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Public Health Service Agencies: Overview and Funding (FY2015-FY2017)

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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 Affordable Care Act (ACA), 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 several years 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). In FY2015 and FY2016, AHRQ received its own discretionary appropriation in lieu of set-aside funds, with the FY2016 level of $428 million below the FY2015 level of $443 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's funding level has fluctuated in the past few years, with the FY2016 level of $11.8 billion above the FY2015 level of $11.2 billion. 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 **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 FDA's funding level in FY2016 was $4.7 billion—above the FY2015 level of $4.5 billion—with user fees accounting for about 43% of FDA's total 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 increased from $10.6 billion in FY2015 to $10.8 billion in FY2016.
- 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 FY2015 and FY2016 from $5.9 billion to $6.2 billion. Appropriations and collections both increased during that period.
- 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 $32.3 billion in FY2016, compared to $30.3 billion in FY2015.
- 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 $3.6 billion in FY2015 and $3.7 billion in FY2016.

This report is a new edition of an earlier product, which remains available: CRS Report R43304, *Public Health Service Agencies: Overview and Funding (FY2010-FY2016)*. It will be updated with information on PHS agency funding for FY2017 once legislative action on appropriations for the new fiscal year is completed.

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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]

While the PHS agencies all provide and support essential public health services, 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 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 discussion of CDC in 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 2009, Congress gave FDA the 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 is comprised of 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 (CERCLA, the "Superfund" law).[6]

Sources of PHS Agency 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]

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). A significant portion of the FY2013 PPHF funds that were originally allocated to CDC and SAMHSA were reallocated to CMS, also for ACA

[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 R44287, *Labor, Health and Human Services, and Education: FY2016 Appropriations*; CRS Report R44061, *Interior, Environment, and Related Agencies: FY2016 Appropriations*; and CRS Report R44240, *Agriculture and Related Agencies: FY2016 Appropriations*.

[9] The HHS Secretary's FY2016 transfer authority was provided in Section 205 of the FY2016 LHHS appropriations act (P.L. 114-113, Division H).

[10] The ACA was signed into law on March 23, 2010 (P.L. 111-148, 124 Stat. 119). On March 30, 2010, the President 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.

implementation. 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 budgeting 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 FY2016 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 specified 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.

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

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[11] For more discussion of ACA implementation funding, see CRS Report R43066, *Federal Funding for Health Insurance Exchanges*.

[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. 114-113, Division H, Section 205.

[13] P.L. 114-113, 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.

Table 1 also shows the set-aside assessments and transfers for the current fiscal year (i.e., 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.

The situation with AHRQ is of particular interest to many. From FY2003 through FY2014, AHRQ did not receive an annual discretionary appropriation. The agency was supported by set-aside funds and, in recent years, by amounts from other sources. In FY2015, however, AHRQ received a discretionary appropriation for the first time in more than a decade in lieu of receiving any set-aside funding. That continues to be the case in FY2016.[15]

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 budget of several PHS agencies.

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

Mandatory Appropriations

The ACA included numerous appropriations that together provided billions of dollars in mandatory spending[16] to support specified grant programs and activities within HHS.[17] A few PHS agencies continue to receive these funds, which are itemized in the funding tables in this report.

The ACA also established and funded three multibillion dollar trust funds to help support PHS agency programs and activities. First, the ACA provided a total of $11 billion in annual appropriations over the five-year period FY2011-FY2015 to the **Community Health Center Fund (CHCF)**.[18] These funds help support the federal health centers program and the National Health Service Corps (NHSC), both of which are administered by HRSA. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[19] 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 A**.

Second, the **Prevention and Public Health Fund (PPHF)**, for which the ACA provided a permanent annual appropriation, is intended to support prevention, wellness, and other public health programs and activities.[20] To date, CDC has received the majority of PPHF funds, while AHRQ, HRSA, and SAMHSA have received smaller amounts. The HHS Secretary transferred almost half of the FY2013 PPHF funds to CMS to support ACA implementation. A table showing the allocation of annual PPHF funding by agency since FY2010 is provided in **Appendix B**.

Finally, the **Patient-Centered Outcomes Research Trust Fund (PCORTF)** 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.[21] A portion of the PCORTF is allocated for AHRQ. More information on the PCORTF, including the appropriation and transfer formulas, is provided in **Appendix C**.

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

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 very small portion of each

[16] Mandatory spending, also known as direct spending, refers to outlays from budget authority that is provided in laws other than annual appropriations acts. Mandatory spending includes spending on entitlement programs.

[17] 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)*.

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

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

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

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

agency's overall budget.[22] 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)[23] 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 FY2016, user fees account for 43% of the agency's funding. More discussion of user fees is provided in the FDA section of this report and in **Appendix D**.

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, which are briefly discussed below, have had an impact on the level of discretionary funding for several PHS agencies since FY2010.

Among the five PHS agencies that are funded through the LHHS appropriations act, AHRQ has witnessed a reduction in discretionary funding over the past six years. However, that reduction has been offset by the receipt of increasing amounts of mandatory funding. Discretionary funding for the other four agencies—CDC, HRSA, NIH, and SAMHSA—has fluctuated in recent years, dipping in FY2013 as a result of the sequestration of discretionary appropriations that fiscal year (see below). Both CDC and HRSA also 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 the Interior/Environment appropriations acts, respectively, have seen their appropriations increase since FY2010. Both agencies also have witnessed a steady increase in funding from other sources; user fees at FDA, and third-party collections at IHS.

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

[23] P.L. 102-571, 106 Stat. 4491.

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, as part of negotiations to raise the debt ceiling, Congress and the President then enacted the Budget Control Act of 2011 (BCA).[24] 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 spending reductions equally divided between the categories of defense and nondefense spending beginning in FY2013. Within each spending category, those further reductions are allocated proportionately to discretionary spending and mandatory spending, subject to certain exemptions and special rules. All the spending summarized in this report falls within the nondefense category.

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 the mandatory spending reductions to be executed each year through 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 (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**).

While all the nonexempt PHS programs with mandatory funding were sequestered in FY2013 and FY2014, several of them avoided sequestration in FY2015 and/or FY2016 because they had no budgetary resources in place at the time the sequester was ordered by the President. The Maternal, Infant, and Early Childhood Home Visiting program, administered by HRSA, is one example of a program for which this occurred. The ACA authorized the home visiting program and funded it through FY2014 (see **Table 7**). Pursuant to the BCA, the President ordered the FY2015 sequestration on March 10, 2014. Because Congress and the President had yet to enact legislation extending funding for the home visiting program, there were no FY2015 budgetary resources to sequester.[25]

[24] 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*.

[25] 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 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).

Table 2. Sequestration of Funding for PHS Agency Programs

FY2013-FY2017

Program	Percent Reduction				
	FY2013	FY2014	FY2015	FY2016	FY2017
Mandatory Spending					
Nonexempt programs	5.1%[a]	7.2%	7.3%	6.8%	6.9%
Community & migrant health centers, IHS	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]

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; and OMB Report to the Congress on the Joint Committee Reductions for Fiscal Year 2017, February 9, 2016.

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

FY2014-FY2017 Discretionary Spending Caps

Table 3 shows the original nondefense discretionary (NDD) spending caps for FY2014-FY2017 established by the BCA. For each of those four fiscal years, the BCA required the caps to be lowered by approximately $37 billion to achieve the necessary reduction in NDD spending.

However, the Bipartisan Budget Act of 2013 (BBA13)[26] amended the BCA by establishing new levels for the FY2014 and FY2015 NDD spending caps, and eliminating the requirement for

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

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)[27] further amended the BCA by establishing new levels for the FY2014 and FY2015 NDD spending caps, and eliminating the requirement for those caps to be lowered. Once again, the BBA15 caps were set at a level that is below the original BCA caps for those two fiscal years (see **Table 3**), but is higher than the BCA-lowered caps that they replace.

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

Table 3. Nondefense Discretionary Spending Limits

Billions of Dollars

	FY2014	FY2015	FY2016	FY2017
Original caps under BCA	510.000	520.000	530.000	541.000
Revised caps under BBA13 and BBA15	491.773	492.356	518.491	518.531

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).

Mandatory Funding Proposals for FY2017

The President's FY2017 budget includes a total of $2.940 billion in proposed new mandatory funding for the PHS agencies: $1.825 billion for NIH; $590 million for SAMHSA; $495 million for HRSA; and $30 million for CDC. These amounts, which are discussed later in this report, would be used to supplement—and in one case replace—discretionary funding for existing programs, or provide funding for new initiatives. It will be up to Congress to decide whether to pass legislation to provide these funds.

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 do not count toward the discretionary spending caps.

Report Roadmap

The remainder of this report consists of seven sections, one for each PHS agency beginning with AHRQ.[28] 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 FY2015 and FY2016 funding levels and the FY2017 budget request. The amounts in the funding tables in this report are taken from the departmental and agency budget documents submitted to the appropriations committees, as well as agency operating plans.[29]

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

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

[29] All the budget documents and operating plans are available at http://www.hhs.gov/budget/.

The funding tables show the post-sequestration amounts for the accounts that were subject to sequestration in FY2015 and FY2016. The amounts shown for the FY2017 request do not reflect sequestration.

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 or, in the case of the FY2017 budget request, that no discretionary funding was requested.

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 give a somewhat distorted view of their available budgetary resources. This effect is 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**). NIH, for example, is assessed approximately $700 million annually. While the funding table for NIH shows the transfer (i.e., receipt) of set-aside funds, which count toward the agency's overall program level funding, the amounts shown for each agency account have not been reduced to reflect the assessment. Thus, NIH appears to have about $700 million more than is in fact the case.

This report is a new edition of an earlier product, which remains available: CRS Report R43304, *Public Health Service Agencies: Overview and Funding (FY2010-FY2016)*.

Agency for Healthcare Research and Quality (AHRQ)[30]

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.[31] Specific research efforts are aimed at reducing the costs of care, promoting patient safety, measuring the quality of health care, and

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

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

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 the Agency for Healthcare Research and Quality (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.

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 also has received mandatory funds from the PPHF and the PCORTF (see **Appendix B** and **Appendix C**). In FY2015, AHRQ received its own discretionary appropriation for the first time in more than a decade in lieu of any set-aside funding.[32] This trend continued in FY2016 with the agency receiving its own discretionary appropriation and no set-aside funds.

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

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

Patient Safety. 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.

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

Source: CRS Analysis and the FY2017 HHS Budget in Brief. http://www.hhs.gov/about/budget/fy2017/budget-in-brief/ahrq/index.html.

[32] 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).

Recent Trends in Agency Funding

Since FY2010, AHRQ's budget has increased from $403 million to $428 million (+$25 million), with transfers from PCORTF growing from $8 million in FY2011 to $94 million in FY2016. Discretionary sources of funding shifted from set-aside transfers to the agency's own discretionary appropriation in both FY2015 and FY2016, and ACA mandatory funds have been a prominent and 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, despite an increasing PCORTF transfer (see **Table 4**).

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

(Millions of Dollars, by Fiscal Year)

Program or Activity	2015	2016	2017 Request
HCQO Research	**229**	**197**	**224**
Health Information Technology Research	28	22	23
Patient Safety	77	74	76
Health Services Research, Data, and Dissemination[a]	112	89	113
PHS Evaluation Set-Aside (non-add)	*(0)*	*(0)*	*(83)*
Prevention/Care Management (USPSTF)	12	12	12
MEPS	**65**	**66**	**69**
Program Support	**70**	**71**	**71**
PCORTF (Patient-Centered Health Research)[b]	**79**	**94**	**106**
Total, Program Level	**443**	**428**	**470**
Less Funds From Other Sources			
PHS Evaluation Set-Aside	0	0	83
PCORTF Transfers	79	94	106
Total, Discretionary Budget Authority	**364**	**334**	**280**

Sources: Prepared by CRS based on AHRQ's congressional budget justification documents and the HHS *Budget in Brief* documents, available at http://www.hhs.gov/budget/.

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

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

b. 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)[33]

Agency Overview

CDC's mission is "to protect America from health, safety and security threats, both foreign and in the [United States]."[34] CDC is organized into a number of centers, institutes, and offices, some focused on specific public health challenges (e.g., chronic disease prevention, injury prevention), and others focused on general public health capabilities (e.g., surveillance and laboratory services).[35] In addition, the Agency for Toxic Substances and Disease Registry (ATSDR) is headed by the CDC Director and is discussed in this section.

Many CDC activities are not specifically authorized but are based in broad, permanent authorities in the PHSA.[36] Four CDC operating divisions are explicitly authorized. The National Institute for Occupational Safety and Health (NIOSH) was permanently authorized by the Occupational Safety and Health Act of 1970.[37] The National Center on Birth Defects and Developmental Disabilities (NCBDDD) was established in PHSA Section 317C by the Children's Health Act of 2000.[38] The National Center for Health Statistics (NCHS) was established in PHSA Section 306 by the Health Services Research, Health Statistics, and Medical Libraries Act of 1974.[39] ATSDR was established by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA, the "Superfund" law).[40] Authorizations of appropriations for NCBDDD, NCHS, and ATSDR have expired, but the programs continue to receive annual appropriations.

CDC provides about $5 billion per year in grants to state, local, municipal, tribal, and foreign governments, and to academic and non-profit entities.[41] It has few regulatory responsibilities.

Recent Trends in Agency Funding

Between FY2010 and FY2016, the total program level for CDC/ATSDR increased from $10.88 billion to $11.78 billion. During that time period, CDC/ATSDR budget authority decreased by 3% from $6.5 billion in FY2010 to $6.3 billion in FY2016. **Table 5** presents funding levels for CDC programs for FY2015 through the FY2017 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;[42] (2) NIOSH activities to support the Energy Employees Occupational Illness Compensation Program Act (EEOICPA);[43] (3) the World Trade Center Health Program (WTCHP);[44] and (4) appropriations provided under

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

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

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

[36] 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.

[37] 29 U.S.C. §671.

[38] 42 U.S.C. §247b-4.

[39] 42 U.S.C. §242k.

[40] 42 U.S.C. §9604(i).

[41] See CDC, Procurements and Grants, http://www.cdc.gov/about/business/funding.htm.

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

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

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

ACA, principally through the PPHF.[45] CDC receives a small amount of funds from authorized user fees, and may also receive funds through the PHS set-aside, 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 FY2016, the CDC/ATSDR total operating budget, or program level, is $11.78 billion. Of this amount,

- $6.27 billion (53%) is composed of discretionary funds (i.e., budget authority) for CDC provided in the LHHS appropriations act;
- $5.42 billion (46%) is composed of mandatory funds for CDC and ATSDR programs, namely the VCF, EEOICPA, and WTCHP, and from the ACA (principally from the PPHF);
- $75 million (<1%) is discretionary funds for ATSDR provided in the Interior/Environment appropriations act; and
- $17 million (<1%) is from authorized user fees and other transfers.

Many of CDC's PPHF-funded activities also receive discretionary appropriations. Exceptions include the Preventive Health and Health Services Block Grant, and the Lead Poisoning Prevention Program, which were funded solely through PPHF distributions for FY2016.[46] For more discussion on the allocation of annual PPHF funding, see **Appendix B**.

In December 2014 Congress provided $1.771 billion in FY2015 emergency supplemental appropriations to CDC for response to the Ebola outbreak. The funds, which are available through FY2019, are to be used for both domestic and international activities. CDC has not presented these funds within its general budget, and they are not presented in **Table 5**.[47] However, the table does include $30 million provided to CDC's Global Health Program from an earlier Ebola supplemental.

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	2015	2016	2017 Request
Immunization and Respiratory Diseases	798	798	748
PPHF Transfer (non-add)	*(210)*	*(324)*	*(336)*
PHSSEF Influenza Transfers (non-add)	*(15)*	*(15)*	*0*
Vaccines for Children[a]	3,851	4,161	4,387
HIV/AIDS, Viral Hepatitis, STI and TB	1,118	1,122	1,127
Emerging & Zoonotic Infectious Diseases	405	580	629
PPHF Transfer (non-add)	*(52)*	*(52)*	*(52)*

[45] CRS Report R41301, *Appropriations and Fund Transfers in the Affordable Care Act (ACA)*. See more information about the PPHF in **Appendix B** of this report.

[46] Budget details are available in CDC, "FY 2017 CDC Budget Overview," table on pp. 10-12, February, 2016, http://www.cdc.gov/budget/fy2017/congressional-justification.html.

[47] CDC, "FY 2015–2019 Ebola Response Funding," http://www.cdc.gov/budget/ebola/index.html. See also CRS Report R44460, *Zika Response Funding: In Brief*.

Program or Activity	2015	2016	2017 Request
Chronic Disease Prevention and Health Promotion	1,199	1,177	1,117
PPHF Transfer (non-add)	*(452)*	*(339)*	*(437)*
ACA Childhood Obesity Demonstration[b]	—	10	—
Birth Defects, Developmental Disabilities, Disability and Health	132	136	136
PPHF Transfer (non-add)	*(0)*	*(0)*	*(68)*
Environmental Health	179	182	182
PPHF Transfer (non-add)	*(13)*	*(17)*	*(14)*
Injury Prevention and Control	170	236	299
Mental Health (New mandatory proposal, non-add)[c]	—	—	*(30)*[c]
Public Health Scientific Services	481	492	501
PPHF Transfer (non-add)	*(0)*	*(0)*	*(36)*
Occupational Safety and Health	335	339	286
PHS Evaluation Set-Aside (non-add)	*(0)*	*(0)*	*(72)*
Global Health	447	427	442
Supplemental Appropriations for Ebola response (non-add)[d]	*(30)*[d]	—	—
Public Health Preparedness and Response	1,353	1,405	1,402
Crosscutting Activities and Program Support	274	274	114
PPHF Transfer (non-add)[e]	*(160)*	*(160)*	*(0)*
Prevention Block Grant (non-add)[e]	*(160)*	*(160)*	*(0)*
Buildings and Facilities	10	10	31
User Fees	2	2	2
Energy Employees Occupational Illness Compensation Program Act (EEOICPA)	50	55	55
World Trade Center Health Program[f]	261	300	335
Agency for Toxic Substances and Disease Registry (ATSDR)	75	75	75
ACA Medical Monitoring (ATSDR)[g]	19	—	—
Total, CDC/ATSDR Program Level	**11,158**	**11,781**	**11,868**
Less Funds From Other Sources			
Vaccines for Children[a]	3,851	4,161	4,387
EEOICPA	50	55	55
PHSSEF Transfers	15	15	0
PHS Evaluation Set-Aside	0	0	72
ACA Mandatory Funds: PPHF Transfers	887	892	944
Other Mandatory Funds	19	10	—
World Trade Center Health Program	261	300	335
User Fees	2	2	2
Proposed New Mandatory Funds	—	—	30

Program or Activity	2015	2016	2017 Request
Total, CDC/ATSDR Discretionary BA	**6,073**	**6,346**	**6,043**
Less ATSDR Discretionary BA	75	75	75
Total, CDC Discretionary BA	**5,998**	**6,271**	**5,967**

Sources: CDC and ATSDR congressional budget justifications and related documents for FY2016 and FY2017, http://www.cdc.gov/fmo.

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

Amounts in this table do not include emergency supplemental Ebola response funding for FY2015-FY2019 provided in P.L. 113-235. These funds are discussed in CRS Report R44460, *Zika Response Funding: In Brief*; and at CDC, "FY 2015–2019 Ebola Response Funding," http://www.cdc.gov/budget/ebola/index.html.

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.

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. Amounts for FY2015 through the FY2017 request are estimates.

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. New mandatory funding for FY2017 is proposed for CDC to assist state health departments in implementing comprehensive suicide prevention programs.

d. Emergency supplemental appropriations for FY2015 for the response to the 2014 Ebola outbreak in West Africa, provided in P.L. 113-164. See note above re: subsequent emergency appropriations for the Ebola response.

e. For several years the budget request has called for elimination of the Preventive Health and Health Services Block Grant (also called the "Prevention Block Grant"). For each of FY2015 and FY2016, Congress provided it with $160 million from the PPHF.

f. Amounts are estimated federal obligations.

g. 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, Montana. The amount presented (i.e., $19 million for FY2015 through FY2019) reflects sequestration as required for non-defense mandatory spending; see **Table 2**.

Food and Drug Administration (FDA)[48]

Agency Overview

FDA regulates the safety of human foods, dietary supplements, cosmetics, and animal foods; and the safety and effectiveness of human drugs, biological products (e.g., vaccines), medical devices, and animal drugs. It 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.

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

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

For more information

CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*.

The Federal Food, Drug, and Cosmetic Act (FFDCA) is the principal source of FDA's statutory authority.[49] FDA is also responsible for administering certain provisions in other laws, most notably the PHSA.[50] 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. 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 several different user fees, which account for 43% of FDA's total FY2016 program level, contribute only to the Salaries and Expenses account.

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 D** presents the authorizing legislation for current FDA user fees, sorted by the dollar amount they contribute to the agency's FY2016 budget. After PDUFA, Congress added 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).[51] Each of the medical product fee authorities requires reauthorization every five years. Several indefinite authorities apply to fees for mammography inspection, color additive certification, export certification, and priority review vouchers.[52]

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[49] 21 U.S.C. §§301 et seq.

[50] 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 at http://www.fda.gov/RegulatoryInformation/Legislation/default.htm.

[51] 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)*; CRS Report R42680, *The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144)*.

[52] User fees provide varying proportions of funding for several FDA programs (see **Table D-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 FY2016, fees account for 65% of the human

Recent Trends in Agency Funding

Between FY2010 and FY2016, FDA's funding increased from $3.1 billion to $4.7 billion. Although discretionary appropriations increased by 16% over that time period, user fee revenue more than doubled. In FY2016, user fees account for 43% of FDA's total funding compared with 24% in FY2010.

The President's FY2017 budget request was for a *total program level* of $4.826 billion, an increase of $81 million (+2%) from the FY2016 total program level of $4.745 billion (see **Table 6**). The FY2017 budget request includes $2.743 billion for budget authority, an increase of $15 million (+0.5%) compared to the FY2016 enacted level of $2.728 billion, and $2.084 billion for user fees, an increase of $66 million (+3%) compared to the FY2016 enacted level of $2.017 billion. In addition to the $2.084 billion in user fees from currently authorized programs, the President requested $202 million in as yet unauthorized fees to support export certification, food facility registration and inspection, food import, international courier, cosmetics, and food contact substance notification activities. With those proposed fees, the President's total user fee request was $2.286 billion, bringing the total program level request to $5.029 billion. The FY2017 request also included $75 million in new mandatory resources to support the Cancer Moonshot Initiative.[53]

drugs program budget, 40% of the biologics budget, 28% of the devices and radiological health budget, 16% of the animal drugs and feeds budget, and 1% of the foods budget. **Appendix D** of this report presents additional detail.

[53] For additional information about the Vice President's Cancer Moonshot, see page 12 of the FDA FY2017 Justification of Estimates for Appropriations Committees, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM485237.pdf.

Table 6. Food and Drug Administration (FDA)

(Millions of Dollars, by Fiscal Year)

Program area	2015[a]	2016	2017 request
Foods	**903**	**999**	**1,024**
Budget Authority	903	987	1,013
User Fees	0	12	12
Human drugs	**1,370**	**1,395**	**1,408**
Budget Authority	482	492	492
User Fees	888	903	917
Biologics	**326**	**355**	**360**
Budget Authority	211	215	215
User Fees	115	139	145
Animal drugs and feeds	**175**	**189**	**193**
Budget Authority	148	159	162
User Fees	27	30	31
Devices and radiological health	**443**	**450**	**460**
Budget Authority	321	323	326
User Fees	122	127	134
Tobacco products	**554**	**564**	**596**
Budget Authority	—	—	—
User Fees	554	564	596
Toxicological research	**63**	**63**	**60**
Budget Authority	63	63	60
User Fees	—	—	—
Headquarters/Commissioner's Office	**261**	**290**	**286**
Budget Authority	173	182	178
User Fees	88	108	108
GSA rent	**220**	**239**	**236**
Budget Authority	169	177	170
User Fees	51	62	66
Other rent and rent-related activities	**162**	**172**	**169**
Budget Authority	116	122	115
User Fees	46	50	54
Export and color certification funds	**11**	**13**	**15**
Budget Authority	—	—	—
User Fees	11	13	15
Food and drug safety	**12**	**0**	**0**
Budget Authority	12	0	0
User Fees	0	0	0

Priority review vouchers	**0**	**8**	**8**
Budget Authority	—	—	—
User Fees	0	8	8
Buildings & Facilities	**9**	**9**	**12**
Budget Authority	9	9	12
User Fees	—	—	—
Total, Program Level	**4,511**[b]	**4,745**	**4,826**[c]
Less Funds From Other Sources			
User Fees	1,903[d]	2,017[e]	2,084[f]
Total, Discretionary Budget Authority	**2,608**[b]	**2,728**	**2,743**

Sources: Prepared by CRS based on congressional budget justification documents and the HHS *Budget in Brief*, available at http://www.hhs.gov/budget/.

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. It also apportions user fee revenue across the program areas as indicated in the Administration's request (e.g., 90% of the animal drug user fee revenue is designated for the animal drugs and feeds program, with the rest going to headquarters and Office of the Commissioner, GSA rent, and other rent and rent-related activities categories).

a. This column shows the FY2015 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 FY2015 for the food program, but user fees for food were authorized in the FY2015 enacted bill.

b. The FY2015 Agriculture appropriations act provided an additional $25 million to FDA for Ebola response and preparedness activities. Adding this amount to the FDA appropriations brought BA to $2,633 million and the total program level to $4,536 million for FY2015.

c. This total does not include the $75 million in proposed new mandatory funding for the Vice President's Cancer Moonshot Initiative.

d. The FY2015 enacted bill included $1 million for fees related to pharmacy compounding that the President's request had not included in the FY2015 request submission.

e. The FY2016 enacted bill included $1 million for fees related to pharmacy compounding (Congressional Budget Office estimate) that the President's request had not included in the FY2016 request submission.

f. For user fees in the Administration's FY2017 request, this column shows only those that have been authorized. Including the $202 million in proposed user fees, the President's total user fee request is $2.286 billion, yielding a total program level request of $5.029 billion.

Health Resources and Services Administration (HRSA)[54]

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;

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

state, local, and tribal governments; and private entities to support health services projects, such as training health care workers or providing specific health services.[55] HRSA also administers the health centers program, which provides grants to non-profit entities that provide primary care services to people who experience financial, geographic, cultural, or other barriers to health care.[56]

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).[57]

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, 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.

Source: HRSA website, http://www.hrsa.gov/about/organization/bureaus/index.html.

As noted in the text box, the majority of HRSA's programs are authorized by the PHSA;[58] others are authorized by the SSA. Additionally, 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.

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

[56] 42 U.S.C. §§254b.

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

[58] 42 U.S.C. §§201 et seq.

Recent Trends in Agency Funding

HRSA funding increased from $8.1 billion in FY2010 to $10.8 billion in FY2016 despite a reduction in its 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 the congressional earmark program that supported health care facility construction and renovation.

The overall growth in HRSA's funding was primarily driven by increasing amounts from the CHCF, 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.

With CHCF funding set to expire at the end of FY2015, Congress included two more years of CHCF funding in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA);[59] see **Table 7** and **Appendix A**. MACRA also extended funding for other HRSA programs that were established and initially funded by the ACA; notably, the Maternal, Infant, and Early Childhood Home Visiting Program and the Teaching Health Center Program.

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 R43920, *National Health Service Corps: Background and Trends in Funding and Recruitment.*

CRS Report R42428, *The Maternal and Child Health Services Block Grant: Background and Funding.*

CRS Report R43177, *Health Workforce Programs in Title VII of the Public Health Service Act.*

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

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

Table 7. Health Resources and Services Administration (HRSA)

(Millions of Dollars, by Fiscal Year)

Bureau or Activity	2015	2016[a]	2017 Request
Primary Care	**5,001**	**5,092**	**5,092**
Health Centers	4,901	*4,992*	4,992
Discretionary BA (non-add)	*(1,392)*	(1,392)	(1,242)
CHCF Transfer (non-add)	*(3,509)*	*(3,600)*	*(3,600)*
New mandatory proposal (non-add)	—	—	*(150)*
Health Centers Tort Claims	100	100	100
Health Workforce	**1,058**	**1,228**	**1,273**
National Health Service Corps (NHSC)	287	*310*	380
Discretionary BA (non-add)	*(0)*	*(0)*	*(20)*
CHCF Transfer (non-add)	*(287)*	*(310)*	*(310)*
New mandatory proposal (non-add)	—	—	*(50)*
Faculty Loan Repayment Program	1	1	1
Training for Diversity[b]	82	82	85
Primary Care Training and Enhancement	39	39	39
Interdisciplinary, Community-Based Linkages[c]	73	129	105
Public Health Workforce Development	21	21	17
Nursing Workforce Development[d]	232	229	229
Children's Hospitals GME Payments	265	295	295
GME Targeted Support (New mandatory proposal)	—	—	*(295)*
Teaching Health Center GME Payments (ACA §5508(c))	—	60	60
Other Health Workforce Programs[e]	39	41	41
National Practitioner Data Bank (User Fees)	19	21	21
Maternal and Child Health	**1,254**	**1,250**	**1,250**
Maternal and Child Health Block Grant	637	638	638
Healthy Start	102	104	104
Maternal, Infant Home Visiting (ACA §2951)	400	400	400
Family-to-Family Health Centers (ACA §5507)[f]	5	5	5
Other Maternal and Child Health Programs[g]	112	103	103
Ryan White HIV/AIDS	**2,319**	**2,323**	**2,332**
PHS Evaluation Fund (non-add)	—	—	*(34)*
Health Care Systems	**103**	**103**	**119**
Health Care Systems Programs[h]	76	76	76
Hansen's Disease Programs	17	17	17
340B Drug Pricing Programs	10	10	26
User fees (non-add)	—	—	*(9)*
Rural Health	**147**	**150**	**144**

Other Activities	**683**	**685**	**706**
Family Planning	286	286	300
Program Management	154	154	157
Vaccine Injury Compensation Program (VICP) Operations	8	8	9
VICP Trust Fund	235	237	240
Total, Program Level	**10,565**	**10,831**	**10,916**
Less Funds From Other Sources			
PHS Evaluation Set-Aside	—	—	34
User Fees	19	19	30
VICP Trust Fund (Mandatory)	235	237	240
ACA Mandatory Funds: CHCF Transfers	3,796	3,910	3,910
ACA Mandatory Funds: Other	5	65	65
Maternal, Infant Home Visiting	400	400	400
Proposed New Mandatory Funds	—	—	495
Total, Discretionary Budget Authority	**6,112**	**6,197**	**5,743**

Source: Prepared by CRS based on congressional budget justification documents and the HHS *Budget in Brief*, available at http://www.hhs.gov/budget/; and from P.L. 114-10.

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

a. Includes funds appropriated in MACRA (P.L. 114-10).

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

c. Interdisciplinary, Community-based Linkages includes the following programs: Area Health Education Centers (AHEC), Geriatric Programs, and Mental and Behavioral Health Education and Training. In FY2017, the President's Budget does not request funding for the Area Health Education Center program.

d. Nursing Workforce Development includes the following programs: 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.

e. Other Health Workforce Programs include Health Care Workforce Assessment, and Oral Health Training.

f. P.L. 113-93 provided $2.5 million for this program for FY2015, which was repealed when P.L. 114-10 provided a full year of funding ($5 million) for this program for FY2015.

g. 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.

h. 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)[60]

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

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

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).[61]

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.[62] In addition, specific IHS programs are authorized by two acts: the Indian Sanitation Facilities Act of 1959[63] and the Indian Health Care Improvement Act (IHCIA).[64] The Indian Sanitation Facilities Act authorizes the IHS to construct sanitation facilities for Indian communities and homes; and 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.

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 FY2016 from $5.1 billion to $6.2 billion (see **Table 8**). This increase was driven both by increased discretionary appropriations, which rose from $4.1 billion to $4.8 billion, and by increased collections, which rose from $891 million to $1.1 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. Given the ruling that stated that these are required costs, the President's Budget includes a proposal to reclassify contract support costs as a mandatory three-year appropriation.[65]

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

[62] 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).

[63] P.L. 86-121; 42 U.S.C. §2004a.

[64] 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*.

[65] 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*.

Table 8. Indian Health Service (IHS)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2015	2016	2017 Request
Clinical and Preventive Services	**4,652**	**4,737**	**4,998**
Clinical Services	4,348[a]	4,431[b]	4,682[b]
Purchased/Referred Care (non-add)[c]	*(914)*	*(914)*	*(962)*
Preventive Health	154	156	166
Special Diabetes Program for Indians[d]	150	150	150
Other Health Services	**831**	**891**	**985**
Urban Health Projects	44	45	48
Indian Health Professions	48	48	59
Indian Health Professions Expansion (non-add)	—	—	*(10)*
Tribal Management/Self-Governance	8	8	8
Direct Operations	68	72	70
Contract Support Costs[e]	663	718	800
Health Facilities	**468**	**532**	**578**
Maintenance and Improvement	62[f]	83[g]	85[g]
Sanitation Facilities Construction	79	99	103
Health Care Facilities Construction	85	105	132
Facilities/Environmental Health Support	220	223	234
Medical Equipment	23	23	24
Total, Program Level	**5,951**	**6,160**	**6,562**
Less Funds from Other Sources			
Collections	1,151	1,194	1,194
Rental of Staff Quarters	8	9	9
Special Diabetes Program for Indians[d]	150	150	150
Tribal Crisis Response Fund	—	—	15[h]
Indian Health Professions Expansion	—	—	10
Total, Discretionary Budget Authority	**4,642**	**4,808**	**5,185**

Sources: Prepared by CRS based on congressional budget justification documents and the HHS *Budget in Brief*, available at http://www.hhs.gov/budget/.

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

a. Includes $1,151 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.

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

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

d. PHSA §330C provides an annual appropriation of $150 million through FY2017 for this program. As discussed earlier in this report, these mandatory funds were subject to a 2% sequestration in FY2013 and FY2014.

e. Beginning in FY2016, Contract Support Costs were funded as an indefinite discretionary appropriation. For FY2018 and beyond, the President's Budget includes a proposal to reclassify Contract Support Costs as a mandatory three-year appropriation.
f. Includes $8 million that IHS received from rental of staff quarters.
g. Includes $9 million that IHS expects to receive from rental of staff quarters.
h. These funds would be available as part of a new Administration initiative to improve Tribal Behavioral Health. The initiative would include crisis response funds for Indian Tribes experiencing behavioral health crises and would increase funding for IHS scholarship and loan repayment for behavioral health providers.

National Institutes of Health (NIH)[66]

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 (collectively called 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 the Office of the Director.

For more information

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

CRS Report R43341, *NIH Funding: FY1994-FY2017*.

CRS Report R43944, *Federal Research and Development Funding: FY2016*.

The bulk of NIH's budget, about 81%, goes out to the extramural research community through grants, contracts, and other awards. The funding supports research performed by more than 30,000 individuals who work at more than 2,500 universities, hospitals, medical schools, and other research institutions around the country and abroad.[67] A smaller proportion of the budget, about 11%, supports the intramural research programs of the ICs, funding research performed by NIH scientists and non-employee trainees in the NIH laboratories and Clinical Center. The remaining 6% funds 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 institutes and centers. 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

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

[67] HHS, *FY2017 Budget in Brief*, p. 47, http://www.hhs.gov/sites/default/files/fy2017-budget-in-brief.pdf.

were consolidated in NCATS, and NCRR's other programs were moved to several other ICs and the OD.

NIH gets almost its entire funding (99.5%) 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 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 small increases in subsequent years. The NIH program level in FY2016 is $32.311 billion.

For FY2017, the Obama Administration requests an NIH program level total of $33.136 billion, an increase of $825 million (2.6%) over FY2016. The FY2017 program level request includes $847 million in PHS set-aside funds and $1.825 billion in proposed new mandatory funding. The FY2017 request includes $755 million for the Vice President's Cancer Moonshot, of which $680 million is allocated for the National Cancer Institute, and $75 million would be transferred from NIH to FDA.

Table 9. National Institutes of Health (NIH)

(Millions of Dollars, by Fiscal Year)

Institutes and Centers (ICs)	2015	2016	2017 Request
Cancer (NCI)	4,953	5,214	5,894
Heart/Lung/Blood (NHLBI)	2,996	3,114	3,114
Dental/Craniofacial Research (NIDCR)	398	413	413
Diabetes/Digestive/Kidney (NIDDK)[a]	1,899	1,966	1,966
Neurological Disorders/Stroke (NINDS)	1,605	1,695	1,695
Allergy/Infectious Diseases (NIAID)	4,418	4,716	4,716
General Medical Sciences (NIGMS)[b]	2,372	2,512	2,512
Child Health/Human Development (NICHD)	1,287	1,338	1,338
Eye (NEI)	677	708	708
Environmental Health Sciences (NIEHS)	667	694	694
NIEHS, Interior/Environment appropriation	77	77	77
Aging (NIA)	1,198	1,598	1,598
Arthritis/Musculoskeletal/Skin (NIAMS)	522	542	542
Deafness/Communication Disorders (NIDCD)	405	423	423
Mental Health (NIMH)	1,434	1,519	1,519
Drug Abuse (NIDA)	1,016	1,051	1,051
Alcohol Abuse/Alcoholism (NIAAA)	447	467	467
Nursing Research (NINR)	141	146	146
Human Genome Research (NHGRI)	499	513	513
Biomedical Imaging/Bioengineering (NIBIB)	327	344	344
Minority Health/Health Disparities (NIMHD)	271	281	281
Complementary/Integrative Health (NCCIH)[c]	124	130	130
Advancing Translational Sciences (NCATS)	633	685	685
Fogarty International Center (FIC)	68	70	70
National Library of Medicine (NLM)	337	396	396
Office of Director (OD)	1,414	1,571	1,716
Buildings & Facilities (B&F)	129	129	129
Total, Program Level	**30,311**	**32,311**	**33,136**
Less Funds From Other Sources			
PHS Evaluation Set-Aside[b]	715	780	847
Type 1 Diabetes Research (NIDDK)[d]	150	150	150
Proposed New Mandatory Funds	—	—	1,825
Total, Discretionary Budget Authority	**29,446**	**31,381**	**30,314**

Sources: Funding amounts for FY2015 and FY2016 are taken from the FY2016 Justification of Estimates for Appropriation Committees, Vol. 1, Overview, table on "Budget Request for Institute and Center," p.85 at http://officeofbudget.od.nih.gov/br.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 (see note e).

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

c. Reflects name change from National Center for Complementary and Alternative Medicine to National Center for Complementary and Integrative Health; provision included in P.L. 113-235.

d. 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)[68]

Agency Overview

SAMHSA is the lead federal agency for increasing access to behavioral health services. It 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 that fund 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 Title V of the PHSA, which organizes SAMHSA in three centers:

- Center for Substance Abuse Treatment (CSAT)[69]
- Center for Substance Abuse Prevention (CSAP)[70]
- Center for Mental Health Services (CMHS)[71]

Each center has general statutory authority, called Programs of Regional and National Significance (PRNS), under which it has established grant programs for states and communities to address their important substance abuse and mental health needs. PHSA Title V also authorizes a number of specific grant programs, referred to as categorical grants.

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.[72] The

For more information

CRS Report R43968, *SAMHSA FY2016 Budget Request and Funding History: A Fact Sheet.*

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

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

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

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

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

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.[73]

In addition to the three statutorily defined centers, SAMHSA's budget reflects a fourth category, "health surveillance and program support," for other activities such as collecting data, providing statistical and analytic support, raising public awareness, developing the behavioral health workforce, and maintaining the National Registry of Evidence-based Programs and Practices.[74]

The last comprehensive reauthorization of SAMHSA and its programs occurred in 2000 as part of the Children's Health Act,[75] which also added "charitable choice" provisions allowing religious organizations to receive funding for substance abuse prevention and treatment services without altering their religious character.[76] Since 2000, Congress has expanded some of SAMHSA's programs and activities without taking up comprehensive reauthorization. Although authorizations of appropriations for most of SAMHSA's grant programs expired at the end of FY2003, many of these programs continue to receive annual discretionary appropriations.

Recent Trends in Agency Funding

Over the past 10 years (FY2007–FY2016), SAMHSA's program-level funding has increased by 12%, from $3.3 billion to $3.7 billion. It has not, however, increased every year. For example, it decreased from FY2012 ($3.6 billion) to FY2013 ($3.4 billion) due to sequestration, then rebounded in FY2014 ($3.6 billion).

Relative to FY2016, SAMHSA's FY2017 request would increase program-level funding by 16% (to $4.3 billion) while decreasing discretionary budget authority by 3% (to $3.5 billion); see **Table 10**. It would make up the difference with increased PHS set-aside funds, increased PPHF transfers, and new mandatory funding proposed for FY2017 and FY2018. The proposed new mandatory funding would support three programs: (1) State Targeted Response Cooperative Agreements, which would aim to increase access to opioid addiction treatment by addressing the most commonly identified barriers to treatment; (2) Evidence-based Early Interventions, which would provide formula grants to states to support early interventions for individuals with serious mental illness; and (3) Cohort Monitoring and Evaluation of Medication-Assisted Treatment, which would evaluate addiction treatment outcomes with the goal of increasing effectiveness.

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

[74] 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 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.

[75] P.L. 106-310, Titles XXXI-XXXIV.

[76] PHSA §1955, 42 U.S.C. §300x-65; PHSA §§581 et seq., 42 U.S.C. §§290kk et seq.

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

(Millions of Dollars, by Fiscal Year)

Program or Activity	2015	2016[a]	2017 Request
Center for Mental Health Services (CMHS)	**1,071**	**1,159**	**1,274**
Mental Health Block Grant	483	533	533
PHS Evaluation Set-Aside (non-add)	*(21)*	*(21)*	*(21)*
Programs of Regional & National Significance	371	407	406
PHS Evaluation Set-Aside (non-add)	—	—	*(10)*
PPHF Transfer (non-add)	*(12)*	*(12)*	*(10)*
Children's Mental Health Services	117	119	119
PATH Homeless Formula Grant	65	65	65
Protection & Advocacy Formula Grant	36	36	36
Evidence-Based Early Interventions (New mandatory proposal)	—	—	115
Center for Substance Abuse Treatment (CSAT)	**2,181**	**2,192**	**2,661**
Substance Abuse Block Grant	1,820	1,858	1,858
PHS Evaluation Set-Aside (non-add)	*(79)*	*(79)*	*(79)*
Programs of Regional & National Significance	361	334	343
PHS Evaluation Set-Aside (non-add)	*(2)*	*(2)*	*(30)*
Monitoring & Evaluation of MAT Outcomes (New mandatory proposal, non-add)	—	—	*(15)*
State Targeted Response Cooperative Agreements (New mandatory proposal)	—	—	460
Center for Substance Abuse Prevention (CSAP)	**175**	**211**	**211**
Programs of Regional & National Significance	175	211	211
PHS Evaluation Set-Aside (non-add)	—	—	*(16)*
Health Surveillance and Program Support	**159**	**169**	**175**
Health Surveillance and Program Support[b]	119	127	125
PHS Evaluation Set-Aside (non-add)	*(30)*	*(30)*	*(29)*
PPHF Transfer (non-add)	—	—	*(18)*
Public Awareness and Support	13	16	13
PHS Evaluation Set-Aside (non-add)	—	—	*(13)*
Performance & Quality Information Systems	13	13	13
PHS Evaluation Funds (non-add)	—	—	*(13)*
Agency-Wide Initiatives	12	13	23
PHS Evaluation Set-Aside (non-add)	*(1)*	*(1)*	*(1)*
Data Request and Publications User Fees	2	2	2
Total, Program Level	**3,586**	**3,731**	**4,322**
Less Funds From Other Sources	—	—	—
PHS Evaluation Set-Aside	134	134	214

PPHF Transfers	12	12	28
Data Request and Publications User Fees	2	2	2
Proposed New Mandatory Funds	—	—	590
Total, Discretionary Budget Authority	**3,439**	**3,584**	**3,489**

Sources: Prepared by CRS based on congressional budget justification documents and the HHS *Budget in Brief*, available at http://www.hhs.gov/budget/.

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

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

b. For the FY2015, FY2016, and FY2017 request amounts, SAMHSA's FY2017 budget request indicates that the figures have been comparably adjusted to reflect (1) the proposed transfer of one program (the Behavioral Health Workforce Education and Training Program) from SAMHSA to HRSA in FY2017, and (2) a proposed single appropriation for a program (the Minority Fellowship Program) that is currently funded through multiple SAMHSA centers.

Appendix A. Community Health Center Fund

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)[77] appropriated two more years of funding to the CHCF. For both FY2016 and FY2017, MACRA provided $3.6 billion for health center operations and $310 million for the NHSC.

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

Table A-1 shows the amounts appropriated to the CHCF for each fiscal year as well as the post-sequestration levels for FY2013-FY2015. 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 A-1. Community Health Center Fund, FY2011-FY2017

(Millions of Dollars, by Fiscal Year)

Program	2011	2012	2013	2014	2015	2016	2017	Total
Health Center Program	1,000	1,200	1,500	2,200	3,600	3,600	3,600	16,700
Post-sequestration (non-add)	—	—	*(1,465)*	*(2,145)*	*(3,509)*	—	*(3,510)*	
National Health Service Corps	290	295	300	305	310	310	310	2,120
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-FY2017), 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.

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

Appendix B. Prevention and Public Health Fund (PPHF)

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. However, the Middle Class Tax Relief and Job Creation Act of 2012 amended the ACA by reducing the PPHF appropriation from FY2013 through FY2021 as part of a package of offsets to help cover the costs of the law.[78] The PPHF annual appropriation is now $1 billion through FY2017, and thereafter will increase in increments to $2 billion for FY2022 and each subsequent fiscal year.

The HHS Secretary is instructed to transfer amounts from the PPHF to 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 FY2016, provisions in appropriations acts explicitly directed the distribution of PPHF funds, prohibiting the Secretary from making further transfers.[79]

As discussed earlier in the report, the PPHF appropriation is fully sequestrable at the applicable percentage rate for nonexempt nondefense mandatory spending (see **Table 2**). Sequestration is applied to the entire appropriation by the Secretary before funds are transferred to the agencies.

The distribution of PPHF funds to HHS agencies for FY2010 through the FY2017 President's budget proposal is presented in **Table B-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 B-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.[80]

In determining the transfer of PPHF funds for FY2010 through FY2013, the Secretary funded a mix of pre-existing programs and activities, and programs and activities newly authorized under the ACA. In directing the distribution of FY2014, FY2015, and FY2016 PPHF funds, annual appropriations acts (and accompanying report language) in most cases funded pre-existing 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.

[78] P.L. 112-96, Section 3205; 126 Stat. 194. Amounts in current law are codified at 42 U.S.C. §300u-11.

[79] 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.

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

Table B-1. PPHF Transfers to HHS Agencies

(Millions of Dollars, by Fiscal Year)

Agency	2010	2011	2012	2013	2014	2015	2016	2017 Proposal [a]
ACL	0	0	20	9	28	28	28	28
AHRQ	6	12	12	6	7	0	0	0
CDC	192	611	809	463	831	886	892	944
CMS	0	0	0	454[b]	0	0	0	0
HRSA	271	20	37	2	0	0	0	0
OS	12	19	30	0	0	0	0	0
SAMHSA	20	88	92	15	62	12	12	28
Sequester	—	—	—	51	72	73	68	—
Total	**500**	**750**	**1,000**	**1,000**	**1,000**	**1,000**	**1,000**	**1,000**

Sources: Prepared by CRS from HHS agency congressional budget justifications, http://www.hhs.gov/budget/; HHS, "Prevention and Public Health Fund," funding distribution tables, http://www.hhs.gov/open/recordsandreports/prevention/index.html; and Prevention and Public Health Fund transfer tables in explanatory statements accompanying appropriations for FY2014 through FY2016.

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. Distribution proposed by the Administration. This is not a budget request, as PPHF funds have already been appropriated. Amounts do not reflect the 6.9% sequestration (i.e., $69 million) for FY2017 required under current law; see **Table 2.**

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

Appendix C. Patient-Centered Outcomes Research Trust Fund

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).[81] 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.[82] Of the total amount transferred to HHS, 80% is to be distributed to AHRQ. **Table C-1** shows the allocation of PCORTF funds through FY2017.

Table C-1. Distribution of PCORTF Funding

(Millions of Dollars, by Fiscal Year)

Funding Recipient	2011	2012	2013	2014	2015	2016 Est.	2017 Est.
PCORI	40	120	289	376	396	472	530
HHS	10	30	72	94	99	118	132
AHRQ (non-add)	*(8)*	*(24)*	*(58)*	*(75)*	*(80)*	*(94)*	*(106)*
Office of the Secretary (non-add)	*(2)*	*(6)*	*(14)*	*(19)*	*(19)*	*(24)*	*(26)*
Total	**50**	**150**	**361**	**470**	**495**	**590**	**662**

Source: CRS calculations using data provided in Office of Management and Budget, *Budget of the U.S. Government, Appendix* (FY2013-FY2017).

[81] PCORI (established by ACA Section 6301(a), adding new SSA Section 1181) is a non-governmental 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.

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

Appendix D. FDA User Fee Authorizations

Table D-1. FDA User Fee Authorizations and Revenue

(Millions of Dollars, In Order of FY2016 Anticipated Revenue)

User Fee	Initial Authorizing Legislation and Year	FY2016 Revenue
Prescription drug	Prescription Drug User Fee Act (PDUFA), 1992 (P.L. 102-300)	851
Tobacco product	Family Smoking Prevention and Tobacco Control Act, 2009 (P.L. 111-31)	599
Generic drug	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	318
Medical device	Medical Device User Fee and Modernization Act (MDUFMA), 2002 (P.L. 107-250)	138
Animal drug	Animal Drug User Fee Act (ADUFA), 2003 (P.L. 108-130)	23
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)	20
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA), 2008 (P.L. 110-316)	10
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

User Fee	Initial Authorizing Legislation and Year	FY2016 Revenue
Total		**2,017**

Source: FY 2017 FDA Justification of Estimates for Appropriations Committees, All Purpose Table, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM485237.pdf.

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