product manufacturers and importers, and the toxicology program receives no user fee funds. In FY2017, fees account for 63% of the human drugs program budget, 36% of the biologics budget, 27% of the devices and radiological health budget, 16% of the animal drugs and feeds budget, and 1% of the foods budget.

[58] For each of fiscal years 2017 through 2025, the following amounts are authorized to be transferred to the FDA Innovation Account: $20 million in FY2017; $60 million in FY2018; $70 million in FY2019; $75 million in FY2020; $70 million in FY2021; $50 million in FY2022; $50 million in FY2023; $50 million in FY2024; and $55 million in FY2025.

[59] This total includes PDUFA, medical device (MDUFA), generic drug (GDUFA), biosimilars (BsUFA), animal drug (ADUFA), animal generic drug (AGDUFA), tobacco product, Mammography Quality Standards Act (MQSA), color and export certification, priority review, food and feed recall, food reinspection, voluntary qualified importer program (VQIP), third party auditor program, and outsourcing facility user fees. It does not include the $4.2 million in proposed additional export certification fees.

direct appropriation would result in a total program level of $5.112 billion—an increase of $367 million over the FY2017 total program level.[60]

In addition to the amounts provided in the enacted FY2017 appropriation, FDA received $20 million from the FDA Innovation Account, provided in the Further Continuing and Security Assistance Appropriations Act, 2017 (P.L. 114-254). The Administration's FY2018 request also includes $60 million from the FDA Innovation Account.[61]

Table 6. Food and Drug Administration (FDA)

(Millions of Dollars, by Fiscal Year)

Program Area	2016[a]	2017	2018 Request
Foods	**998**	**1,037**	**922**
Budget Authority	998	1,026	910
User Fees	0	12	12
Human drugs	**1,452**	**1,330**	**1,612**
Budget Authority	487	492	179
User Fees	964	838	1,432
Biologics	**329**	**340**	**366**
Budget Authority	215	215	96
User Fees	114	124	270
Animal drugs and feeds	**188**	**195**	**183**
Budget Authority	159	163	108
User Fees	29	32	76
Devices and radiological health	**448**	**448**	**490**
Budget Authority	323	330	140
User Fees	124	119	350
Tobacco products	**477**	**596**	**626**
Budget Authority	—	—	—
User Fees	477	596	626
Toxicological research	**63**	**63**	**60**
Budget Authority	63	63	60
User Fees	—	—	—
Headquarters/Commissioner's Office	**302**	**285**	**322**
Budget Authority	191	185	125
User Fees	110	100	197

[60] The FY2017 program level of $4.745 billion includes $4.725 billion provided in the 2017 Consolidated Appropriations Act (P.L. 115-31), user fees, and the $20 million provided in the second continuing resolution (P.L. 114-254) pursuant to the 21st Century Cures Act (Division A of P.L. 114-255).

[61] Ibid.

GSA rent	**220**	**232**	**250**
Budget Authority	162	170	128
User Fees	58	62	121
Other rent and rent-related activities[b]	**168**	**164**	**190**
Budget Authority	122	115	72
User Fees	46	49	117
Export and color certification funds	**14**	**15**	**15**
Budget Authority	—	—	—
User Fees	14	15	15
Food and drug safety[c]	**2**	**0**	**0**
Budget Authority	2	0	0
User Fees	0	0	0
Priority review vouchers	**0**	**8**	**8**
Budget Authority	—	—	—
User Fees	0	8	8
Buildings & Facilities	**8**	**12**	**9**
Budget Authority	8	12	9
User Fees	—	—	—
FDA Innovation Account[d]	—	**20**	**60**
Budget Authority	—	20	60
User Fees	—	—	—
Total, Program Level	**4,668**	**4,745**[e]	**5,112**
Less Funds From Other Sources			
User Fees	1,938	1,954	3,223[f]
Total, Discretionary Budget Authority	**2,730**	**2,791**	**1,888**

Sources: Amounts for FY2016 and the FY2018 request are from the FDA FY2018 *Justification of Estimates for Appropriations Committees*, available at http://www.hhs.gov/budget/. The FY2017 amounts are from the 2017 Consolidated Appropriations Act (P.L. 115-31) and its Explanatory Statement (for H.R. 244 in the May 3, 2017 Congressional Record), and the 2017 Further Continuing and Security Assistance Appropriations Act (P.L. 114-254).

Notes: Individual amounts may not add to subtotals or totals due to rounding.

Consistent with the Administration and congressional committee formats, each program area includes funding designated for the responsible FDA center (e.g., the Center for Drug Evaluation and Research or the Center for Food Safety and Applied Nutrition) and the portion of effort budgeted for the agency-wide Office of Regulatory Affairs to commit to that area.

a. This column shows the FY2016 actual amounts. A "0" in this column does not reflect a lack of authorization for that program. For example, user fees for food are listed as "0," meaning that no fees were collected in FY2016 for the food program, but user fees for food were authorized in the FY2016-enacted bill.

b. Other rent and rent-related activities include White Oak consolidation.

c. The FY2013 Sequestration Operating Plan notes food safety and drug safety items that had not been included in the program-level appropriations. Subsequent years' bills have not specified this distinct item.

d. In December 2016, a measure was enacted providing FY2017 continuing appropriations through April 28, 2017 (P.L. 114-254). The law provided to the FDA an additional $20 million for FY2017, pursuant to the

21st Century Cures Act (Division A of P.L. 114-255), which establishes an FDA Innovation Account as a funding source for the agency's activities and programs authorized in Division A of the Cures Act (e.g., changes to the drug and device FDA approval pathways).

e. Not included in this total is the $10 million provided by section 752 of P.L. 115-31 for FDA to "prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses domestically and internationally and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and for related administrative activities... to remain available until expended." Adding this $10 million to the FDA appropriations would bring budget authority to $2.801 billion and the total program level to $4.755 billion for FY2017.

f. This $3.223 billion in user fees does not include the $4.2 million in proposed additional export certification fees. Including the proposed export certification fees would bring the FY2018 request for user fees to $3.228 billion, yielding a total program level request of $5.116 billion.

Health Resources and Services Administration (HRSA)[62]

Agency Overview

HRSA is the federal agency charged with improving access to health care for those who are uninsured, isolated, or medically vulnerable. The agency currently awards funding to more than 3,000 grantees, including community-based organizations; colleges and universities; hospitals; state, local, and tribal governments; and private entities to support health services projects, such as training health care workers or providing specific health services.[63] HRSA also administers the health centers program, which provides grants to nonprofit entities that provide primary care services to people who experience financial, geographic, cultural, or other barriers to health care.[64]

HRSA is organized into five bureaus (see text box below) and 10 offices. Some offices focus on specific populations or health care issues (e.g., Office of Women's Health, Office of Rural Health Policy), while others provide agency-wide support or technical assistance to HRSA's regional offices (e.g., Office of Planning, Analysis and Evaluation; Office of Regional Operations).[65]

[62] This section was written by Elayne J. Heisler, Specialist in Health Services.

[63] See HRSA's website at http://www.hrsa.gov.

[64] 42 U.S.C. §§254b.

[65] See HRSA's website at http://www.hrsa.gov.

HRSA Bureaus

The **Bureau of Primary Health Care** administers the Health Centers program, authorized under Title III of the PHSA. Community and other health centers provide access to primary care for individuals who are low-income, uninsured, or living where health care is scarce.

The **Bureau of Health Workforce** administers scholarship, loan, and loan repayment programs that help underserved communities recruit and retain health professionals. These programs include the National Health Service Corps, NURSE Corps, and the Faculty Loan Repayment Program. The bureau also administers a number of programs for health professions training and development of diversity and cultural competence in the health workforce. These programs include the Oral Health Training Program, the Nursing Workforce Diversity Program, the Children's Hospitals Graduate Medical Education Program, the Teaching Health Center Graduate Medical Education program funded under ACA, and the Scholarships for Disadvantaged Students Program. The Bureau of Health Professions also administers the National Practitioner and Healthcare Integrity Protection Data Banks and the National Center for Health Workforce Analysis. Titles III, VII, and VIII of the PHSA authorize programs in this bureau.

The **Maternal and Child Health Bureau** administers the Maternal and Child Health Block Grant and other programs that support the infrastructure for maternal and child health services, including the Maternal, Infant, and Early Childhood Home Visiting Program that was authorized and funded by ACA. These programs are authorized in Title V of the Social Security Act (SSA). This bureau also administers Healthy Start, newborn hearing screening, autism monitoring and services, and other programs authorized under Titles III, XI, XII, and XIX of the PHSA.

The **HIV/AIDS Bureau** administers the Ryan White HIV/AIDS program, which is the largest discretionary grant program within HRSA and is focused on HIV/AIDS care. The Ryan White HIV/AIDS program administers grant programs that provide early intervention, minority, and family services. It also administers the AIDS Drug Assistance Program (ADAP). Title XXVI of the PHSA authorizes the Ryan White HIV/AIDS programs.

The **Healthcare Systems Bureau** provides national leadership and direction in targeted areas, such as organ and bone marrow transplantation, poison control centers, and others. It also administers the 340B drug pricing program. Titles III and XII of the PHSA authorize programs in this bureau.

As noted in the text box, the majority of HRSA's programs are authorized by the PHSA;[66] others are authorized by the SSA. In addition, Section 427(e) of the Federal Mine Safety and Health Amendments Act (P.L. 95-164) authorizes the Black Lung Program, which supports clinics that provide services to retired coal miners and others.

Recent Trends in Agency Funding

HRSA funding increased from $8.1 billion in FY2010 to $10.7 billion in FY2017; this increase occurred despite a reduction in the agency's discretionary appropriation during that time (see **Table 7**). Specifically, discretionary appropriations declined by about 17%, falling from $7.5 billion to $6.2 billion. Much of the decline in discretionary appropriations occurred because of the loss of discretionary appropriations for the National Health Service Corps (NHSC) and the elimination of a program that supported health care facility construction and renovation through the congressional direction of funds to specific facilities.

[66] 42 U.S.C. §§201 et seq.

The overall growth in HRSA's funding was primarily driven by increasing amounts from the CHCF (see **Table B-1**), which more than offset the decline in discretionary funding. CHCF funding has partially supplanted (i.e., replaced) discretionary health center funding and has become the sole source of funding for the NHSC program, which has not received an annual discretionary appropriation since FY2011. The President's FY2018 budget would further reduce the agency's discretionary appropriation, but it would continue the funding of the CHCF among other mandatory HRSA funding streams. These funding streams include the Maternal, Infant, and Early Childhood Home Visiting Program and the Teaching Health Center Program, two new programs created in the ACA, and the Family-to-Family Health Information Centers, which received an extension of its mandatory funding in the ACA and subsequent legislation.[67]

For more information

CRS Report R44054, *Health Resources and Services Administration (HRSA) Funding: Fact Sheet*

CRS Report R43937, *Federal Health Centers: An Overview*

CRS Report R43930, *Maternal and Infant Early Childhood Home Visiting (MIECHV) Program: Background and Funding*.

CRS Report R43920, *National Health Service Corps: Background, Funding, and Programs*

CRS Report RL33644, *Title X (Public Health Service Act) Family Planning Program*

Table 7. Health Resources and Services Administration (HRSA)

(Millions of Dollars, by Fiscal Year)

Bureau or Activity	2016[a]	2017[a]	2018 Request[b]
Primary Care	**5,092**	**4,997**	**5,089**
Health Centers	*5,091*	4,997	5,089
Discretionary BA (non-add)[c]	*(1,489)*	*(1,487)*	*(1,489)*
CHCF Transfer (non-add)	*(3,600)*	*(3,509)*	*(3,600)*[b]
Health Workforce	**1,177**	**1,203**	**771**
National Health Service Corps (NHSC)	310	289	310[b]
CHCF Transfer (non-add)	*(310)*	*(289)*	*(310)*
Training for Diversity[d]	82	83	—
Primary Care Training and Enhancement	39	39	—
Interdisciplinary, Community-Based Linkages[e]	79	129	—
Public Health Workforce Development	21	17	—
Nursing Workforce Development[f]	229	229	83[g]
Children's Hospitals GME Payments	295	300	295
Teaching Health Center GME Payments (ACA §5508(c))	60	56	60[b]
Other Health Workforce Programs[h]	41	42	5
National Practitioner Data Bank (User Fees)	21	19	18
Maternal and Child Health	**1,250**	**1,238**	**1,200**
Maternal and Child Health Block Grant	637	640	667

[67] For the funding histories of these programs, see CRS Report R44662, *Health Care-Related Expiring Provisions of the 115th Congress, First Session*.

Healthy Start	104	118[i]	128
Maternal, Infant Home Visiting (ACA §2951)	400	372	400[b]
Family-to-Family Health Centers (ACA §5507)	5	5	5[b]
Other Maternal and Child Health Programs[i]	103	103	—
Ryan White HIV/AIDS	**2,323**	**2,313**	**2,260**
Health Care Systems	**103**	**104**	**99**
Other Health Care Systems Programs[k]	76	77	76
Hansen's Disease Programs	17	17	14
340B Drug Pricing Programs	10	10	10
Rural Health	**150**	**156**	**74**
Other Activities	**701**	**688**	**715**
Family Planning	286	286	286
Program Management	154	154	152
Vaccine Injury Compensation Program (VICP) Operations	8	8	9
VICP Trust Fund	253	240	268
Total, Program Level	**10,795**	**10,699**	**10,210**
Less Funds From Other Sources			
User Fees	21	19	18
VICP Trust Fund (Mandatory)	253	240	268
ACA Mandatory Funds: CHCF Transfers	3,910	3,805	3,910[b]
ACA Mandatory Funds: Other	465	433	465[b]
Total, Discretionary Budget Authority	**6,140**	**6,202**	**5,549**

Source: Amounts for FY2016 and the FY2018 request are from the HRSA FY2018 *Justification of Estimates for Appropriations Committees*, available at http://www.hhs.gov/budget/. The FY2017 amounts are from the 2017 Consolidated Appropriations Act (P.L. 115-31) and its Explanatory Statement (for H.R. 244 in the May 3, 2017 Congressional Record).

Notes: Individual amounts may not add to subtotals or totals due to rounding.

a. Includes funds appropriated in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10).

b. Includes proposal for FY2018 mandatory funding for programs that currently receive mandatory funds through FY2017.

c. Includes funding for Native Hawaiian Programs, Health Center Tort Claims, and Free Clinics Medical Malpractice.

d. Training for Diversity includes the following programs: Centers for Excellence, Scholarships for Disadvantaged Students, Faculty Loan Repayment, and the Health Careers Opportunity Program.

e. Interdisciplinary, Community-based Linkages include Area Health Education Centers (AHEC), Geriatric Programs, and Mental and Behavioral Health Education and Training. FY2016 amounts reflect the Behavioral Health Workforce Education and Training Program (a component of the Mental and Behavioral Health Education and Training).

f. Nursing Workforce Development includes NURSE Corps (formerly the Nursing Education Loan Repayment and Scholarship Program); Advanced Nursing Education; Nursing Workforce Diversity; Nurse Education, Practice, Quality and Retention; Nurse Faculty Loan Program; and Comprehensive Geriatric Education.

g. The FY2018 budget proposes funding the NURSE Corps program but does not propose funding for other Nursing Workforce Development programs. Other Health Workforce Programs include Health Care Workforce Assessment, and Oral Health Training.

h. Other Health Workforce Programs include Health Care Workforce Assessment and Oral Health Training.

i. Includes $15 million appropriated in the Water Infrastructure Improvements for the Nation Act (P.L. 114-322). See CRS Report R44723, *Overview of Further Continuing Appropriations for FY2017 (H.R. 2028)*http://www.crs.gov/Reports/R44723.

j. Other Maternal and Child Health Programs include Autism and Other Developmental Disorders, Traumatic Brain Injury, Sickle Cell Services Demonstration, Universal Newborn Hearing Screening, Emergency Medical Services for Children, and Heritable Disorders. In FY2016, the Traumatic Brain Injury program was transferred to the Administration for Community Living and, therefore, was not funded under HRSA.

k. Health Care Systems Programs include Organ Transplantation, National Cord Blood Inventory, C.W. Bill Young Cell Transplantation Program, and Poison Control Centers.

Indian Health Service (IHS)[68]

Agency Overview

IHS provides health care for approximately 2.2 million eligible American Indians/Alaska Natives through a system of programs and facilities located on or near Indian reservations, and through contractors in certain urban areas. IHS provides services to members of 566 federally recognized tribes, either directly or through facilities and programs operated by Indian Tribes or Tribal Organizations through self-determination contracts and self-governance compacts authorized in the Indian Self-Determination and Education Assistance Act (ISDEAA).[69]

For more information

CRS Report R43330, *The Indian Health Service (IHS): An Overview*

CRS Report R44040, *Indian Health Service (IHS) Funding: Fact Sheet*

The Snyder Act of 1921 provides general statutory authority for IHS.[70] In addition, specific IHS programs are authorized by two acts: the Indian Sanitation Facilities Act of 1959[71] and the Indian Health Care Improvement Act (IHCIA).[72] The Indian Sanitation Facilities Act authorizes the IHS to construct sanitation facilities for Indian communities and homes. IHCIA authorizes programs such as urban health, health professions recruitment, and substance abuse and mental health treatment, and permits IHS to receive reimbursements from Medicare, Medicaid, the State Children's Health Insurance Program (CHIP), the Department of Veterans Affairs (VA), and third-party insurers.

As discussed earlier, IHS receives its appropriations through the Interior/Environment appropriations act. IHS funding is not subject to the PHS set-aside (see earlier discussion in "PHS Evaluation Set-Aside").

[68] This section was written by Elayne J. Heisler, Specialist in Health Services.

[69] P.L. 93-638; 25 U.S.C. §§450 et seq.

[70] P.L. 67-85, as amended; 25 U.S.C. §13. The Snyder Act established this authority as part of the Bureau of Indian Affairs within the Department of the Interior. The Transfer Act of 1954 (P.L. 83-568) transferred this authority to the U.S. Surgeon General within the Department of Health, Education, and Welfare (now HHS).

[71] P.L. 86-121; 42 U.S.C. §2004a.

[72] P.L. 94-437, as amended; 25 U.S.C. §§1601 et seq., and 42 U.S.C. §§1395qq and 1396j (and amending other sections). This act was permanently reauthorized by the ACA. See CRS Report R41630, *The Indian Health Care Improvement Act Reauthorization and Extension as Enacted by the ACA: Detailed Summary and Timeline*, by Elayne J. Heisler.

Recent Trends in Agency Funding

IHS's funding, which includes discretionary appropriations and collections from third-party payers of health care, increased between FY2010 and FY2017 from $5.1 billion to $6.3 billion (see **Table 8**). This increase was driven both by increased discretionary appropriations, which rose from $4.1 billion to $5.0 billion, and by increased collections, which rose from $891 million to $1.2 billion. Much of the funding increase was used to support clinical services. Discretionary appropriations, in particular, have increased funding for purchased/referred care, a subset of the clinical services budget line that applies to funds used to refer patients to an outside provider when the IHS cannot provide a service within its system. Funding allocated for contract support costs has also increased since FY2014.

Contract support costs are funds that Indian Tribes and Tribal Organizations receive, in addition to operating funds, when they operate a facility or program under an ISDEAA contract or compact. According to the U.S. Supreme Court, these costs must be fully funded even if Congress does not appropriate sufficient funds to cover all tribes' contract support costs. According to IHS, beginning in FY2016, the amount allocated for contract support costs is sufficient for the contracts and compacts that IHS enters into.[73] Contract support costs had previously been included in the Indian Health Service account, but in more recent years they have been delineated separately in IHS budget documents. The IHS's FY2018 budget notes that contract support costs receive a separate discretionary indefinite appropriation in FY2018.[74]

Table 8. Indian Health Service (IHS)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2016	2017	2018 Request
Clinical and Preventive Services	**4,737**	**4,860**	**4,753**
Clinical Services	4,431[a]	4,553[a]	4,446[a]
Purchased/Referred Care (non-add)[b]	*(914)*	*(929)*	*(914)*
Preventive Health	156	160	157
Special Diabetes Program for Indians[c]	150	147	150
Other Health Services	**171**	**175**	**165**
Urban Health Projects	44	48	45
Indian Health Professions	48	49	43
Tribal Management/Self-Governance	8	8	5[d]
Direct Operations	72	70	72
Health Facilities	**532**	**554**	**456**
Maintenance and Improvement	82[e]	84[f]	69[f]
Sanitation Facilities Construction	99	102	75

[73] CRS Legal Sidebar WSLG119, *Supreme Court Holds the Government Liable for Contract Support Costs in Indian Self-Determination Contracts Even When Congress Fails to Appropriate Adequate Funds*.

[74] U.S. Department of Health and Human Services, Indian Health Service, "Justification of Estimates for Appropriations Committees, FY2018," https://www.ihs.gov/budgetformulation/includes/themes/newihstheme/display_objects/documents/FY2018CongressionalJustification.pdf, p. CJ-147.

Health Care Facilities Construction	105	118	100
Facilities/Environmental Health Support	223	227	192
Medical Equipment	23	23	20
Contract Support Costs[g]	**718**	**800**	**718**
Total, Program Level	**6,160**	**6,307**	**6,092**
Less Funds from Other Sources			
Collections	1,194	1,194	1,194
Rental of Staff Quarters	9	9	9
Special Diabetes Program for Indians[c]	150	147	150
Total, Discretionary Budget Authority	**4,808**	**4,957**	**4,739**

Sources: Amounts for FY2016 and the FY2018 request are from the IHS FY2018 *Justification of Estimates for Appropriations Committees*, available at http://www.hhs.gov/budget/. The FY2017 amounts are from the 2017 Consolidated Appropriations Act (P.L. 115-31) and its Explanatory Statement (for H.R. 244 in the May 3, 2017 Congressional Record).

Notes: Individual amounts may not add to subtotals or totals due to rounding.

a. Includes $1,194 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.

b. This was previously referred to as "Contract Health Services."

c. PHSA §330C provides an annual appropriation of $150 million through FY2017 for this program. This amount was reduced in FY2013, FY2014, and FY2017 by 2% because of budget sequestration. See CRS Report R42050, *Budget "Sequestration" and Selected Program Exemptions and Special Rules*.

d. The FY2018 budget does not request funds for Tribal Management Grants.

e. Includes $9 million that IHS received from rental of staff quarters.

f. Includes $9 million that IHS expects to receive from rental of staff quarters.

g. Beginning in FY2016, Contract Support Costs were funded as an indefinite discretionary appropriation.

National Institutes of Health (NIH)[75]

Agency Overview

NIH is the primary agency of the federal government charged with performing and supporting biomedical and behavioral research. Its activities cover a wide range of basic, clinical, and translational research, as well as research training and health information collection and dissemination. The agency is organized into 27 research institutes and centers, headed by the NIH Director. The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly in areas of research that involve multiple institutes. The institutes and centers (ICs) focus on particular diseases, areas of human health and development, or aspects of research support. Each IC plans and manages its own research programs in coordination with OD.

[75] This section was written by Judith A. Johnson, Specialist in Biomedical Policy.

For more information

CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*

CRS Report R43341, *NIH Funding: FY1994-FY2018*

CRS Report R44516, *Federal Research and Development Funding: FY2017*

More than 80% of NIH's budget funds extramural research through grants, contracts, and other awards. This funding supports research performed by more than 300,000 individuals who work at over 2,500 universities, hospitals, medical schools, and other research institutions around the country and abroad.[76] About 10% of the NIH budget supports the intramural research programs of the ICs, funding research performed by the nearly 6,000 NIH scientists, most of whom are located on the NIH campus in Bethesda, MD. The remainder of the budget supports various research management, support, and facilities' needs.

NIH derives its statutory authority from the PHSA. Title III, Section 301, of the PHSA grants the HHS Secretary broad permanent authority to conduct and sponsor research. In addition, Title IV, "National Research Institutes," authorizes in greater detail various activities, functions, and responsibilities of the NIH Director and the ICs. All of the ICs are covered by specific provisions in the PHSA, but they vary considerably in the amount of detail included in the statutory language. There are few time-and-dollar authorization levels specified for individual activities. Congress mandated a significant reorganization of IC responsibilities in the FY2012 Consolidated Appropriations Act (P.L. 112-74, Division F) by creating a new National Center for Advancing Translational Sciences (NCATS) and eliminating the National Center for Research Resources (NCRR). Activities relating to translational sciences from NCRR and many other ICs were consolidated in NCATS, and NCRR's other programs were moved to several other ICs and OD.

Almost all NIH funding (99.5%) is from annual discretionary appropriations. As shown in **Table 9**, the annual LHHS appropriations act provides separate appropriations to 24 of the ICs, the OD, and the Buildings and Facilities account. One of the ICs (Environmental Health Sciences) also receives funding for Superfund-related activities from the Interior/Environment appropriations act. In addition, NIH receives a mandatory annual appropriation ($150 million) for type 1 diabetes research.

Recent Trends in Agency Funding

Between FY1994 and FY1998, funding for NIH grew from $11.0 billion to $13.7 billion in nominal terms. Over the next five years, Congress doubled the NIH budget to $27.2 billion in FY2003. In each of these years, the agency received annual funding increases of 14% to 16%. Since FY2003, however, NIH funding has increased more gradually in nominal dollars. Funding peaked in FY2010 before declining in FY2011 through FY2013, with increases in subsequent years. The NIH program level in FY2016 was $32.311 billion.

The Obama Administration requested an FY2017 NIH program level total of $33.136 billion, an increase of $825 million (2.6%) over FY2016. Temporary FY2017 funding for NIH was provided until May 5, 2017, by three continuing resolutions (P.L. 114-223, P.L. 114-254, and P.L. 115-30). Generally, these continuing resolutions (CRs) provided a formulaic extension of FY2016 funding levels with an across-the-board adjustment and limited exceptions for particular accounts and activities. One exception is that Section 194 of the second CR appropriated $352 million (available until expended) into an NIH Innovation account to carry out four NIH Innovation

[76] HHS, *FY2018 Budget in Brief*, May 2017, p. 38, https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf.

Projects as described in Section 1001(b)(4) of the 21st Century Cures Act (P.L. 114-255).[77] The Cures Act created the NIH Innovation account and specified that funds in the account must be appropriated in order to be available for expenditure; the appropriation in Section 194 of the second CR was needed to fulfill this requirement. Projects authorized by the Cures Act are the Precision Medicine Initiative, the BRAIN Initiative, cancer research, and regenerative medicine using adult stem cells.

The explanatory statement accompanying the FY2017 LHHS Appropriations Act (Division H of H.R. 244; P.L. 115-31) states that it provides $34.084 billion for NIH activities, a $2 billion (6.2%) increase over FY2016. This amount is calculated by including the $824 million from the evaluation tap, as well as $352 million for the NIH Innovation account that was previously appropriated to the agency for FY2017. Adding the amounts for Superfund-related activities ($77 million in Division G of H.R. 244; P.L. 115-31) and the mandatory type 1 diabetes program ($150 million) brings the FY2017-enacted NIH program level to $34.311 billion. The NIH Operating Plan for FY2017 provides current details on agency spending.[78] The $352 million amount in the NIH Innovation account is divided between NCI ($300 million) and OD ($52 million).

President Trump's FY2018 budget requests an NIH program level total of $26.92 billion, a decrease of $7.391 billion (-21.5%) compared with the FY2017-enacted amount.[79] Under the FY2018 budget request, all NIH ICs would receive a decrease compared to FY2017, but the Fogarty International Center would be eliminated and the Office of the NIH Director would retain $25 million in international research and related activities. The Trump budget request also proposes the consolidation of the Agency for Healthcare Research and Quality (AHRQ) with NIH, forming a new Institute, the National Institute for Research on Safety and Quality (NIRSQ). The FY2018 budget proposal includes $272 million in budget authority for NIRSQ "to preserve key research activities previously carried out by AHRQ."[80] In addition, NIRSQ is projected to receive $107 million in mandatory resources from the Patient-Centered Outcomes Research Trust Fund to continue the targeted dissemination of study results to help patients and providers make better informed health care decisions.[81]

[77] For further information, see CRS Report R44720, *The 21st Century Cures Act (Division A of P.L. 114-255)*, and CRS Report R44723, *Overview of Further Continuing Appropriations for FY2017 (H.R. 2028)*.

[78] NIH Operating Plan for FY2017, posted on June 21, 2017, https://officeofbudget.od.nih.gov/pdfs/FY18/FY%202017%20NIH%20Operating%20Plan.pdf.

[79] The proposed decrease to the NIH program level would be larger (-22.5%, rather than -21.5%) if the FY2017 NIH program level were adjusted to include FY2017 funding for the Agency for Healthcare Research and Quality (AHRQ). This adjustment would make the FY2017 estimate more comparable with the FY2018 request level, given the FY2018 President's budget proposal to consolidate AHRQ functions within NIH.

[80] Department of Health and Human Services, *Fiscal Year 2018 Budget in Brief*, Washington, DC, May 2017, p. 37, https://www.hhs.gov/sites/default/files/Consolidated%20BIB_ONLINE_remediated.pdf.

[81] Ibid., p. 42.

Table 9. National Institutes of Health (NIH)

(Millions of Dollars, by Fiscal Year)

Institutes and Centers (ICs)	2016	2017	2018 Request
Cancer (NCI)	5,206	5,389	4,474
Heart/Lung/Blood (NHLBI)	3,109	3,207	2,535
Dental/Craniofacial Research (NIDCR)	413	426	321
Diabetes/Digestive/Kidney (NIDDK)[a]	1,964	2,021	1,600
Neurological Disorders/Stroke (NINDS)	1,693	1,784	1,356
Allergy/Infectious Diseases (NIAID)	4,750	4,907	3,783
General Medical Sciences (NIGMS)[b]	2,509	2,651	2,186
Child Health/Human Development (NICHD)	1,338	1,380	1,032
Eye (NEI)	707	733	550
Environmental Health Sciences (NIEHS)[c]	770	791	593
Aging (NIA)	1,596	2,049	1,304
Arthritis/Musculoskeletal/Skin (NIAMS)	541	558	418
Deafness/Communication Disorders (NIDCD)	422	437	326
Mental Health (NIMH)	1,517	1,602	1,245
Drug Abuse (NIDA)	1,049	1,091	865
Alcohol Abuse/Alcoholism (NIAAA)	467	483	361
Nursing Research (NINR)	146	150	114
Human Genome Research (NHGRI)	513	529	400
Biomedical Imaging/Bioengineering (NIBIB)	343	357	283
Minority Health/Health Disparities (NIMHD)	280	289	215
Complementary/Integrative Health (NCCIH)	130	135	102
Advancing Translational Sciences (NCATS)	684	706	557
Fogarty International Center (FIC)	70	72	—
National Library of Medicine (NLM)	395	408	373
Office of Director (OD)	1,571	1,678	1,452
Buildings & Facilities (B&F)	129	129	99
NIH Innovation Account	—	352	—
Research on Safety & Quality (NIRSQ)	—	—	379[d]
Total, Program Level	**32,311**	**34,311**	**26,920**
Less Funds From Other Sources			
PHS Evaluation Set-Aside	780	824	780
Type 1 Diabetes Research (NIDDK)[e]	150	150	150
Superfund (Interior approp. to NIEHS)	77	77	60
Patient-Centered Outcomes Research Trust Fund	—	—	107
Total, LHHS Discretionary Budget Authority	**31,304**	**33,260**	**25,824**

Sources: Funding amounts for FY2016 and the FY2018 request are taken from NIH, *FY2018 Justification of Estimates for Appropriations Committees, Vol. I, Overview,* "Budget Request by Institute and Center (Summary Table)," p. 81. FY2017 funding amounts are taken from Division H of H.R. 244 and the accompanying explanatory statement in the March 5, 2017, Congressional Record (Part III), p. H3982-H3984. FY2017 Operating Plan funding amounts are found at https://officeofbudget.od.nih.gov/cy.html.

Notes: Totals may differ from the sum of the components due to rounding.

a. Amounts for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) include $150 million in mandatory funding for type 1 diabetes research.

b. Amounts for National Institute of General Medical Sciences (NIGMS) include the PHS set-aside funds.

c. Amounts for National Institute of Environmental Health Sciences (NIEHS) include Interior Appropriation for Superfund research.

d. This amount is also represented in the AHRQ section of the report.

e. Mandatory funds available to NIDDK for type 1 diabetes research under PHSA §330B (provided by P.L. 114-10 for FY2016 and FY2017).

Substance Abuse and Mental Health Services Administration (SAMHSA)[82]

Agency Overview

SAMHSA is the lead federal agency for increasing access to behavioral health services. SAMHSA supports community-based mental health and substance abuse treatment and prevention services through formula grants to the states and U.S. territories and through competitive grant programs to states, territories, tribal organizations, local communities, and private entities. SAMHSA also engages in a range of other activities, such as technical assistance, data collection, and workforce development.

SAMHSA and most of its programs and activities are authorized under PHSA Title V, which organizes SAMHSA in four centers:

- Center for Substance Abuse Treatment (CSAT)[83]
- Center for Substance Abuse Prevention (CSAP)[84]
- Center for Mental Health Services (CMHS)[85]
- Center for Behavioral Health Statistics and Quality (CBHSQ)[86]

Each of CSAT, CSAP, and CMHS has general statutory authority, called Programs of Regional and National Significance (PRNS), under which it administers numerous grants and other programs. PHSA Title V also authorizes a number of specific grant programs, referred to as categorical grants.

For more information

CRS Report R44860, *SAMHSA FY2018 Budget Request and Funding History: A Fact Sheet*

SAMHSA's two largest grant programs are separately authorized under PHSA Title XIX, Part B. The Community Mental Health Services block grant falls within CMHS.[87] The full amount of the Substance Abuse Prevention and Treatment block grant falls within CSAT, although no less than 20% of each state's block grant must be used for prevention.[88]

SAMHSA's budget is organized in four categories, three of which correspond to CSAT, CSAP, and CMHS. The fourth category, "health surveillance and program support," does not correspond directly to CBHSQ; it supports data collection, analytic support, public awareness campaigns, behavioral health workforce initiatives, and the National Registry of Evidence-based Programs and Practices (among other programs and activities).[89]

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[82] This section was written by Erin Bagalman, Analyst in Health Policy.

[83] PHSA Title V, Part B, Subpart 1; 42 U.S.C. §§290bb et seq.

[84] PHSA Title V, Part B, Subpart 2; 42 U.S.C. §§290bb-21 et seq.

[85] PHSA Title V, Part B, Subpart 3; 42 U.S.C. §§290bb-31 et seq.

[86] PHSA Title V, Part A, Section 505; 42 U.S.C. §§290aa-4 et seq.

[87] PHSA Title XIX, Part B, Subpart I; 42 U.S.C. §§300x et seq.

[88] PHSA Title XIX, Part B, Subpart II; 42 U.S.C. §§300x-21 et seq.

[89] In the Consolidated Appropriations Act, 2012 (P.L. 112-74, Division F, Title II; 125 Stat. 1073), and the accompanying conference report (H.Rept. 112-331, pp. 1139-1142), Congress rejected proposed changes to SAMHSA's budget structure in the FY2012 budget request. Congress directed that future budget requests reflect the (continued...)

In the 114th Congress, the Helping Families in Mental Health Crisis Reform Act of 2016 (Division B of P.L. 114-255) made numerous changes to SAMHSA's statutory authorities—reauthorizing, modifying, or codifying existing programs and activities; authorizing new programs and activities; and repealing authorities for programs and activities that had not been funded. Also in the 114th Congress, the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198) included authorizations of appropriations for SAMHSA-administered grant programs, and Section 1003 of the 21st Century Cures Act (Division A of P.L. 114-255) authorized appropriations for grants to support state responses to opioid abuse.[90]

Recent Trends in Agency Funding

SAMHSA's program-level funding increased by 13% from FY2016 ($3.8 billion) to FY2017 ($4.3 billion). SAMHSA's largest center, CSAT, received a 24% increase, attributable mostly to the $500 million appropriated for the newly authorized grants to support state responses to opioid abuse. Smaller increases—in terms of both dollar amounts and percentages—went to CMHS (1%) and CSAP (6%). Program-level funding decreased by 28% for health surveillance and program support.

Relative to FY2017 as enacted, SAMHSA's FY2018 request would decrease program-level funding by 9% (to $3.9 billion) and discretionary budget authority by 8% (to $3.8 billion); see **Table 10**. Funding for CSAT would stay within 1% of its FY2017-enacted amount. Funding for CMHS would decrease by 23%, including a 26% decrease in the mental health block grant and a 31% decrease in mental health PRNS. Funding for CSAP would decrease by 33%. Funding would decrease by 11% for health surveillance and program support.

Table 10. Substance Abuse and Mental Health Services Administration (SAMHSA)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2016	2017[a]	2018 Request
Center for Mental Health Services (CMHS)	**1,167**	**1,181**	**912**
Mental Health Block Grant	533	563	416
PHS Evaluation Funds (non-add)	*(21)*	*(21)*	*(16)*
Programs of Regional and National Significance	415	399	277
PPHF Transfer (non-add)	*(12)*	*(12)*	—
Children's Mental Health Services	119	119	119
PATH Homeless Formula Grant	65	65	65
Protection & Advocacy Formula Grant	36	36	36
Center for Substance Abuse Treatment (CSAT)	**2,195**	**2,713**	**2,696**
Substance Abuse Block Grant	1,858	1,858	1,855
PHS Evaluation Funds (non-add)	*(79)*	(79)	*(79)*

(...continued)

structure of the three centers (i.e., CMHS, CSAT, and CSAP) and the Health Surveillance and Program Support account. SAMHSA's subsequent budget requests have reflected this structure.

[90] Prior to the 114th Congress, the last comprehensive reauthorization of SAMHSA and its programs occurred in 2000 as part of the Children's Health Act (P.L. 106-310, Titles XXXI-XXXIV), which also added "charitable choice" provisions allowing religious organizations to receive funding for substance abuse prevention and treatment services without altering their religious character. See PHSA Section 1955 (42 U.S.C. §300x-65); PHSA Sections 581 et seq. (42 U.S.C. §§290kk et seq.).

Program or Activity	2016	2017[a]	2018 Request
Programs of Regional and National Significance	337	354	342
PHS Evaluation Funds (non-add)	*(2)*	*(2)*	*(2)*
State Targeted Response to the Opioid Crisis[b]	—	500	500
Center for Substance Abuse Prevention (CSAP)	**211**	**223**	**150**
Programs of Regional and National Significance	211	223	150
Health Surveillance and Program Support	**208**	**150**	**134**
Health Surveillance and Program Support	206	148	132
PHS Evaluation Funds (non-add)	*(31)*	*(31)*	*(23)*
Data Request and Publications User Fees	2	2	2
Total, Program Level	**3,781**	**4,267**	**3,892**
Less Funds From Other Sources			
PHS Evaluation Funds	134	134	120
PPHF Transfers	12	12	—
Data Request and Publications User Fees	2	2	2
Total, Discretionary Budget Authority	**3,634**	**4,119**	**3,771**

Sources: Amounts for FY2016 and the FY2018 request are drawn from SAMHSA's *Justification of Estimates for Appropriations Committees* for FY2017 and FY2018, available at http://www.hhs.gov/budget. FY2017-enacted amounts are primarily drawn from the explanatory statement accompanying the Consolidated Appropriations Act, 2017, available in the *Congressional Record*, vol. 163, pp. 37-39 (May 3, 2017); however, these amounts have been adjusted to reflect $500 million appropriated in an earlier continuing resolution for FY2017 (P.L. 114-254) and an estimated $1.5 million from Data Request and Publications User Fees authorized in P.L. 115-31. The user fee estimate is drawn from SAMHSA's FY2018 justification.

Notes: Individual amounts may not sum to subtotals or totals due to rounding.

a. Amounts may change during the fiscal year due to transfers, reprogramming, or other adjustments.

b. The 21st Century Cures Act (P.L. 114-255 Section 1003) requires that the amounts appropriated for this program for FY2017 and FY2018, up to the amounts transferred, are to be subtracted from any cost estimates provided for purposes of budget controls. Effectively, the appropriations from the account will not be counted against any spending limits, such as the statutory discretionary spending limits; that is, the amounts appropriated from the account will be considered outside those limits for FY2017 and FY2018.

Appendix A. Supplemental Appropriations

Several one-time appropriations for HHS, and PHS agencies in particular, are discussed below.

Ebola and Zika Response

In late 2014, Congress provided almost $2.8 billion in supplemental FY2015 appropriations to HHS agencies for response to the Ebola outbreak.[91] In September 2016, Congress provided $933 million in supplemental FY2016 appropriations to HHS agencies for response to the Zika virus outbreak.[92] Both appropriations were designated as emergency spending and made available for a mix of domestic and international response activities. The HHS Secretary and/or agency directors were granted specific transfer authorities in each act. Also in each act, additional funds were provided to other departments and agencies for aspects of the international response to each outbreak. In May 2017, Congress provided $10 million to FDA to "prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines, including the review, regulation, and post market surveillance of vaccines and therapies, and for related administrative activities ... to remain available until expended."[93]

Table A-1 summarizes the amounts and purposes of HHS funds *as appropriated* for the Ebola and Zika outbreaks, and emerging health threats. As the Zika outbreak was unfolding, some unobligated funds for the Ebola response were reprogrammed to the Zika response mission. Details of those transfers are discussed elsewhere.[94]

Table A-1. Emergency Funding to HHS for Ebola and Zika Responses

Dollars in Millions

Agency/ Office	Amount	Purpose
Ebola Response (FY2015)		
CDC	1,771	Various domestic and international activities in several CDC accounts, available through FY2019.
NIH	238	Clinical trials on investigational vaccines and treatments, available through FY2016.
FDA	25	Development, review, and regulation of vaccines and treatments, available until expended.
OS	733	Establishment of regional Ebola Treatment Centers, health worker training and protective gear, and contracts for manufacture of vaccines and treatments for clinical trials, available through FY2019.
Total	**2,767**	

[91] P.L. 113-235, the Consolidated and Further Continuing Appropriations Act, 2015. See CRS Report R43807, *FY2015 Funding to Counter Ebola and the Islamic State (IS)*.

[92] P.L. 114-223, Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act. See CRS Report R44460, *Zika Response Funding: Request and Congressional Action*.

[93] P.L. 115-31 Section 752.

[94] See CRS Report R44460, *Zika Response Funding: Request and Congressional Action*, in particular Appendix B.

Agency/ Office	Amount	Purpose
Zika Response (FY2016)		
CDC	394	Various domestic and international activities in several CDC accounts, available through FY2017.
NIH	152	Clinical trials on vaccines and other investigational medical products, available through FY2017.
OS	387	Transfer to HRSA for primary care and maternal and child health programs, especially in the territories; contracts to develop and manufacture vaccines and diagnostic tests; and uncompensated health care costs for Zika treatment, available through FY2017.
Total	**933**	
Emerging Health Threats, Including Ebola and Zika (FY2017)		
FDA	10	Prevent, prepare for, and respond to emerging health threats, including the Ebola and Zika viruses, domestically and internationally and to develop necessary medical countermeasures and vaccines.
Total	**10**	

Source: P.L. 113-235, the Consolidated and Further Continuing Appropriations Act, 2015.

Lead Poisoning Prevention

In December 2016, in a continuing resolution (P.L. 114-254), Congress provided $55 million in FY2017 appropriations to HHS for the response to lead exposures in water, in addition to the annual appropriations for these activities that were continued by the law.[95] **Table A-2** summarizes the amounts and purposes of these funds.

Table A-2. Additional Funding to HHS for Response to Lead Exposures in Water

Dollars in Millions

Agency/ Office	Amount	Purpose
CDC	40	$17.5 million to establish a lead exposure registry in an affected city (presumably Flint, MI), and $2.5 million to establish an advisory committee on federal lead poisoning prevention efforts, available through FY2020. In addition, $20 million for childhood lead poisoning prevention program grants, available through FY2018.
HRSA	15	For the Infant Healthy Start Program, which provides grants to address a variety of family, maternal, and child health issues. Funds available through FY2018.
Total	55	

Source: P.L. 114-254, the Further Continuing and Security Assistance Appropriations Act, 2017, Sections 198-200.

[95] P.L. 114-254, the Further Continuing and Security Assistance Appropriations Act, 2017. See CRS Report R44723, *Overview of Further Continuing Appropriations for FY2017 (H.R. 2028)*.

Appendix B. Community Health Center Fund

Affordable Care Act (ACA) Section 10503 established a Community Health Center Fund (CHCF) to provide supplemental funding for community and other health centers and the National Health Service Corps (NHSC). The law provided annual appropriations to the CHCF totaling $11 billion over the five-year period FY2011 through FY2015. Of that total, $9.5 billion was for health center operations, and the remaining $1.5 billion was for the NHSC.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[96] appropriated two more years of funding for the CHCF. For both FY2016 and FY2017, MACRA provided $3.6 billion for health center operations and $310 million for the NHSC. The President's FY2018 budget proposes extending CHCF funding for two more years.

CHCF funding has partially supplanted discretionary funding for the health center program and entirely replaced discretionary funding for the NHSC (see **Table 7**).

Table B-1 shows the amounts appropriated to the CHCF for each fiscal year, as well as the post-sequestration levels for FY2013-FY2015 and FY2017. As discussed earlier in this report, the FY2016 CHCF funding was not subject to sequestration. CHCF funds are awarded to the various types of health centers that are supported by the federal health center program. Those include community health centers and migrant health centers, as well as facilities that serve the homeless and residents of public housing. Sequestration of CHCF funding for community health centers and migrant health centers is capped at 2%, whereas CHCF funding for the other types of facilities (i.e., health centers for the homeless and for public housing residents) and for the NHSC is fully sequestrable at the applicable rate for nonexempt nondefense mandatory spending (see **Table 2**).

Table B-1. Community Health Center Fund, FY2011-FY2017 (Actual) and FY2018 (Proposed)

(Millions of Dollars, by Fiscal Year)

Program	2011	2012	2013	2014	2015	2016	2017	2018[a]	Total
Health Center Program	1,000	1,200	1,500	2,200	3,600	3,600	3,600	3,600	20,300
Post-sequestration (non-add)	—	—	*(1,465)*	*(2,145)*	*(3,509)*	—	*(3,516)*	—	
National Health Service Corps	290	295	300	305	310	310	310	310	2,430
Post-sequestration (non-add)	—	—	*(285)*	*(283)*	*(287)*	—	*(289)*	—	
Total	**1,290**	**1,495**	**1,800**	**2,505**	**3,910**	**3,910**	**3,910**		**18,820**

Sources: Prepared by CRS based on ACA Section 10503, MACRA Section 221, and the HHS *Budget in Brief* (FY2015-FY2018), available at http://www.hhs.gov/budget/.

Notes: The ACA also included a one-time appropriation of $1.5 billion for health center construction and renovation. Those funds are separate from the CHCF and are not included in this table.

a. The President's FY2018 budget proposes a two-year extension of the CHCF.

[96] P.L. 114-10, 129 Stat. 87.

Appendix C. Prevention and Public Health Fund (PPHF)

Affordable Care Act (ACA) Section 4002 established the Prevention and Public Health Fund (PPHF), to be administered by the HHS Secretary, and provided it with a *permanent annual appropriation*. Under the ACA as originally enacted, PPHF's annual appropriation would increase from $500 million for FY2010 to $2 billion for FY2015 and each subsequent fiscal year. Congress has amended the provision two times, rescinding a portion of PPHF funds as an offset for the costs of other activities. The Middle Class Tax Relief and Job Creation Act of 2012 (P.L. 112-96) reduced PPHF appropriations for FY2013 through FY2021. The 21st Century Cures Act (P.L. 114-255) reduced PPHF appropriations for FY2018 through FY2024. Further information, including amounts currently authorized and appropriated for each fiscal year, is provided in CRS Report R44796, *The ACA Prevention and Public Health Fund: In Brief*.

The PPHF authority directs the HHS Secretary to transfer amounts from the PPHF to HHS agencies for prevention, wellness, and public health activities. The funds are available to the Secretary at the beginning of each fiscal year. The Administration's annual budget sets out the intended distribution and use of PPHF funds for that fiscal year. The Secretary determined the distribution of PPHF funds for FY2010 through FY2013. For FY2014 through FY2017, provisions in appropriations acts explicitly directed the distribution of PPHF funds, prohibiting the Secretary from making further transfers.[97]

As discussed earlier in this report, the PPHF appropriation is fully sequestrable at the applicable percentage rate for nonexempt nondefense mandatory spending (see **Table 3**). Sequestration is applied to the entire appropriation before funds are designated for or transferred to the agencies.

The distribution of PPHF funds to HHS agencies for FY2010 through FY2017, and proposed in the FY2018 budget, is presented in **Table C-1**. Further details regarding PPHF distributions to CDC and SAMHSA are provided in the respective agency budget tables in the body of this report.

For FY2013, the Secretary transferred almost half of available PPHF funds to CMS for ACA implementation, as shown in **Table C-1**. This transfer reduced the PPHF funds that had been initially allocated to CDC and other PHS agencies. Along with the sequestration of discretionary funding in FY2013, the loss of PPHF funds that year had a significant effect on CDC's budget.[98]

In determining the transfer of PPHF funds for FY2010 through FY2013, the Secretary funded a mix of preexisting programs and activities, and programs and activities newly authorized under the ACA. In directing the distribution PPHF funds for FY2014 through FY2017, annual appropriations acts (and accompanying report language) generally directed funds to preexisting programs and activities. In some cases the PPHF contribution for FY2016 made up more than 50% of a program's total funding. Examples include CDC immunization grants to states (54%) and tobacco prevention activities (60%). The CDC Preventive Health and Health Services Block Grant and the lead poisoning prevention program received 100% of their FY2016 funding from the PPHF.

[97] See, for example, for FY2015, P.L. 113-235, Consolidated and Further Continuing Appropriations Act, 2015, §219 of general provisions for Labor, Health and Human Services, and Education, 128 Stat. 2489.

[98] See CDC, "FY2013 Operating Plan" and "FY2013 Sequester Impacts," http://www.cdc.gov/budget/fy2013/operating-plans.html.

Table C-1. PPHF Transfers to HHS Agencies

(Millions of Dollars, by Fiscal Year)

Agency	2010	2011	2012	2013	2014	2015	2016	2017	2018 Request
ACL	0	0	20	9	28	28	28	28	0
AHRQ	6	12	12	6	7	0	0	0	0
CDC	192	611	809	463	831	886	892	891	841
CMS	0	0	0	454[a]	0	0	0	0	0
HRSA	271	20	37	2	0	0	0	0	0
OS	12	19	30	0	0	0	0	0	0
SAMHSA	20	88	92	15	62	12	12	12	0
Sequestered	—	—	—	51	72	73	68	69	59
Total	**500**	**750**	**1,000**	**1,000**	**1,000**	**1,000**	**1,000**	**1,000**	**900**

Sources: Prepared by CRS based on HHS agency congressional budget justifications for FY2012 through FY2018, http://www.hhs.gov/budget/; and HHS, "Prevention and Public Health Fund," funding distribution tables, https://www.hhs.gov/open/prevention.

Notes: Individual amounts may not add to totals due to rounding. ACL is the Administration for Community Living; OS is the Office of the HHS Secretary.

a. Funds were used to implement insurance exchanges under the ACA. CMS, *Justification of Estimates for Appropriations Committees, Fiscal Year 2015,* p. 349, http://www.hhs.gov/budget/.

Appendix D. Patient-Centered Outcomes Research Trust Fund

Affordable Care Act (ACA) Section 6301(e) established the Patient-Centered Outcomes Research Trust Fund (PCORTF) to support comparative clinical effectiveness research at both HHS and the Patient-Centered Outcomes Research Institute (PCORI).[99] The law provided annual funding to the PCORTF over the period FY2010-FY2019 from the following three sources: (1) annual appropriations, (2) fees on health insurance and self-insured plans, and (3) transfers from the Medicare Part A and Part B trust funds.

Specifically, the ACA appropriated the following amounts to the PCORTF: (1) $10 million for FY2010; (2) $50 million for FY2011; and (3) $150 million for each of FY2012 through FY2019. In addition, for each of FY2013 through FY2019, the ACA appropriated an amount equivalent to the net revenues from a new fee that the law imposes on health insurance policies and self-insured plans. For policy/plan years ending during FY2013, the fee equals $1 multiplied by the number of covered lives. For policy/plan years ending during each subsequent fiscal year through FY2019, the fee equals $2 multiplied by the number of covered lives. Finally, transfers to PCORTF from the Medicare Part A and Part B trust funds are calculated by multiplying the average number of individuals entitled to benefits under Medicare Part A, or enrolled in Medicare Part B, by $1 (for FY2013) or by $2 (for each of FY2014 through FY2019).

For each of FY2011 through FY2019, the ACA requires 80% of the PCORTF funds to be made available to PCORI, and the remaining 20% of funds to be transferred to the HHS Secretary for carrying out PHSA Section 937.[100] Of the total amount transferred to HHS, 80% is to be distributed to AHRQ. In the FY2018 budget request, the President proposes to incorporate AHRQ under NIH by creating a new institute, the National Institute for Research on Safety and Quality (NIRSQ); therefore, for FY2018, the funds that would have otherwise gone to AHRQ are shown as going to NIRSQ. **Table D-1** shows the allocation of PCORTF funds through FY2018.

Table D-1. Distribution of PCORTF Funding

(Millions of Dollars, by Fiscal Year)

Funding Recipient	2012	2013	2014	2015	2016	2017 Est.	2018 Est.
PCORI	120	289	376	396	469	463	533
HHS	30	72	94	99	117	116	133
AHRQ (non-add)	*(24)*	*(58)*	*(75)*	*(80)*	*(94)*	*(93)*	—
NIH/NIRSQ (non-add)							*(106)*
Office of the Secretary (non-add)	*(6)*	*(14)*	*(19)*	*(19)*	*(23)*	*(23)*	*(27)*
Total	**150**	**361**	**470**	**495**	**586**	**579**	**666**

Source: CRS calculations using data provided in Office of Management and Budget, *Budget of the U.S. Government, Appendix* (FY2013-FY2018).

[99] PCORI (established by ACA Section 6301(a), adding new SSA Section 1181) is a nongovernmental body authorized by Congress to evaluate existing research and to conduct original research examining the relative health outcomes, clinical effectiveness, and appropriateness of different medical treatments. See http://www.pcori.org.

[100] ACA Section 6301(b) added a new PHSA Section 937 requiring the broad dissemination of research findings published by PCORI. See **Table 4**.

Appendix E. FDA User Fee Authorizations

Table E-1. FDA User Fee Authorizations and Anticipated Collections

(Millions of Dollars, in Order of FY2017 Anticipated Collections)

User Fee	Initial Authorizing Legislation and Year	FY2017 Anticipated Collections
Prescription drug	Prescription Drug User Fee Act (PDUFA), 1992 (P.L. 102-300)	755
Tobacco product	Family Smoking Prevention and Tobacco Control Act, 2009 (P.L. 111-31)	635
Generic drug	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	323
Medical device	Medical Device User Fee and Modernization Act (MDUFMA), 2002 (P.L. 107-250)	126
Animal drug	Animal Drug User Fee Act (ADUFA), 2003 (P.L. 108-130)	24
Biosimilars	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	22
Mammography	Mammography Quality Standards Act (MQSA), 1992 (P.L. 102-539)	21
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA), 2008 (P.L. 110-316)	11
Color certification	Color Additive Amendments of 1960 (P.L. 86-618)	9
Rare pediatric disease priority review voucher	Prescription Drug User Fee Amendments of 2012 (P.L. 112-144)	8
Food reinspection	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	6
Voluntary qualified importer (VQIP)	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	5
Export certification	FDA Export Reform and Enhancement Act of 1996 [for medical products] (P.L. 104-134); Food Safety Modernization Act (FSMA), 2011 [for foods] (P.L. 111-353)	5
Food recall	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	1
Outsourcing facility	Drug Quality and Security Act (DQSA), 2013 (P.L. 113-54)	1
Third party auditor program	Medical Device User Fee and Modernization Act (MDUFMA), 2002 (P.L. 107-250)	1
Tropical disease priority review voucher	Food and Drug Administration Amendments Act (FDAAA), 2007 (P.L. 110-85)	0
Total		**1,954**

Source: The FY2017 amounts are from the Consolidated Appropriations Act, 2017 (P.L. 115-31).

Note: Individual amounts may not add to the total due to rounding.

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