

Public Health Service Agencies: Overview and Funding (FY2010-FY2016)

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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 a direct appropriation. Instead, it relied on redistributed (“set-aside”) funds from other PHS agencies for most of its funding, with supplemental amounts from the ACA’s Patient-Centered Outcomes Research Trust Fund (PCORTF). In FY2015, AHRQ received its own appropriation in lieu of set-aside funds. Overall, the agency’s total funding rose from \$403 million to \$465 million between FY2010 and FY2015. That increase came despite a decrease in discretionary funding over that period, which was more than offset by increasing amounts of PCORTF funding.
- 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 fluctuated between FY2010 and FY2015, with the overall level increasing slightly from \$10.9 billion to \$11.3 billion over that period. CDC experienced a drop in its discretionary appropriations during that time, which was offset by funding from other sources, primarily the ACA’s Prevention and Public Health Fund (PPHF). 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. FDA saw its funding increase significantly between FY2010 and FY2015 from \$3.1 billion to \$4.5 billion. The agency is funded with annual discretionary appropriations and industry user fees. While appropriations increased modestly over the FY2010-FY2015 period, user fees more than doubled and now account for 42% 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 \$8.1 billion in FY2010 to \$10.3 billion in FY2015 despite a significant drop in its discretionary appropriation during that time. The growth in overall funding was driven largely by increasing amounts from the ACA’s Community Health Center Fund (CHCF).
- 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 FY2010 and FY2015 from \$5.1 billion to \$5.9 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. Its funding dropped from \$31.2 billion in FY2010 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, has remained at about \$3.6 billion over the FY2010-FY2015 period.

Congress has yet to complete work on any of the regular appropriations bills for FY2016, which began on October 1, 2015. On September 30, the President signed the Continuing Appropriations Act, 2016 (*P.L. 114-53*). The measure provides continuing appropriations through December 11, 2016. It funds discretionary programs at the same rate (and under the same conditions) as in FY2015, minus an across-the-board reduction of 0.2108%. For entitlement and other mandatory spending that is funded through appropriation acts, *P.L. 114-53* provides funding to maintain program levels under current law. This report will be updated with information on PHS agency funding for FY2016 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 eight 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 (FFDCA).³ HRSA's maternal and child health programs are authorized by the Social Security 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 subdivisions 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 the 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.

³ 21 U.S.C. §§301 et seq.

(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 through the Departments of Labor, Health and Human Services, and Education, and Related Agencies (Labor-HHS-ED) appropriations act. Funding for ATSDR and IHS is provided through 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

The economic stimulus package enacted in February 2009—the American Reinvestment and Recovery Act (ARRA)—provided a total of \$15.1 billion in supplemental FY2009 discretionary appropriations to five of the PHS agencies.⁹ Details of the allocation of those funds are provided in **Appendix A**. Almost all of the ARRA appropriations were designated as two-year funds, available for obligation through the end of FY2010.

Transfers

The annual Labor-HHS-ED 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.¹⁰

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 R43967, *Labor, Health and Human Services, and Education: FY2015 Appropriations*, coordinated by (name redacted); CRS Report R43617, *Interior, Environment, and Related Agencies: FY2015 Appropriations*, by (name redacted); and CRS Report R43669, *Agriculture and Related Agencies: FY2015 Appropriations*, coordinated by (name redacted).

⁹ P.L. 111-5, 123 Stat. 115. The PHS agency appropriations were included in Title VII (Interior/Environment) and Title VIII (Labor-HHS-ED) of Division A of ARRA. In addition to these discretionary appropriations, ARRA included several HHS mandatory spending provisions. For example, ARRA temporarily increased federal payments to states under the Medicaid and the Temporary Assistance for Needy Families (TANF) programs. ARRA also incorporated the Health Information Technology for Economic and Clinical Health (HITECH) Act, which established multibillion dollar incentive programs under Medicare and Medicaid to encourage hospitals and physicians to adopt and use interoperable electronic health record technology. For more information, see, *American Recovery and Reinvestment Act of 2009* (P.L. 111-5): *Summary and Legislative History*, by (name redacted) et al.

¹⁰ The HHS Secretary’s FY2015 transfer authority was provided in Section 206 of the FY2015 Labor-HHS-ED appropriations act (P.L. 113-235, Division G).

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). 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). A significant portion of the FY2013 PPHF funds that were originally allocated to CDC and SAMHSA were reallocated to CMS for ACA implementation. In FY2014, NIH was again the primary source of transfers to CMS to support ACA implementation.¹¹

PHS Program Evaluation Set-Aside

In addition to the transfer authority provided in the annual Labor-HHS-ED 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. This long-standing budgeting authority is known as the PHS Program Evaluation Set-Aside (set-aside), or PHS budget "tap."

Under this authority the appropriations of a number of HHS agencies and offices 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 Labor-HHS-ED appropriations act has specified a higher amount. The FY2015 Labor-HHS-ED appropriations act capped the set-aside at 2.5%.¹² Following passage of the annual Labor-HHS-ED 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.¹³

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. 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. The agency received \$8 million in set-aside funding, making it a significant net donor of such funds. Similarly, HRSA contributed more set-aside funds than it received in FY2013. On the other hand, AHRQ, CDC, and SAMHSA each were net recipients of set-aside funding in FY2013. The Administration for Children and Families (ACF) and the Office of the Secretary (OS) also received set-aside funds.

The FY2013 assessments and transfers of set-aside funding shown in **Table 1** are broadly representative of the distribution of such funds during each of the preceding fiscal years extending back to the mid-2000s. In FY2014, the allocation of set-aside funding was comparable

¹¹ For more discussion of ACA implementation funding, see, *Federal Funding for Health Insurance Exchanges*, by (name redacted) and (name redacted).

¹² P.L. 113-235, Division G, Section 205; 128 Stat. 2485. Note: The President's FY2016 budget proposed increasing the maximum amount of set-aside funds to 3.0%.

¹³ 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 Labor-HHS-ED 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.

to that of FY2013 but with one key difference. For the first time, CMS was a recipient of set-aside funds.¹⁴

In FY2015, congressional appropriators made substantial changes to the allocation of set-aside funds by transferring most of the funding to NIH and eliminating any transfers to AHRQ, CDC, and HRSA. As shown in **Table 1**, NIH went from being by far the largest net donor of set-aside funds to a net recipient of such funding in FY2015. Meanwhile, AHRQ and CDC experienced a significant net loss of set-aside funding in FY2015. The situation with AHRQ is of particular interest. 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 smaller 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.

Table 1. PHS Evaluation Set-Aside Fund Assessments and Transfers in FY2013 and FY2015

Dollars in Thousands

Agency/ Office	FY2013			FY2015		
	Total Assessments	Total Transfers	Net Gain (Loss)	Total Assessments	Total Transfers	Net Gain (Loss)
NIH	709,536	8,200	(701,336)	688,604	715,000	26,396
HRSA	126,340	25,000	(101,340)	209,583	—	(209,583)
CDC	116,170	375,048	258,878	148,884	—	(148,884)
SAMHSA	53,867	129,667	75,800	29,337	133,667	104,330
AHRQ	78	365,362	365,284	7,340	—	(7,340)
CMS	—	—	—	—	196,000	196,000
ACF	—	5,762	5762	—	—	—
ACL	158	—	(158)	590	—	(590)
OS	19,412	116,522	97,110	27,657	67,328	39,671
Total	1,025,561	1,025,561		1,111,995	1,111,995	

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 2015,” Report to Congress.

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.¹⁵ As discussed briefly below, these additional sources of funding are a substantial component of the budget of several PHS agencies.

¹⁴ Complete details of the FY2014 set-aside fund assessments and transfers are not publicly available.

¹⁵ 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.

Mandatory Appropriations

The Patient Protection and Affordable Care Act (ACA)¹⁶ included numerous appropriations that together are providing billions of dollars in mandatory spending to support new and existing grant programs and other activities.¹⁷ Some of the ACA appropriations fund specific programs and activities within the PHS agencies. These appropriations are itemized in the funding tables in this report.

The ACA also established three multibillion dollar trust funds to help support PHS agency programs and activities. First, the **Community Health Center Fund (CHCF)**, for which the ACA provided a total of \$11 billion in annual appropriations over the five-year period FY2011-FY2015, is supporting the federal health centers program and the National Health Service Corps (NHSC), both administered by HRSA.¹⁸ A table summarizing each fiscal year's CHCF appropriation and the allocation of funds appears in **Appendix B**.¹⁹

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 broader analysis of the allocation of PPHF funding is provided in **Appendix C**.

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 D**.

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

¹⁶ 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.

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)*, by (name redacted).

¹⁸ ACA Section 10503(a)-(b).

¹⁹ The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10, 129 Stat. 87) appropriated two more years of funding for the CHCF—a total of \$3.910 billion for each of FY2016 and FY2017—to support health center operations and the NHSC.

²⁰ ACA Section 4002.

²¹ ACA Section 6301(d)-(e).

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 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.

It has been almost 25 years since 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 post-approval regulation of safety and effectiveness. FDA's user fee programs now support the agency's regulation of prescription drugs, animal drugs, medical devices, tobacco products, and 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 FY2015, user fees accounted for 42% of the FDA's overall budget. More discussion of user fees is provided in the FDA section of this report and in **Appendix E**.

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 7** 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 helped reduce discretionary funding for several PHS agencies over the past six years (i.e., FY2010-FY2015). Among the five PHS agencies that are funded through the Labor-HHS-ED appropriations act, only SAMHSA received funding in FY2015 that was essentially level with the amount it received in FY2010. CDC, HRSA, and NIH each received a smaller discretionary appropriation in FY2015 than they had received in FY2010. Similarly, AHRQ's discretionary appropriation in FY2015 was less than the amount of set-aside funding the agency received in FY2010. With the exception of NIH, which is funded almost entirely by discretionary appropriations, the decline in discretionary funding for the other three agencies (i.e., AHRQ, CDC, and HRSA) has been offset by the receipt of mandatory ACA funds.

FDA and IHS, neither of which receives discretionary funding through the Labor-HHS-ED appropriation act, have seen their appropriations increase over the six-year period FY2010-FY2015. Both agencies have also 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. Congress and the President then enacted the Budget Control Act of 2011 (BCA),²⁴ which amended the Balance Budget and Emergency Deficit Control Act of 1985 (BBEDCA).²⁵ The BCA established enforceable discretionary spending limits, or caps, for defense and nondefense spending for each of FY2012 through FY2021 and triggered annual spending reductions, equally divided between defense and nondefense spending, beginning in FY2013. Within each spending category the cuts are divided proportionately between discretionary spending and nonexempt mandatory spending. All the spending summarized in this report falls within the nondefense category.

Under the BCA, the spending reductions are achieved through a combination of sequestration (i.e., an across-the-board cancellation of budgetary resources) and 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 BBEDCA's sequestration exemptions and special rules.

Mandatory Spending

The BCA requires the mandatory spending reductions to be executed each year by 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, funding for the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) also is 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 there were no budgetary resources at the time the sequestration was ordered by the President. The Maternal, Infant, and Early Childhood Home Visiting program, administered by HRSA, is one example of this anomaly. The ACA authorized the Home Visiting program and funded it through FY2014 (see **Table 6**). Pursuant to the BCA, the President ordered the FY2015 sequestration on March 10, 2014, the day the FY2015 budget was released. But Congress and the President had yet to enact legislation extending funding for the Home Visiting program, so there were no FY2015 budgetary resources to sequester.²⁶

²⁴ P.L. 112-25, 125 Stat. 240. For more information, see CRS Report R41965, *The Budget Control Act of 2011*, by (name redacted), (name redacted), and (name redacted), and CRS Report R42949, *The American Taxpayer Relief Act of 2012: Modifications to the Budget Enforcement Procedures in the Budget Control Act*, by (name redacted)

²⁵ P.L. 99-177; Title II, 99 Stat. 1038.

²⁶ 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 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) Teaching Health Center Graduate Medical Education program (FY2016); (4) Family-to-Family Information Centers (FY2014, FY2015, FY2016); and (5) IHS and NIH (continued...)

Discretionary Spending

Under the BCA, FY2013 discretionary spending was subject to sequestration. In general, PHS agency discretionary appropriations for that year were fully sequesterable at the applicable percentage rate for nonexempt nondefense discretionary (NDD) spending (see **Table 2**). As a result, each agency saw a dip in its discretionary funding for FY2013. OMB also determined that FDA user fees for FY2013 were fully sequesterable at the NDD percentage rate. But it concluded that IHS's third-party collections in FY2013 were exempt from sequestration.

Table 2. Sequestration of Funding for PHS Agency Programs
FY2013-FY2016

Program	Percent Reduction			
	FY2013	FY2014	FY2015	FY2016
Mandatory Spending				
Nonexempt programs	5.1% ^a	7.2%	7.3%	6.8%
Community health centers, migrant health centers, IHS	2.0%	2.0%	2.0%	2.0%
Discretionary Spending				
Nonexempt programs	5.0% ^a	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.

- 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.

For each of the remaining years (i.e., FY2014 through FY2021), the annual reductions in discretionary spending required under the BCA are achieved by lowering the discretionary spending caps by the total dollar amount of the required reduction. This means that congressional appropriators get to decide how to apportion the cuts within the lowered spending cap rather than having the cuts applied across-the-board to all nonexempt accounts through the sequestration process.

For FY2014, OMB lowered the NDD spending cap by about \$37 billion. However, the Bipartisan Budget Act of 2013 (BBA)²⁷ subsequently amended the BCA by establishing new NDD spending caps for FY2014 and FY2015 and eliminating the BCA requirement that these caps be lowered. This gave congressional appropriators more funding for those two fiscal years.

The BBA set the FY2014 cap for NDD spending at \$491.773 billion. That level was about \$22 billion above the BCA-lowered FY2014 cap that it replaced and almost \$24 billion above the FY2013 post-sequestration NDD funding level. The BBA's FY2015 NDD spending cap of \$492.356 billion is only slightly higher than the FY2014 cap, but it is approximately \$9 billion above the BCA-lowered FY2015 cap that it replaces.

(...continued)

mandatory diabetes funding (FY2015, FY2016).

²⁷ P.L. 113-67, Division A; 127 Stat. 1165.

In FY2016, discretionary spending levels are once again subject to the original requirements of the BCA. The law set the FY2016 cap for NDD spending at \$530.000 billion, which OMB has lowered to \$493.491 billion pursuant to the BCA.²⁸

Report Roadmap

The remainder of this report consists of seven sections, one for each PHS agency beginning with AHRQ.²⁹ Each section includes an overview of the agency's statutory authority and principal activities, and a brief summary of the agency's funding over the period FY2010-FY2015. This material is accompanied by a detailed funding table showing the FY2010-FY2015 funding levels and the FY2016 budget request for the agency. 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.³⁰ Specific documents are listed in the source note under each table.

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 from sources other than the agency's discretionary appropriations to specific accounts. Almost all of the CDC accounts are funded with discretionary appropriations plus amounts from multiple other sources (see **Table 4**).

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 FY2016 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 (i.e., CDC, HRSA, NIH, and SAMHSA) give a somewhat distorted view of their available budgetary resources. This effect is particularly significant in the case of NIH. As mentioned earlier, NIH is assessed approximately \$700 million annually, and until FY2015 the agency received \$8 million each year in set-aside transfers. While the funding table for NIH shows receipt of set-aside funds, which count towards the agency's overall program level

²⁸ Office of Management and Budget, *OMB Sequestration Preview Report to the President and Congress for Fiscal Year 2016*, February 2, 2015, https://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/sequestration/2016_sequestration_preview_report_president.pdf.

²⁹ ATSDR and its budget are included in the discussion of CDC.

³⁰ All the budget documents and operating plans are available at <http://www.hhs.gov/budget/>.

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.

Note that the funding tables show the post-sequestration amounts for the accounts that were subject to sequestration in FY2013-FY2015. The amounts shown for the FY2016 request do not reflect sequestration.

Congress has yet to complete work on any of the regular appropriations bills for FY2016, which began on October 1, 2015. On September 30, the President signed the Continuing Appropriations Act, 2016 (P.L. 114-53). The measure provides continuing appropriations through December 11, 2016. It funds discretionary programs at the same rate (and under the same conditions) as in FY2015, minus an across-the-board reduction of 0.2108%. For entitlement and other mandatory spending that is funded through appropriation acts, P.L. 114-53 provides funding to maintain program levels under current law. This report will be updated with information on PHS agency funding for FY2016 once legislative action on appropriations for the new fiscal year is completed.

Agency for Healthcare Research and Quality (AHRQ)³¹

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. Specific research efforts are aimed at reducing the costs of care, promoting patient safety, measuring the quality of health care, and improving health care services, organization, and financing. AHRQ also 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).

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 FY2005.³² 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 focuses on six priority areas, summarized in the text box below.

For more information

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

Healthcare Costs, Quality and Outcomes (HCQO) Research Areas

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

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

Patient-Centered Health. Research comparing the effectiveness of different treatment options (previously referred to as comparative effectiveness research).

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.

Value. Research and projects supporting value in health care, focusing on reducing cost and improving quality.

Prevention/Care Management. Research on improving the delivery of primary care and preventive services.

³¹ This section was written by (name redacted), Specialist in Health Policy.

³² See the AHRQ website at <http://www.ahrq.gov>.

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 C** and **Appendix D**). In FY2015, AHRQ received its own discretionary appropriation for the first time in more than a decade in lieu of any set-aside funding.

Agency Funding Since FY2010

AHRQ's program level has increased steadily over the past several years with decreases in discretionary funding being more than offset by transfers of ACA mandatory funds (see **Table 3**). Specifically, since FY2010, the agency's budget has increased by \$62 million, and transfers mostly from PCORTF have more than offset decreases in PHS evaluation set-aside dollars. Although the majority of agency funding came from PHS evaluation set-aside dollars during this period—and an agency-specific discretionary appropriation in FY2015—funding from PCORTF has also grown considerably from \$8 million in FY2011 to \$101 million in FY2015.

Table 3. Agency for Healthcare Research and Quality (AHRQ)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015	2016 Request
Health Costs, Quality and Outcomes (HCQO) Research	276	266	272	300	304	330	339
Health Information Technology Research	28	28	26	26	30	28	23
Patient Safety Research	91	66	66	67	72	77	76
Patient-Centered Health Research ^a	21	29	41	68	—	—	—
PCORTF Transfer (non-add) ^a	—	(8)	(24)	(58)	—	—	—
PCORTF Transfer ^a	—	—	—	—	65	101	116
Health Services Research, Data, and Dissemination ^b	112	112	108	111	111	112	112
Value	4	4	4	4	3	—	—
Prevention/Care Management	21	28	28	26	23	12	12
PPHF Transfer (non-add)	(6)	(12)	(12)	(6)	(7)	—	—
Medical Expenditure Panel Surveys (MEPS)	59	59	59	61	64	65	69
Program Support	68	68	74	68	69	70	72
Total, Program Level	403	392	405	429	436	465	479
Less Funds From Other Sources							
PHS Evaluation Set-Aside	397	372	369	365	364	0	88
PCORTF Transfers	—	8	24	58	65	101	116
PPHF Transfers	6	12	12	6	7	—	—
Total, Discretionary Budget Authority	0	0	0	0	0	364	276

Sources: Funding amounts for FY2010 and FY2011 are taken from AHRQ's FY2012 and FY2013 congressional budget justification documents. Funding amounts for FY2012 and FY2013 are taken from AHRQ's Sequestration Operating Plan for FY2013. Funding amounts for FY2014 and FY2015 are taken from the FY2016 HHS Budget in Brief and the FY2015 congressional budget justification. The funding amounts for the FY2016 President's Request are taken from the FY2016 HHS Budget in Brief. All these documents are available at <http://www.hhs.gov/budget/>.

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

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

Centers for Disease Control and Prevention (CDC)³³

Agency Overview

According to CDC, its 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., injury prevention), 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.

Table 4 presents funding levels for CDC programs for FY2010 through the FY2016 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 (WTC) Health Program;⁴⁴ and (4) appropriations provided under ACA, principally through the PPHF.⁴⁵ CDC also receives annual set-aside funds and authorized user fees, and may also receive funding through supplemental appropriations and other transfers.

³³ This section was written by (name redacted), 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/niosh/topics/wtc/>.

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

Agency Funding Since FY2010

Compared with FY2010, CDC's budget authority for FY2015 is lower, and its program level is higher (see **Table 4**). Two of CDC's mandatory funding sources—ACA funding, principally from the PPHF, and the WTC Health Program—have, in whole or part, replaced discretionary funding for some ongoing activities.

Both budget authority and program level reached their lowest points since FY2010 in FY2013, a result of sequestration of most mandatory and discretionary funds, and redirection of some PPHF funds to ACA implementation (see **Appendix C**). VFC and EEOICPA funds are exempt from sequestration. The PPHF and WTC Health Program are not, and sequestration of these mandatory funds has continued each fiscal year since FY2013.

In 2014 CDC implemented the “Working Capital Fund,” a revolving fund to be used by agency programs to pay for agency-wide business services—such as procurement and human resources—that received direct appropriations in the past.⁴⁶ CDC now applies certain business services funds previously assigned to the Cross-cutting Activities and Program Support account to the programmatic accounts instead. Although this does not change the amount of funds available to the agency, it has the effect of increasing the amounts budgeted to programmatic accounts. CDC has adjusted its accounting from FY2012 forward to make budget lines comparable from year to year. Of note, **Table 4** reflects this adjustment, such that amounts presented for FY2012 and later years are not necessarily comparable to amounts presented for FY2010 and FY2011.

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 yet presented these funds within its general budget, and they are not presented in **Table 4**. More information is available on the CDC website.⁴⁷

⁴⁶ See CDC, “Working Capital Fund,” <http://www.cdc.gov/fmo/topic/wcf/index.html>.

⁴⁷ CDC, “FY2015 Ebola Response Funding,” <http://www.cdc.gov/fmo/topic/Budget%20Information/index.html>.

**Table 4. 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	2010	2011	2012	2013 ^a	2014	2015	2016 Request
Immunization and Respiratory Diseases	721	748	815	718	783	798	748
<i>PHS Evaluation Set-Aside (non-add)</i>	(13)	(13)	(13)	(13)	(13)	(0)	(0)
<i>PPHF Transfer (non-add)</i>	(0)	(100)	(190)	(91)	(160)	(210)	(210)
<i>PHSSEF Transfer (non-add)</i>	—	(156)	—	(12)	—	(15)	—
Vaccines for Children ^b	3,761	3,953	4,006	3,607	3,557	3,981	4,109
HIV/AIDS, Viral Hepatitis, STI and TB	1,119	1,116	1,163	1,095	1,118	1,118	1,162
<i>PHS Evaluation Set-Aside (non-add)</i>	(0)	(0)	(0)	(4)	(0)	(0)	(0)
<i>PPHF Transfer (non-add)</i>	(30)	(0)	(10)	(0)	(0)	(0)	(0)
Emerging & Zoonotic Infectious Diseases	281	304	362	341	390	405	699
<i>PPHF Transfer (non-add)</i>	(20)	(52)	(52)	(44)	(52)	(52)	(55)
Chronic Disease Prevention and Health Promotion	924	1,075	1,211	1,003	1,186	1,198	1,058
<i>PPHF Transfer (non-add)</i>	(59)	(301)	(411)	(233)	(446)	(451)	(480)
Birth Defects, Developmental Disabilities, Disability and Health	144	136	142	134	129	132	132
<i>PPHF Transfer (non-add)</i>	(0)	(0)	(0)	(0)	(0)	(0)	(68)
Environmental Health	181	170	158	142	179	179	179
<i>PPHF Transfer (non-add)</i>	(0)	(35)	(35)	(21)	(13)	(13)	(37)
Injury Prevention and Control	149	144	146	139	150	170	257
Public Health Scientific Services	441	468	517	493	481	481	539
<i>PHS Evaluation Set-Aside (non-add)</i>	(248)	(248)	(248)	(248)	(86)	(0)	(0)
<i>PPHF Transfer (non-add)</i>	(32)	(72)	(70)	(52)	(0)	(0)	(64)
Occupational Safety and Health	375	316	325	323	332	335	283
<i>PHS Evaluation Set-Aside (non-add)</i>	(92)	(92)	(111)	(111)	(112)	(0)	(0)
Global Health	354	340	377	363	416	447	448

Program or Activity	2010	2011	2012	2013 ^a	2014	2015	2016 Request
<i>Supplemental Ebola funds (non-add)^c</i>	—	—	—	—	—	30	—
Public Health Preparedness and Response	1,522	1,415	1,382	1,279	1,368	1,353	1,382
<i>PPHF Transfer (non-add)</i>	(0)	(10)	(0)	(0)	(0)	(0)	(0)
<i>PHSSEF Transfer (non-add)</i>	—	(69)	(30)	—	—	—	—
Crosscutting Activities and Program Support ^d	661	605	236	227	275	274	114
<i>PPHF Transfer (non-add)</i>	(50)	(41)	(41)	(23)	(160)	(160)	(0)
<i>Prevention Block Grant (non-add)</i>	(100)	(80)	(80)	(75)	(160)	(160)	(0)
Buildings and Facilities	69	0	25	24	24	10	10
Childhood Obesity (ACA Sec. 4306) ^e	25	—	—	—	—	—	—
User Fees	2	2	2	2	2	2	2
EEOICPA (NIOSH mandatory)	55	55	55	51	50	50	55
World Trade Center Health Program (NIOSH mandatory) ^f	—	71	188	231	236	243	268
ATSDR	77	77	76	72	75	75	75
Medical Monitoring (ATSDR/ACA Sec. 10323(b))	23	—	—	—	—	19	—
Total, CDC/ATSDR Program Level	10,884	10,995	11,187	10,243	10,750	11,269	11,519
Less Funds From Other Sources							
Vaccines for Children ^b	3,761	3,953	4,006	3,607	3,557	3,981	4,109
EEOICPA	55	55	55	51	50	50	55
PHSSEF Transfers	—	225	30	12	—	15	—
PHS Evaluation Set-Aside	352	352	371	375	211	0	0
ACA Mandatory Funds: PPHF Transfers	192	611	809	463	831	886	914
ACA Mandatory Funds: Other	48	—	—	—	—	19	—
World Trade Center Health Program	—	71	188	231	236	243	268
User Fees	2	2	2	2	2	2	2
Total, CDC/ATSDR Discretionary BA	6,474	5,726	5,725	5,503	5,864	6,073	6,172
Less ATSDR (discretionary BA)	77	77	76	72	75	75	75

Program or Activity	2010	2011	2012	2013 ^a	2014	2015	2016 Request
Total, CDC Discretionary BA	6,397	5,649	5,649	5,430	5,788	5,998	6,096

Sources: CDC and ATSDR congressional budget justifications and related documents for FY2012 through FY2016, <http://www.cdc.gov/fmo>.

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

Mandatory amounts displayed for FY2013 through FY2015 reflect sequestration as required for non-defense mandatory spending.

BA and program level amounts for FY2012 and subsequent fiscal years reflect a realignment of funds from certain business services in the Cross-cutting Activities and Program Support account into most other accounts, in order to implement the Working Capital Fund, discussed in the text of this report. As a result, amounts for these years are not necessarily comparable to amounts for previous years.

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. EEOICPA is Energy Employees Occupational Illness Compensation Program Act.

- a. Amounts for FY2013 include a transfer of \$79 million from other HHS agencies, pursuant to the Secretary's transfer authority (see discussion under "Transfers").
- b. 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 FY2014 through the FY2016 request are estimates.
- c. Amounts include \$30 million for FY2015 for the response to the 2014 Ebola outbreak in West Africa (P.L. 113-164). Amounts do not include subsequent supplemental FY2015 funding for response to the outbreak provided in P.L. 113-235. These funds are discussed in CRS Report R43807, *FY2015 Funding to Counter Ebola and the Islamic State (IS)*, coordinated by (name redacted) and at CDC, "FY2015 Ebola Response Funding," <http://www.cdc.gov/fmo/topic/Budget%20Information/index.html>.
- d. For the purposes of this table, Cross-cutting Activities and Program Support excludes amounts for Buildings and Facilities, which are displayed in a separate row. Amounts for FY2010 include amounts previously designated as Public Health Leadership and Support, Business Services Support, and Preventive Health and Health Services Block Grant.
- e. 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 childhood obesity demonstration program; \$10 million for the two-year period FY2016 through FY2017.
- f. Beginning July 1, 2011 (i.e., for the final quarter of FY2011), the World Trade Center Health Program, previously funded through discretionary appropriations to NIOSH, was replaced by a mandatory program. Amounts are federal obligations only. Amounts for FY2015 and FY2016 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.

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, radiation-emitting products, and animal drugs. In 2009, Congress gave FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health.

Seven centers within FDA represent the broad program areas for which the agency has responsibility: 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.

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 much smaller amount for the Buildings and Facilities account. The several different user fees, which account for 42% of FDA's total FY2015 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 E** presents the authorizing legislation for current FDA user fees, sorted by the dollar amount they contribute to the agency's FY2015 budget. After PDUFA, Congress added user fee authorities regarding

For more information

CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by (name redacted) .

CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by (name redacted)

CRS Report R42130, *FDA Regulation of Medical Devices*, by (name redacted) .

⁴⁸ This section was written by (name redacted), Specialist in Drug Safety and Effectiveness.

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>.

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

Agency Funding Since FY2010

Between FY2010 and FY2015, FDA's funding increased from \$3.1 billion to \$4.5 billion (see **Table 5**). Although congressionally provided appropriations increased 10% over that period, user fee revenue more than doubled. In FY2015, user fees account for 42% of FDA's total funding. Continuing funding issues for the agency include adequate resources to carry out food safety activities (the President's request includes a \$301 million increase above the FY2015 level), the risk of user fees' being subject to subsequent sequestrations, and the ongoing challenge of performing increasing congressionally directed tasks without concomitant resources increases.

⁵¹ CRS Report R42366, *Prescription Drug User Fee Act (PDUFA): 2012 Reauthorization as PDUFA V*, by (name redacted); CRS Report R42508, *The FDA Medical Device User Fee Program*, by (name redacted) ; CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*, coordinated by (name redacted); CRS Report R42680, *The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144)*, coordinated by (name redacted); CRS Report R43290, *The Proposed Drug Quality and Security Act (H.R. 3204)*, by (name redacted)

⁵² User fees provide varying proportions of funding for several FDA programs (see **Table E-1**). For example, the agency's tobacco regulatory activities are entirely supported through user fees paid by tobacco product manufacturers and importers, and the toxicology program receives no user fee funds. In FY2015, fees account for 64% of the human drugs program budget, 39% of the biologics budget, 27% of the devices and radiological health budget, 15% of the animal drugs and feeds budget, and 1% of the foods budget. **Appendix E** of this report presents additional detail.

Table 5. Food and Drug Administration (FDA)

(Millions of Dollars, by Fiscal Year)

Program area	2010	2011	2012	2013	2014	2015	2016 Request ^a
Foods	783	836	883	813	900	914	999
BA	783	836	866	797	883	903	987
User Fees	—	—	17	17	17	10	12
Human drugs	884	950	979	1,187	1,289	1,339	1,371
BA	462	478	478	439	466	482	485
User Fees	421	472	501	748	823	856	886
Biologics	291	302	329	308	338	344	350
BA	206	212	212	195	211	211	215
User Fees	86	90	117	113	127	133	135
Animal drugs and feeds	154	159	166	155	173	175	193
BA	134	139	138	126	142	148	166
User Fees	20	20	28	29	32	27	27
Devices and radiological health	370	379	376	384	428	440	452
BA	314	322	323	296	321	321	328
User Fees	57	56	53	88	107	119	125
Tobacco products	64	136	455	459	501	532	564
BA	—	—	—	—	—	—	—
User Fees	64	136	455	459	501	532	564
Toxicological research	59	61	60	55	62	63	59
BA	59	61	60	55	62	63	59
User Fees	—	—	—	—	—	—	—
Headquarters/Commissioner's Office	178	187	223	251	275	277	288
BA	141	150	154	160	172	173	181
User Fees	37	37	69	91	103	104	106

Program area	2010	2011	2012	2013	2014	2015	2016 Request ^a
GSA rent	178	178	205	199	220	228	238
BA	145	151	161	150	162	169	177
User Fees	32	27	45	49	58	60	61
Other rent and rent-related activities	124	129	132	157	178	163	186
BA	103	100	106	118	133	116	137
User Fees	21	30	26	40	46	47	49
Export and color certification funds	10	11	11	12	12	14	14
BA	—	—	—	—	—	—	—
User Fees	10	11	11	12	12	14	14
Food and drug safety	—	—	—	46^b	0	0	0
BA	—	—	—	46	0	0	0
User Fees	—	—	—	0	0	0	0
Priority review vouchers	—	—	—	—	—	8	8
BA	—	—	—	—	—	0	0
User Fees	—	—	—	—	—	8	8
Buildings & Facilities	22	13	9	5	9	9	9
BA	22 ^c	13	9	5	9	9	9
User Fees	—	—	—	—	—	—	—
Total, Program Level	3,118	3,339	3,832	4,031	4,387	4,505^d	4,731
Less Funds From Other Sources							
User Fees	748	879	1,326	1,645	1,826	1,909	1,988
Total, Discretionary Budget Authority	2,369	2,460	2,506	2,386	2,561	2,596^d	2,744

Sources: Funding amounts for FY2010 and FY2011 are taken from FDA's FY2012 and FY2013 congressional budget justification documents. Funding amounts for FY2012 and FY2013 are taken from FDA's FY2013 Sequestration Operating Plan; the FY2013 figures reflect sequestration. FY2014 amounts are from FDA's FY2014 Operating Plan, issued after enactment of the Consolidated Appropriations Act, 2014. FY2015 and FY2016 request amounts are taken from the FY2016 congressional budget justification.

Notes: 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. For user fees in the Administration's FY2016 request, this column shows only the \$1,988 million in fees that have been authorized. The request included an additional \$199 million in proposed fees, allocated across several FDA program areas. With these proposed user fees, the President's request for user fees totals \$2,187 million yielding a total program level request of \$4,930 million.
- b. The FY2013 Sequestration Operating Plan notes food safety and drug safety items that had not been included in the program-level appropriations.
- c. The FY2010 Buildings & Facilities appropriation included about \$7 million for the National Center for Natural Products Research, as directed by the Committee on Appropriations.
- d. 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 \$2,622 million and the total program level to \$4,530 million for FY2015.

Health Resources and Services Administration (HRSA)⁵³

Agency Overview

HRSA is the federal agency charged with improving access to health care for those who are uninsured, isolated, or medically vulnerable. The agency currently awards funding to more than 3,000 grantees, including community-based organizations; colleges and universities; hospitals; state, local, and tribal governments; and private entities to support health services projects, such as training health care workers or providing specific health services.⁵⁴ 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.

HRSA is organized into five bureaus (see text box below) and ten 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).⁵⁵

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.

As noted in the text box, the majority of HRSA's programs are authorized by the PHSA or, in some cases, by the SSA. Additionally, Section 427(e) of the Federal Mine Safety and Health

⁵³ This section was written by (name redacted), Specialist in Health Services.

⁵⁴ See HRSA's website at <http://www.hrsa.gov>.

⁵⁵ See HRSA's website at <http://www.hrsa.gov>.

Amendments Act (P.L. 95-164) authorizes the Black Lung Program, which supports clinics that provide services to retired coal miners and others.

Agency Funding Since FY2010

HRSA funding increased from \$8.1 billion in FY2010 to \$10.3 billion in FY2015 despite a reduction in its discretionary appropriation during that time (see **Table 6**). Specifically, discretionary appropriations declined by about 18%; falling from \$7.5 billion to \$6.1 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. While CHCF funding may have been intended to supplement annual discretionary appropriations for the health centers program and the NHSC, the funds have partially supplanted (i.e., replaced) discretionary health center funding and have 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; P.L. 114-10); see **Table 6** and **Appendix B**. 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.

For more information

CRS Report R44054, *Health Resources and Services Administration (HRSA) FY2016 Budget Request and Funding History: Fact Sheet*, by (name redacted)

CRS Report R43937, *Federal Health Centers: An Overview*, by (name redacted)

CRS Report R43920, *National Health Service Corps: Changes in Funding and Impact on Recruitment*, by (name redacted)

CRS Report R42428, *The Maternal and Child Health Services Block Grant: Background and Funding*, by (name redacted)

CRS Report R43177, *Health Workforce Programs in Title VII of the Public Health Service Act*, by (name redacted)

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

Table 6. Health Resources and Services Administration (HRSA)

(Millions of Dollars, by Fiscal Year)

Bureau or Activity	2010	2011	2012	2013	2014	2015	2016 Request	2016 Enacted
Primary Care	2,253	4,149	2,817	2,992	3,636	5,001	4,191	—
Health Centers	2,141	2,481	2,672	2,856	3,542	4,901	4,092	—
<i>CHCF Transfer (non-add)</i>	—	(1,000)	(1,200)	(1,465)	(2,145)	(3,509)	—	(3,600) ^a
<i>New mandatory proposal for FY2016 (non-add)</i>	—	—	—	—	—	—	(2,700) ^b	—
Health Centers Tort Claims	44	100	95	89	95	100	100	—
School Based Health Centers (ACA Sec. 4101(a))	50	50	50	47	—	—	—	—
Health Center Construction (ACA Sec. 10503(c))	—	1,500	—	—	—	—	—	—
Hansen's Disease Programs ^c	18	18	—	—	—	—	—	—
Health Workforce^d	1,249	1,357	1,086	1,001	1,043	1,058	1,799	—
National Health Service Corps (NHSC)	141	315	295	285	283	287	810	—
<i>CHCF Transfer (non-add)</i>	—	(290)	(295)	(285)	(283)	(287)	—	(310) ^a
<i>New mandatory proposal for FY2016 (non-add)</i>	—	—	—	—	—	—	(523) ^b	—
Faculty Loan Repayment Program	1	1	1	1	1	1	1	—
Training for Diversity ^e	96	95	85	80	81	82	85	—
Primary Care Training and Enhancement	237	39	39	37	37	39	39	—
<i>PPHF Transfer (non-add)</i>	(198)	—	—	—	—	—	—	—
Rural Physician Training Grants	—	—	—	—	—	—	4	—
Interdisciplinary, Community-Based Linkages ^f	72	72	73	62	71	73	53	—
<i>PPHF Transfer (non-add)</i>	—	—	(12)	(2)	—	—	—	—
Public Health Workforce Development	30 ^g	30	33	8	18	21	17	—
<i>PPHF Transfer (non-add)</i>	(21) ^g	(20)	(25)	—	—	—	—	—
Nursing Workforce Development ^h	290	242	231	218	223	232	232	—
<i>PPHF Transfer (non-add)</i>	(47)	—	—	—	—	—	—	—
Children's Hospitals GME Payments	317	268	265	251	264	265	100 ⁱ	—

Bureau or Activity	2010	2011	2012	2013	2014	2015	2016 Request	2016 Enacted
GME Targeted Support (New mandatory proposal)	—	—	—	—	—	—	400 ⁱ	—
Teaching Health Center GME Payments (ACA Sec.5508(c))	—	230	—	—	—	—	—	60 ^j
Other Health Workforce Programs ^k	41	41	35	34	37	39	39	—
National Practitioner Data Bank (User Fees)	24	24	28	27	27	19	20	—
Maternal and Child Health	984	1,128	1,208	1,193	1,220	1,254	1,352	—
Maternal and Child Health Block Grant	661	656	639	605	632	637	637	—
Healthy Start	105	104	104	98	101	102	102	—
Maternal, Infant Home Visiting (ACA Sec. 2951)	100	250	350	380	371	400 ^l	—	400 ^l
<i>New mandatory proposal for FY2016</i>	—	—	—	—	—	—	500 ^m	—
Family-to-Family Health Centers (ACA Sec. 5507) ⁿ	5	5	5	5	5	3	—	5
Other Maternal and Child Health Programs ^o	113	113	112	105	110	112	112	—
Ryan White HIV/AIDS	2,315	2,337	2,392	2,249	2,313	2,319	2,323	—
Health Care Systems	267	87	101	95	103	103	118	—
Health Care Systems Programs ^p	93	82	96	91	75	76	76	—
Hansen's Disease Programs	—	—	18	17	17	17	17	—
Health Center Infrastructure (ACA Sec. 10502)	100	—	—	—	—	—	—	—
State Health Access Grants	74	—	—	—	—	—	—	—
340B Drug Pricing Programs		4	4	4	10	10	25	—
<i>User fee (non-add)</i>		—	—	—	—	—	(8)	—
Rural Health	185	138	138	131	142	147	128	—
Other Activities	813	467	460	436	446	448	465	—
Congressional Earmarks	337	—	—	—	—	—	—	—
Family Planning	317	299	294	278	286	286	300	—
Program Management	147	162	160	151	153	154	157	—
Healthy Weight Collaborative (PPHF Transfer)	5	—	—	—	—	—	—	—

Bureau or Activity	2010	2011	2012	2013	2014	2015	2016 Request	2016 Enacted
Vaccine Injury Compensation Program Operations	7	6	6	6	6	8	8	—
Total, Program Level	8,067	9,663	8,202	8,097	8,902	10,330	10,375	N/A
Less Funds From Other Sources								
PHS Evaluation Set-Aside	25	25	25	25	25	—	—	—
User Fees	24	24	28	27	27	19	27	—
ACA Mandatory Funds: PPHF Transfers	271	20	37	2	—	—	—	—
ACA Mandatory Funds: CHCF Transfers	—	1,290	1,495	1,750	2,428	3,796	—	3,910
ACA Mandatory Funds: Other	255	2,035	405	432	376	403	—	465
New Mandatory Proposals for FY2016	—	—	—	—	—	—	4,123	—
Total, Discretionary Budget Authority	7,492	6,269	6,212	5,861	6,046	6,112	6,225	N/A

Sources: The funding amounts are from congressional budget justification documents and HHS’s *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.

- The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10) appropriated two more years of funding to the CHCF; \$3,600 million for each of FY2016 and FY2017 for health center operations, and \$310 million for each of FY2016 and FY2017 for the NHSC.
- The President’s FY2016 budget proposed the following new mandatory funding for FY2016 to replace the expiring CHCF: \$2.7 billion for health center operations, and \$523 million for the NHSC. Congress and the President have since enacted P.L. 110-14, which included an additional two years of funding for the CHCF (see table note “a”).
- Beginning in FY2012, funding for the Hansen’s Disease Programs appears under Health Care Systems.
- Health Workforce does not include the Home Health Aide Demonstration, which was authorized and funded by ACA Section 5507(a). The demonstration received an annual appropriation of \$5 million for each of FY2010 through FY2012. [Note: HRSA’s Bureau of Health Workforce was created in May 2014 by combining the Bureau of Health Professions, which administered most of HRSA’s primary care training programs, and the Bureau of Clinician Recruitment and Service, which administered the NHSC, NURSE Corps, and the Faculty Loan Repayment Program.]
- Training for Diversity includes the following programs: Centers for Excellence, Scholarships for Disadvantaged Students, and the Health Careers Opportunity Program.
- Interdisciplinary, Community-based Linkages includes the following programs: Area Health Education Centers (AHEC), Geriatric Programs, and Mental and Behavioral Health Education and Training.
- Total includes \$6 million for State Health Workforce Development grants.
- 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.

- i. The President's FY2016 budget proposed new mandatory funding for Targeted Support for Graduate Medical Education, which would be used to provide additional support for the Children's Hospital GME Payment Program and full support for the Teaching Health Center GME program.
- j. MACRA (P.L. 114-10) appropriated \$60 million for each of FY2016 and FY2017 for GME payments to teaching health centers.
- k. Other Health Workforce Programs include HealthCare Workforce Assessment, Oral Health Training, and the Patient Navigator Program (funded through FY2011).
- l. MACRA (P.L. 114-10) appropriated \$400 million for the home visiting program for each of FY2015 through FY2017.
- m. The President's FY2016 budget proposed new mandatory funds to extend and expand the home visiting program through FY2025, including \$500 million for FY2016. However, MACRA (P.L. 114-10) provided three more years of funding for the program (see table note "l").
- n. ACA Section 5507(b) funded family-to-family information centers through FY2012. Several subsequently enacted laws, most recently MACRA (P.L. 114-10), have extended that funding through FY2017.
- o. 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.
- p. 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)⁵⁶

Agency Overview

IHS provides health care for approximately 2.2 million eligible American Indians/Alaska Natives through a system of programs and facilities located on or near Indian reservations, and through contractors in certain urban areas. IHS provides services to members of 566 federally recognized tribes either directly or through facilities and programs operated by Indian Tribes or Tribal Organizations through self-determination contracts and self-governance compacts authorized in the Indian Self-Determination and Education Assistance Act (ISDEAA).⁵⁷

The Snyder Act of 1921 provides general statutory authority for IHS.⁵⁸ In addition, specific IHS programs are authorized by two acts: the Indian Sanitation Facilities Act of 1959⁵⁹ and the Indian Health Care Improvement Act (IHCIA).⁶⁰ 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 Program Evaluation Set-Aside.

For more information

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

CRS Report R44040, *Indian Health Service FY2016 Budget Request and Funding History: Fact Sheet*, by (name redacted)

Agency Funding Since FY2010

IHS's funding, which includes discretionary appropriations and collections from third-party payers of health care, increased between FY2010 and FY2015 from \$5.1 billion to \$5.9 billion (see **Table 7**). This increase was driven both by increased discretionary appropriations, which rose from \$4.1 billion to \$4.6 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. Collections received from providing clinical services are also used to augment the clinical services budget.

⁵⁶ This section was written by (name redacted), Specialist in Health Services.

⁵⁷ P.L. 93-638; 25 U.S.C. §§450 et seq.

⁵⁸ 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).

⁵⁹ P.L. 86-121; 42 U.S.C. §2004a.

⁶⁰ P.L. 94-437, as amended; 25 U.S.C. §§1601 et seq., and 42 U.S.C. §§1395qq and 1396j (and amending other sections). This act was permanently reauthorized by the ACA. See CRS Report R41630, *The Indian Health Care Improvement Act Reauthorization and Extension as Enacted by the ACA: Detailed Summary and Timeline*, by (name redacted).

Table 7. Indian Health Service (IHS)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015	2016 Request
Clinical and Preventive Services	4,139	4,171	4,335	4,277	4,436	4,607	4,858
Clinical Services	3,845 ^a	3,877 ^b	4,038 ^c	3,987 ^d	4,142 ^e	4,303 ^f	4,545 ^g
<i>Purchased/Referred Care (non-add)^h</i>	<i>(779)</i>	<i>(780)</i>	<i>(844)</i>	<i>(801)</i>	<i>(879)</i>	<i>(914)</i>	<i>(984)</i>
Preventive Health	144	144	147	143	147	154	163
Special Diabetes Program for Indians ⁱ	150	150	150	147	147	150	150
Other Health Services	560	559	636	603	753	831	886
Urban Health Projects	43	43	43	41	41	44	44
Indian Health Professions	41	41	41	38	28	48	48
Tribal Management/Self-Governance	9	9	9	8	6	8	8
Direct Operations	69	69	72	68	66	68	68
Contract Support Costs	398	398	471	448	612	663	718
Health Facilities	401	411	448	427	460	469	649
Maintenance and Improvement	60 ^j	60 ^j	61 ^k	59 ^k	62 ^l	62 ^l	98 ^l
Sanitation Facilities Construction	96	96	80	75	79	79	115
Health Care Facilities Construction	29	39	85	77	85	85	185
Facilities/Environmental Health Support	193	193	199	194	211	220	227
Medical Equipment	23	23	23	21	23	23	24
Total, Program Level	5,100	5,140	5,418	5,307	5,649	5,906	6,392
Less Funds from Other Sources							
Collections	891	915	954	1,021	1,060	1,106	1,131
Rental of Staff Quarters	6	6	8	8	8	8	9
Special Diabetes Program for Indians ⁱ	150	150	150	147	147	150	150
Total, Discretionary Budget Authority	4,052	4,069	4,306	4,131	4,435	4,642	5,103

Sources: Funding amounts for FY2010, FY2011, and FY2012 are taken from IHS's FY2012, FY2013, and FY2014 congressional budget justification documents, respectively. Funding amounts for FY2013, FY2014, and FY2015 are taken from the FY2015 HHS Budget in Brief. Funding amounts for FY2016 are taken from the FY2016 HHS Budget in Brief. These documents are available at <http://www.hhs.gov/budget/>.

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

- a. Includes \$891 million in collections from Medicare, Medicaid, CHIP, private insurance, and other programs.
- b. Includes \$915 million in collections from Medicare, Medicaid, CHIP, private insurance, and other programs.
- c. Includes \$954 million in collections from Medicare, Medicaid, CHIP, private insurance, and other programs.
- d. Includes an estimated \$1,021 million in collections from Medicare, Medicaid, CHIP, private insurance, and other programs.
- e. Includes an estimated \$1,060 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.
- f. Includes an estimated \$1,106 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.
- g. Includes an estimated \$1,131 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.
- h. This was previously referred to as "Contract Health Services."
- i. PHSA Section 330C provides an annual appropriation of \$150 million through FY2017 for this program. These mandatory funds are subject to a 2% sequestration (not shown for FY2015 and FY2016).
- j. Includes \$6 million that IHS received from rental of staff quarters.
- k. Includes \$8 million that IHS received from rental of staff quarters.
- l. Includes \$8 million that IHS estimates the agency will receive from rental of staff quarters.

National Institutes of Health (NIH)⁶¹

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.

The bulk of NIH's budget, about 83%, goes out to the extramural research community through grants, contracts, and other awards. The funding supports research performed by more than 300,000 non-federal scientists and technical personnel who work at more than 2,500 universities, hospitals, medical schools, and other research institutions around the country and abroad.⁶² A smaller proportion of the budget, about 11%, supports the intramural research programs of the NIH institutes and centers, 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 Secretary of HHS 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 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 8**, the annual Labor-HHS-ED appropriations act provides separate appropriations to 24 of the ICs, the OD, and the Buildings and Facilities account. One of the ICs (Environmental Health

For more information

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

CRS Report R43341, *NIH Funding: FY1994-FY2016*, by (name redacted) .

CRS Report R43944, *Federal Research and Development Funding: FY2016*, coordinated by (name redacted)

⁶¹ This section was written by (name redacted), Specialist in Biomedical Policy.

⁶² U.S. Department of Health and Human Services, *FY2015 Budget in Brief*, March 4, 2014, p. 39, <http://www.hhs.gov/budget/fy2015/fy-2015-budget-in-brief.pdf>.

Sciences) also receives funding from the Interior/Environment appropriations act. In addition, NIH receives a mandatory appropriation for type 1 diabetes research.

Agency Funding Since FY2010

NIH's funding in FY2015 is about 5% below the FY2010 level. This decline can be viewed as part of a broader funding trend that dates back to FY2003, the year Congress completed a five-year doubling of NIH's budget that resulted in the agency's funding increasing from \$13.6 billion in FY1998 to \$27.2 billion in FY2003.

Following the doubling period, NIH had several years of modest funding increases. Funding for the agency peaked in FY2010 at \$31.2 billion before decreasing in each of the next three years. Overall, NIH's budget has failed to keep pace with the rising cost of biomedical research—as measured by the Biomedical Research and Development Price Index (BRDPI)—since the end of the doubling period. In constant (i.e., BRDPI-adjusted) 2012 dollars, NIH funding in FY2015 is 22% lower than the FY2003 level.⁶³

⁶³ For more information, see CRS Report R43341, *NIH Funding: FY1994-FY2016*, by (name redacted) .

Table 8. National Institutes of Health (NIH)
(Millions of Dollars, by Fiscal Year)

Institutes and Centers (ICs)	2010 ^a	2011 ^b	2012 ^c	2013	2014	2015	2016 Request
Cancer (NCI)	5,098	5,059	5,067	4,783	4,932	4,953	5,098
Heart/Lung/Blood (NHLBI)	3,094	3,070	3,076	2,900	2,989	2,996	3,072
Dental/Craniofacial Research (NIDCR)	413	410	410	387	398	398	407
Diabetes/Digestive/Kidney (NIDDK) ^d	1,959	1,942	1,945	1,835	1,884	1,749	1,788
Neurological Disorders/Stroke (NINDS)	1,634	1,622	1,625	1,532	1,589	1,605	1,660
Allergy/Infectious Diseases (NIAID) ^e	4,815	4,776	4,486	4,230	4,401	4,418	4,615
General Medical Sciences (NIGMS)	2,048	2,034	2,428	2,291	2,362	1,657	1,587
Child Health/Human Development (NICHD)	1,327	1,318	1,320	1,245	1,283	1,287	1,318
Eye (NEI)	706	701	702	656	676	677	695
Environmental Health Sciences (NIEHS)	695	684	685	646	665	667	682
NIEHS, Interior/Environment appropriation ^f	79	79	79	75	77	77	77
Aging (NIA)	1,108	1,100	1,121	1,039	1,172	1,198	1,267
Arthritis/Musculoskeletal/Skin (NIAMS)	538	534	535	505	520	522	533
Deafness/Communication Disorders (NIDCD)	418	415	416	392	404	405	416
Mental Health (NIMH)	1,494	1,477	1,479	1,394	1,420	1,434	1,489
Drug Abuse (NIDA)	1,067	1,051	1,052	992	1,018	1,016	1,047
Alcohol Abuse/Alcoholism (NIAAA)	462	458	459	433	446	447	460
Nursing Research (NINR)	145	144	145	136	141	141	145
Human Genome Research (NHGRI)	524	511	513	483	498	499	515
Biomedical Imaging/Bioengineering (NIBIB)	316	314	338	319	327	327	337
Minority Health/Health Disparities (NIMHD)	211	210	276	260	268	271	282
Complementary/Integrative Health (NCCIH) ^g	129	128	128	121	124	124	128
[former] Center for Research Resources (NCRR)	1,267	1,258	—	—	—	—	—
Advancing Translational Sciences (NCATS)	—	—	575	542	634	633	660

Institutes and Centers (ICs)	2010 ^a	2011 ^b	2012 ^c	2013	2014	2015	2016 Request
Fogarty International Center (FIC)	70	69	70	66	68	68	70
National Library of Medicine (NLM)	349	345	346	360	337	337	394
Office of Director (OD)	1,177	1,167	1,459	1,411	1,303	1,414	1,443
Buildings & Facilities (B&F)	100	50	125	118	128	129	129
Total, Program Level	31,243	30,926	30,860	29,151	30,070	30,311	31,311
Less Funds From Other Sources							
PHS Evaluation Set-Aside ^h	8	8	8	8	8	715	847
Type I Diabetes Research (NIDDK) ⁱ	150	150	150	142	139	150	150
Total, Discretionary Budget Authority	31,084	30,767	30,702	29,001	29,923	29,446	30,314

Sources: Funding amounts for FY2010 are taken from the NIH FY2012 congressional budget justification. Amounts for FY2011 are from the FY2013 justification. Amounts for FY2012 are from the FY2014 justification, available (along with older years) at <http://officeofbudget.od.nih.gov/>. Funding amounts for FY2013 are from the FY2015 HHS Budget in Brief. Funding amounts for FY2014, FY2015, and FY2016 are taken from the FY2016 Justification of Estimates for Appropriation Committees, Vol. I, Overview, table on “Budget Request for Institute and Center,” p.85 at <http://officeofbudget.od.nih.gov/br.html>.

Notes: FY2010 through FY2013 IC and NLM amounts are not comparable to FY2014 as they do not reflect transfers from ICs to NLM. FY2010 and FY2011 are not adjusted for comparability for the NCATS/NCRR reorganization. Totals may differ from the sum of the components due to rounding.

- FY2010 reflects real transfer of \$1 million from HHS Office of the Secretary to NIMH, \$4.6 million transfer to HRSA Ryan White program (Secretary’s authority), and transfers among ICs for the Genes, Environment, and Health Initiative (NIH Director’s authority).
- FY2011 reflects real transfer of almost \$1 million from HHS Office of the Secretary to NIMH for the Interagency Autism Coordinating Committee.
- FY2012 reflects Secretary’s transfer of \$8.727 million to HRSA for Ryan White AIDS and Secretary’s net transfer of \$18.273 million for Alzheimer’s disease research to NIA from other ICs.
- Amounts for NIDDK do not include mandatory funds for type I diabetes research (see note i).
- FY2010 and FY2011 amounts include funds appropriated to NIAID for transfer to the Global Fund to Fight AIDS, Tuberculosis, and Malaria (\$300 million in FY2010 and \$297.3 million in FY2011). FY2010 amount also includes BioShield transfer of \$304 million; for more information, see CRS Report R43607, *The Project BioShield Act: Issues for the 113th Congress*, by (name redacted).
- This is a separate account in the Interior/Environment appropriations act for NIEHS research activities related to Superfund.
- 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.
- For each of FY2010 through FY2014, the \$8 million in set-aside funds was allocated to NLM. All of the FY2015 set-aside funds (i.e., \$715 million) were allocated to NIGMS.
- PHSA Section 330B provides an annual appropriation of \$150 million through FY2017 for this program. These mandatory funds were subject to sequestration in FY2013 and FY2014, but not in FY2015 or FY2016 (as discussed earlier in the report).

Substance Abuse and Mental Health Services Administration (SAMHSA)⁶⁴

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)⁶⁵
- Center for Substance Abuse Prevention (CSAP)⁶⁶
- Center for Mental Health Services (CMHS)⁶⁷

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.⁶⁸ The

full amount of the Substance Abuse Prevention and Treatment block grant falls within CSAT, although no less than 20% of each state's block grant must be used for prevention.⁶⁹

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.⁷⁰

For more information

CRS Report R43968, *SAMHSA FY2016 Budget Request and Funding History: A Fact Sheet*, by (name redacted)

⁶⁴ This section was written by (name redacted), Analyst in Health Policy.

⁶⁵ PHSA Title V, Part B, Subpart 1; 42 U.S.C. §§290bb et seq.

⁶⁶ PHSA Title V, Part B, Subpart 2; 42 U.S.C. §§290bb-21 et seq.

⁶⁷ PHSA Title V, Part B, Subpart 3; 42 U.S.C. §§290bb-31 et seq.

⁶⁸ PHSA Title XIX, Part B, Subpart I; 42 U.S.C. §§300x et seq.

⁶⁹ PHSA Title XIX, Part B, Subpart II; 42 U.S.C. §§300x-21 et seq.

⁷⁰ 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.

The last comprehensive reauthorization of SAMHSA and its programs occurred in 2000 as part of the Children's Health Act,⁷¹ which also added "charitable choice" provisions allowing religious organizations to receive funding for substance abuse prevention and treatment services without altering their religious character.⁷² 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.

Agency Funding Since FY2010

From FY2010 through FY2015, SAMHSA's program-level funding has generally hovered around \$3.6 billion, dropping to \$3.4 billion in FY2013 due to sequestration and rebounding to \$3.6 billion in FY2014 (see **Table 9**). The current (FY2015) distribution of funding across CMHS (30%), CSAT (60%), CSAP (5%), and Health Surveillance and Program Support (5%) overstates the amount allocated to substance abuse treatment and understates the amount allocated to substance abuse prevention because CSAT's funding reflects the entire amount of the Substance Abuse Prevention and Treatment block grant, including the 20% set-aside for prevention. Relative to FY2015 funding, the FY2016 request would increase program-level funding by 1% while decreasing discretionary budget authority by 2%; it would make up the difference with increased funding from the set-aside and PPHF transfers.

⁷¹ P.L. 106-310, Titles XXXI-XXXIV.

⁷² PHS Act §1955, 42 U.S.C. §300x-65; PHS Act §§581 et seq., 42 U.S.C. §§290kk et seq.

Table 9. Substance Abuse and Mental Health Services Administration (SAMHSA)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015	2016 Request
Center for Mental Health Services (CMHS)	1,005	1,022	994	910	1,078	1,071	1,078
Mental Health Block Grant	421	420	460	437	483	483	483
PHS Evaluation Set-Aside (non-add)	(21)	(21)	(21)	(21)	(21)	(21)	(21)
Programs of Regional & National Significance	361	384	316	267	377	371	377
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	—	5
PPHF Transfer (non-add)	(20)	(45)	(45)	—	(12)	(12)	(38)
Children's Mental Health Services	121	118	117	111	117	117	117
PATH Homeless Formula Grant	65	65	65	61	65	65	65
Protection & Advocacy Formula Grant	36	36	36	34	36	36	36
Center for Substance Abuse Treatment (CSAT)	2,253	2,214	2,229	2,114	2,176	2,181	2,141
Substance Abuse Block Grant	1,799	1,783	1,800	1,710	1,815	1,820	1,820
PHS Evaluation Set-Aside (non-add)	(79)	(79)	(79)	(79)	(79)	(79)	(79)
Programs of Regional & National Significance	452	431	429	404	361	361	321
PHS Evaluation Set-Aside (non-add)	(9)	(2)	(2)	(2)	(2)	(2)	(30)
PPHF Transfer (non-add)	—	(25)	(29)	—	(50)	—	—
Prescription Drug Monitoring (NASPER) ^a	2	—	—	—	—	—	—
Center for Substance Abuse Prevention (CSAP)	202	186	186	176	175	175	211
Programs of Regional & National Significance	202	186	186	176	175	175	211
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	—	(16)
Health Surveillance and Program Support	102	177	160	154	193	194	237
Health Surveillance and Program Support	102	171	124	123	119	119	129
PHS Evaluation Set-Aside (non-add)	(23)	(29)	(27)	(27)	(30)	(30)	(29)
PPHF Transfer (non-add)	—	(18)	(18)	(15)	—	—	(20)
Public Awareness and Support	—	—	14	14	13	13	16
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	—	(16)
Performance & Quality Information Systems	—	—	13	9	13	13	13
PHS Evaluation Funds (non-add)	—	—	—	—	—	—	(13)
Agency-Wide Initiatives	—	5	9	8	46	47	78

Program or Activity	2010	2011	2012	2013	2014	2015	2016 Request
<i>PHS Evaluation Set-Aside (non-add)</i>	—	—	—	—	—	(1)	(1)
Data Request and Publications User Fees ^b	—	—	—	—	2	2	2
St. Elizabeths Hospital ^c	1	—	—	—	—	—	—
Total, Program Level	3,583	3,599	3,569	3,354	3,622	3,621	3,666
Less Funds From Other Sources							
PHS Evaluation Set-Aside	132	132	130	130	133	134	211
PPHF Transfers	20	88	92	15	62	12	58
Data Request and Publications User Fees ^b	—	—	—	—	2	2	2
Total, Discretionary Budget Authority	3,431	3,380	3,347	3,210	3,426	3,474	3,396

Sources: SAMHSA Justification of Estimates for Appropriations Committees for FY2012 (FY2010 figures), FY2013 (FY2011 figures), FY2014 (FY2012 figures), FY2015 (FY2013 figures), and FY2016 (FY2014, FY2015, and FY2016 request figures), available at <http://www.hhs.gov/budget/>.

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

- a. The Full-Year Continuing Appropriations Act, 2011 (P.L. 112-10) prohibited the funding of grants originally authorized under the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER, P.L. 109-60) and first funded in FY2009. These grants have not been funded since FY2010. See CRS Report R42593, *Prescription Drug Monitoring Programs*, by (name redacted), (name redacted), and (name redacted).
- b. The Consolidated Appropriations Act, 2014 (P.L. 113-76), authorized SAMHSA to collect fees “for the costs of publications, data, data tabulations, and data analysis completed under [PHSA Title V] and provided to a public or private entity upon request, which shall be credited to this appropriations and shall remain available until expended for such purposes.”
- c. Upon the transfer of the West Campus of St. Elizabeths Hospital from HHS to the General Services Administration (GSA) in 2004, HHS and GSA signed a Memorandum of Agreement that required (among other things) HHS to pay for remediation (clean-up) of hazardous substances found on the site after the date of transfer. Funding for this purpose has not been needed since FY2010.

Appendix A. American Recovery and Reinvestment Act (ARRA): FY2009 Supplemental Appropriations

Through ARRA, Congress appropriated a total of \$22.4 billion in supplemental FY2009 discretionary appropriations for health and human services programs administered by HHS. Of that total amount, \$15.1 billion was provided directly to, or allocated for, programs and activities administered by the PHS agencies (see text box below).⁷³ In most instances the funding was to remain available for obligation through the end of FY2010 (i.e., September 30, 2010). Essentially all the ARRA discretionary funds provided to HHS have been obligated.⁷⁴

ARRA Funding for PHS Agency Programs

Agency for Healthcare Research and Quality (AHRQ): \$1.1 billion

These funds were used to support comparative effectiveness research (now called patient-centered outcomes research). Of the total amount: \$300 million was administered by AHRQ; \$400 million was transferred to NIH; and the remaining \$400 million was allocated at the discretion of the HHS Secretary and used primarily to develop the infrastructure for comparative effectiveness research.

Health Resources and Services Administration (HRSA): \$2.5 billion

These funds were used to support HRSA programs as follows: \$1.5 billion for health center construction, renovation, equipment, and health information technology (HIT); \$500 million to support new health center delivery sites and service areas and expand services at existing sites; \$300 million for the National Health Service Corps; and \$200 million for HRSA's health workforce programs.

Indian Health Service (IHS): \$500 million

These funds were used to support the following IHS facility and infrastructure projects: \$227 million for health facilities construction; \$100 million for maintenance and improvement; \$85 million for HIT activities; \$68 million for sanitation facilities construction; and \$20 million for health equipment, including HIT. [Note: IHS received an additional \$90 million in ARRA discretionary funds from the Environmental Protection Agency for sanitation facilities construction.]

National Institutes of Health (NIH): \$10 billion

These funds were used to support NIH activities as follows: \$8.2 billion for intramural and extramural scientific research; \$1.3 billion for extramural research facility construction, renovation, and equipment; and \$500 million for the construction, repair, and improvement of NIH's facilities. NIH also received a transfer of \$400 million from AHRQ for comparative effectiveness research (see above).

Prevention and Wellness Fund: \$1 billion

These funds were used as follows: \$300 million for CDC's immunization program; \$50 million for CDC and CMS to support state and local efforts to reduce health care-associated infections; and \$650 million for CDC to support an evidence-based clinical and community-based prevention and wellness program—Communities Putting Prevention to Work (CPPW)—focused on increasing levels of physical activity, improving nutrition, reducing obesity rates, and decreasing smoking prevalence and exposure to secondhand smoke.

⁷³ P.L. 111-5, 123 Stat. 115. The HHS appropriations were included in Title VIII (Labor-HHS-ED) of Division A of ARRA. In addition to these discretionary appropriations, ARRA included several HHS mandatory spending provisions. For more information, see CRS Report R40537, *American Recovery and Reinvestment Act of 2009 (P.L. 111-5): Summary and Legislative History*, by (name redacted) et al.

⁷⁴ HHS maintains a Recovery Act website at <http://www.hhs.gov/recovery/>. It includes detailed implementation plans for all the ARRA-funded programs, up-to-date information on ARRA obligations and outlays (by state), and links to the Recovery Act websites maintained by individual HHS agencies.

Appendix B. 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 is for health center operations and the remaining \$1.5 billion is for the NHSC.

Table B-1 shows the amounts appropriated for each fiscal year as well as the post-sequestration levels for FY2013-FY2015. 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**).

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10) 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. **Table B-1** shows the amounts for FY2016.

While CHCF funding may have been intended to supplement—not supplant—annual discretionary appropriations for the health center program and the NHSC, these mandatory funds have partially supplanted discretionary funding for the health center program and entirely replaced discretionary funding for the NHSC (see **Table 6**).

Table B-1. Community Health Center Fund, FY2011-FY2016

(Millions of Dollars, by Fiscal Year)

Program	2011	2012	2013	2014	2015	2016	Total
Health Center Program	1,000	1,200	1,500	2,200	3,600	3,600	13,100
<i>Post-sequestration (non-add)</i>			(1,465)	(2,145)	(3,509)	^a	
National Health Service Corps	290	295	300	305	310	310	1,810
<i>Post-sequestration (non-add)</i>			(285)	(283)	(287)	^a	
Total	1,290	1,495	1,800	2,505	3,910	3,910	14,910

Sources: Prepared by CRS based on ACA Section 10503 and the HHS FY2016 Budget in Brief, available at <http://www.hhs.gov/budget/>.

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

a. As discussed earlier in the report, the FY2016 CHCF funding was not subject to sequestration.

Appendix C. 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, 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 partly cover the costs of the law.⁷⁵ 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 and FY2015 funds, Congress explicitly directed the distribution of PPHF funds, prohibiting the Secretary from making further transfers.⁷⁶

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 FY2016 President's budget proposal is presented in **Table C-1**. Further details regarding PPHF distributions to AHRQ, CDC, HRSA, and SAMHSA are provided in the respective agency budget tables in the body of this report.⁷⁷

For FY2013, the Secretary transferred almost half of available PPHF funds to CMS for ACA implementation, as shown in **Table C-1**. This transfer reduced the PPHF funds that had been provided to some of the PHS agencies from what they had received for FY2012. Along with the sequestration of discretionary funding in FY2013, the loss of PPHF funds that year had a significant effect on CDC's budget for FY2013.⁷⁸

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 and FY2015 PPHF funds, Congress in most cases provided PPHF funds to pre-existing programs and activities.

⁷⁵ P.L. 112-96, Section 3205; 126 Stat. 194.

⁷⁶ See, for FY2015, P.L. 113-235, Consolidated and Further Continuing Appropriations Act, 2015, Sec. 219 of general provisions for Labor, Health and Human Services, and Education, 128 Stat. 2489.

⁷⁷ See also references to the PPHF in text and tables in CRS Report RL33880, *Funding for the Older Americans Act and Other Aging Services Programs*, by (name redacted) and (name redacted)

⁷⁸ CDC describes the trends in budget authority and PPHF transfers for the agency as a whole in an FY2015 budget fact sheet (p. 2) at <http://www.cdc.gov/fmo/topic/Budget%20Information/FY-2015-Fact-Sheets/CDC-Overview.pdf>.

Table C-1. PPHF Transfers to HHS Agencies
(Millions of Dollars, by Fiscal Year)

Agency	2010	2011	2012	2013	2014	2015	2016 Proposal ^a
ACL	0	0	20	9	28	28	28
AHRQ	6	12	12	6	7	0	0
CDC	192	611	809	463	831	886	914
CMS	0	0	0	454 ^b	0	0	0
HRSA	271	20	37	2	0	0	0
OS	12	19	30	0	0	0	0
SAMHSA	20	88	92	15	62	12	58
Sequester	—	—	—	51	72	73	—
Total	500	750	1,000	1,000	1,000	1,000	1,000

Sources: Prepared by Congressional Research Service based on HHS agency congressional budget justifications for FY2012 through FY2016, <http://www.hhs.gov/budget/>; and HHS, “Prevention and Public Health Fund,” funding distribution tables, <http://www.hhs.gov/open/recordsandreports/prevention/index.html>.

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 6.8% sequestration (i.e., \$68 million) for FY2016 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 D. Patient-Centered Outcomes Research Trust Fund

Section 6301(e) of the ACA 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).⁷⁹ 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 2019, 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 fiscal years 2014 through 2019).

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 937.⁸⁰ Of the total amount transferred to HHS, 80% is to be distributed to AHRQ. **Table D-1** shows the allocation of PCORTF funds through FY2016.

Table D-1. Distribution of PCORTF Funding
(Millions of Dollars, by Fiscal Year)

Funding Recipient	2010	2011	2012	2013	2014	2015 Est.	2016 Est.
PCORI	10	40	120	289	376	506	578
HHS	—	10	30	72	94	127	145
AHRQ (<i>non-add</i>)	—	(8)	(24)	(58)	(75)	(102)	(116)
Office of the Secretary (<i>non-add</i>)	—	(2)	(6)	(14)	(19)	(25)	(29)
Total	10	50	150	361	470	633	723

Source: CRS calculations using data provided in Office of Management and Budget, Budget of the U.S. Government, Appendix (FY2013-FY2016).

⁷⁹ 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.

⁸⁰ ACA Section 6301(b) added a new PHSA Section 937 requiring the broad dissemination of research findings published by PCORI. See **Table 3**.

Appendix E. FDA User Fee Authorizations

Table E-1. FDA User Fee Authorizations and Revenue
(Dollars in Millions, In Order of FY2015 Anticipated Revenue)

User Fee	Initial Authorizing Legislation and Year	FY2015 Revenue
Prescription drug	Prescription Drug User Fee Act (PDUFA), 1992 (P.L. 102-300)	798
Tobacco product	Family Smoking Prevention and Tobacco Control Act, 2009 (P.L. 111-31)	566
Generic drug	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	312
Medical device	Medical Device User Fee and Modernization Act (MDUFMA), 2002 (P.L. 107-250)	128
Animal drug	Animal Drug User Fee Act (ADUFA), 2003 (P.L. 108-130)	22
Biosimilars	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	21
Mammography	Mammography Quality Standards Act (MQSA), 1992 (P.L. 102-539)	20
Color certification	Color Additive Amendments of 1960 (P.L. 86-618)	8
Rare pediatric disease priority review voucher	Prescription Drug User Fee Amendments of 2012 (P.L. 112-144)	8
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA), 2008 (P.L. 110-316)	7
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
Tropic disease priority review voucher	Food and Drug Administration Amendments Act (FDAAA), 2007 (P.L. 110-85)	0
Total		1,909

Source: FY 2016 FDA Justification of Estimates for Appropriations Committees, All Purpose Table, <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM437622.pdf>.

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