Public Health Service Agencies: Overview and Funding

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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. AHRQ does not receive a direct appropriation. It relies 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). AHRQ's total funding rose from $403 million to $464 million between FY2010 and FY2014 despite a decrease in set-aside funding over that period. The drop in set-aside funds 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 FY2014 but the overall level was sustained at about $10.8 billion. 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 FY2014 from $3.1 billion to $4.4 billion. The agency is funded with annual discretionary appropriations and industry user fees. While appropriations increased modestly over the FY2010-FY2014 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 $8.9 billion in FY2014 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 significantly between FY2010 and FY2014 from $5.1 billion to $5.8 billion. Appropriations and collections both increased during that period.
- The **National Institute 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 $30.2 billion in FY2014.

- 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-FY2014 period.

Congress has yet to complete work on any of the regular appropriations bills for FY2015, which began on October 1, 2014. On September 19, 2014, the President signed the Continuing Appropriations Resolution, 2015 (P.L. 113-164; H.J.Res. 124), which provides continuing appropriations through December 11, 2014. Generally, P.L. 113-164 funds discretionary programs at the same rate (and under the same conditions) as in FY2014, minus an across-the-board reduction of 0.0554%. This report will be updated with information on PHS agency funding for FY2015 once legislative action on appropriations for the new fiscal year is completed.

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Introduction to the Public Health Service 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]

Collectively, the PHS agencies provide and support essential public health services. Individually, the missions of the PHS agencies 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

[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.

largely derive 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 (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, 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

[3] 21 U.S.C. §§301 et seq.

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

[5] 25 U.S.C. §§1601 et seq.

[6] 42 U.S.C. §9604(i).

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

[8] For an overview of each of these three appropriations acts, see CRS Report CRS Report R43236, *Labor, Health and Human Services, and Education (L-HHS-ED): FY2014 Appropriations*, coordinated by Karen E. Lynch; CRS Report R43142, *Interior, Environment, and Related Agencies: FY2013 and FY2014 Appropriations*, by Carol Hardy Vincent; and CRS Report R43110, *Agriculture and Related Agencies: FY2014 and FY2013 (Post-Sequestration) Appropriations*, coordinated by Jim Monke.

[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 CRS Report R40537, *American Recovery and Reinvestment Act of 2009 (P.L. 111-5): Summary and Legislative History*, by Clinton T. Brass et al.

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]

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 to 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 (discussed in more detail later in this report). In FY2014, NIH once again accounted for the lion's share 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 PHSA programs to evaluate their implementation and effectiveness. Under this budget mechanism, which is known as the PHS Program Evaluation Set-Aside ("set-aside"), the appropriations of a number of HHS agencies and offices are subject to a budget "tap." The tapped funds are redistributed within the department for evaluation and other specified purposes. 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 FY2014 Labor-HHS-ED appropriations act capped the set-aside at 2.5%.[12] For FY2015, the President's budget proposed increasing the maximum amount of set-aside funds to 3.0%.

Following passage of the annual Labor-HHS-ED appropriations act, the HHS Budget Office calculates the amount of set-aside funds to be tapped from the various donor agencies and offices. It then allocates those funds to recipient agencies and programs, including offices within the Office of the Secretary, based on the amounts specified in the appropriations act.[13]

NIH, whose annual discretionary appropriation exceeds that of all the other PHS agencies combined, is by far the largest donor of set-aside funds. NIH contributed $710 million (69%) of the $1.026 billion in tapped funds in FY2013. However, the agency got back only $8 million,

[10] The HHS Secretary's FY2014 transfer authority is provided in Section 206 of the FY2014 Labor-HHS-ED appropriations act (P.L. 113-76, Division H).

[11] For more discussion of ACA implementation funding, see CRS Report R43066, *Federal Funding for Health Insurance Exchanges*, by Annie L. Mach and C. Stephen Redhead.

[12] P.L. 113-76, Division H, Section 205, 128 Stat. 382.

[13] See Chapter I of HHS, Office of the Assistant Secretary for Planning and Evaluation, "Evaluation: Performance Improvement 2009," Washington, DC, 2010, pp. 6-8, http://aspe.hhs.gov/pic/perfimp/2009/report.pdf. Most of the funds appropriated for CDC, HRSA, NIH, and SAMHSA are subject to the set-aside. 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. Funds appropriated for programs not authorized by the PHSA, such as HRSA's maternal and child health block grant, are also excluded.

making it a significant net donor of set-aside funds. Similarly, HRSA contributed more set-aside funds than it received in FY2013. On the other hand both CDC and SAMHA were net recipients of set-aside funding.[14] AHRQ is also a recipient of this funding. Importantly, AHRQ has not received an annual discretionary appropriation in recent years. The agency has been entirely supported by set-aside funds and smaller amounts from other sources (see **Table 2**).

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, and in more detail in the relevant sections later in this report, these additional sources of funding are a substantial component of the budget of several PHS agencies.

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 $11.000 billion in annual appropriations over the five-year period FY2011-FY2015, is supporting the federal health center program and the National Health Service Corps (NHSC), both administered by HRSA.[18] The contribution of CHCF funds to HRSA's budget is discussed in more detail in the HRSA section of this report. A table summarizing each fiscal year's CHCF appropriation and the allocation of funds appears in **Appendix B**.

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.[19] 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. The

[14] See HHS, "Use of Public Health Service Set-Aside Authority for Fiscal Year 2013, Report to Congress." This report includes a table that lists the amount of set-aside funds donated and received by each agency and office in FY2013.

[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.

[16] 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 amended multiple health care and revenue provisions in ACA. A number of other subsequently enacted laws have made more targeted changes to specific ACA provisions. All references to ACA in this report refer to the law as amended.

[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 C. Stephen Redhead.

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

[19] ACA Section 4002.

contribution of PPHF funds to CDC's budget is discussed in more detail in the CDC section of this report. 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.[20] 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.

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.[21] 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 more than 20 years since the Prescription Drug User Fee Act (PDUFA)[22] 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 and approving new product applications. User fees also support information technology infrastructure. 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 FY2014, user fees accounted for 42% of the FDA 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 6** of this report.

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

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

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

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 five years (i.e., FY2010-FY2014). Among the five PHS agencies that are funded through the Labor-HHS-ED appropriations act, only SAMHSA received funding in FY2014 that was essentially level with the amount it received in FY2010. CDC, HRSA, and NIH each received a smaller discretionary appropriation in FY2014 than they had received in FY2010. Similarly, AHRQ's set-aside funding in FY2014 was less than the amount provided to the agency in FY2010. With the exception of NIH, however, 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 both seen their appropriations increase over the five-year period FY2010-FY2014. Both agencies have also witnessed a steady increase in funding from other sources; user fees at FDA, and third-party collections at IHS. ATSDR's funding, which is included in the discussion of CDC, has been essentially flat since FY2010. All these funding trends are examined in more detail in the upcoming sections of this report.

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),[23] which amended the Balance Budget and Emergency Deficit Control Act of 1985 (BBEDCA).[24] 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.

[23] P.L. 112-25, 125 Stat. 240. A detailed analysis of the BCA, and the amendments made to it by the American Taxpayer Relief Act of 2012 and the Bipartisan Budget Act of 2013, is beyond the scope of this report. For more information, see CRS Report R41965, *The Budget Control Act of 2011*, by Bill Heniff Jr., Elizabeth Rybicki, and Shannon M. Mahan, and CRS Report R42949, *The American Taxpayer Relief Act of 2012: Modifications to the Budget Enforcement Procedures in the Budget Control Act*, by Bill Heniff Jr.

[24] P.L. 99-177, Title II, 99 Stat. 1038.

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 1**), with two key exceptions. First, the funds for the CDC-administered Vaccines for Children program come from Medicaid, which is exempt from sequestration. Second, for legal reasons beyond the scope of this report, OMB made the determination that the cuts in ACA (i.e., 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 1**).

Discretionary Spending

Under the BCA, only FY2013 discretionary spending was subject to sequestration. In general, PHS agency discretionary appropriations for that year were fully sequestrable at the applicable percentage rate for nonexempt nondefense discretionary (NDD) spending (see **Table 1**). 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 sequestrable at the NDD percentage rate. But it concluded that IHS's third-party collections in FY2013 were exempt from sequestration.

Table 1. Impact of BCA Annual Spending Reductions on PHS Agency Funding

FY2013-FY2015

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

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. Beginning in FY2014, the annual spending reductions in discretionary spending are achieved by lowering the discretionary spending caps rather than by sequestration. Thus, congressional appropriators, working within the caps, get to determine how to apply the cuts across programs.

For each of the remaining years (i.e., FY2014 through FY2021), the annual reductions in discretionary spending 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 $37 billion. However, the Bipartisan Budget Act of 2013 (BBA)[25] subsequently amended the BCA by establishing new NDD spending caps for FY2014 and FY2015 and eliminating the BCA requirement that these caps be lowered. Congressional appropriators now have more funding available for those two fiscal years. The new FY2014 NDD cap is $22 billion above the BCA-lowered FY2014 cap that it replaced, and almost $24 billion above the FY2013 post-sequestration NDD funding level. The new FY2015 spending cap, which is virtually unchanged from the new FY2014 cap, is $9 billion above the BCA-lowered FY2015 cap that it replaced.

Report Roadmap

The remainder of this report consists of seven sections, one for each PHS agency beginning with AHRQ.[26] Each section includes (1) an overview of the agency's statutory authority and principal activities; (2) a summary of agency funding over the period FY2010-FY2014; and (3) highlights of the agency's FY2015 budget request. This material is accompanied by a detailed funding table showing the FY2010-FY2014 funding levels and the FY2015 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.[27] 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 3**). As already discussed, AHRQ is a special case because it does not receive any discretionary appropriations. Instead, it relies entirely on set-aside funds supplemented by smaller amounts of ACA funding (see **Table 2**).

A dash is used in the funding tables to indicate either that there was no mandatory funding appropriated for that fiscal year or that there was no request and appropriation of discretionary funds for that year. A zero indicates that congressional appropriators chose to disregard an authorization or request for funding and provide no funds.

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

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

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

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

the amount of set-aside funds received. They do not reflect the amount of funding tapped from agency accounts. As a result, the funding tables for the four donor agencies (i.e., CDC, HRSA, NIH, and SAMHSA) give a somewhat distorted view of available budgetary resources. This effect is particularly significant in the case of NIH. As mentioned earlier, NIH loses approximately $700 million as a result of the tap and gets back only $8 million. While funding tables for NIH show the receipt of $8 million in set-aside funds, which count towards the agency's overall program level funding, the amounts shown for each agency account have not been reduced to reflect the tap. 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 both in FY2013 and in FY2014. The amounts shown for the FY2015 request do not reflect sequestration.

Congress has yet to complete work on any of the regular appropriations bills for FY2015, which began on October 1, 2014. On September 19, 2014, the President signed the Continuing Appropriations Resolution, 2015 (P.L. 113-164; H.J.Res. 124), which provides continuing appropriations through December 11, 2014. Generally, P.L. 113-164 funds discretionary programs at the same rate (and under the same conditions) as in FY2014, minus an across-the-board reduction of 0.0554%. This report will be updated with information on PHS agency funding for FY2015 once legislative action on appropriations for the new fiscal year is completed.

Agency for Healthcare Research and Quality (AHRQ)

Agency Overview

AHRQ is the federal agency charged with supporting 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 Surveys (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.[28] Congress has yet to revisit the agency and further reauthorize its funding. Despite the expired authorizations of appropriations, AHRQ continues to get annual funding.

Since FY2003, AHRQ has not received any annual discretionary appropriations. Instead, the agency has relied almost entirely on the PHS evaluation set-aside to fund its activities and programs. Over the past few years AHRQ has received additional funds from the PPHF and the PCORTF (see **Table 2**).

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.

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.

FY2010-FY2014 Funding

As shown in **Table 2**, AHRQ's total program level increased by $61 million (15%) between FY2010 and FY2014, from $403 million to $464 million. This overall growth was the result of increasing ACA fund transfers during this time, which offset a $33 million (8.3%) decrease in set-aside funding for the agency. Between FY2010 and FY2014, total transfers from the PPHF and the PCORTF increased from $6 million to $100 million. During FY2011 and FY2012, transfers from the PPHF increased, but returned in FY2013 and FY2014 to close to the FY2010 level, while PCORTF transfers increased steadily according to the statutory formulas (see **Appendix D**). The total program level for the agency for FY2014 includes $364 million in set-aside funding and a total of $100 million in ACA fund transfers (i.e., $7 million from the PPHF and $93 million from the PCORTF).

Notable shifts in program area funding levels between FY2010 and FY2014 include the changing level for Patient-Centered Health Research, which increased by $72 million during this period, as a result of the fund transfers from PCORTF. Funds transferred from the PPHF have supported an increase in funding for prevention and care management activities over this period, and have been used in part to fund the activities of the U.S. Preventive Services Task Force (USPSTF). Finally, funding for Patient Safety Research decreased between FY2010 and FY2014 by $19 million.

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

FY2015 Budget Request

For FY2015, the President requested a total program level of $440 million for AHRQ, which represents a decrease of $24 million (5.2%) from the FY2014 program level of $464 million (see **Table 2**). The FY2015 request includes $334 million in set-aside funds and a transfer of $106 million from the PCORTF. It continues the trend of decreasing set-aside funding being offset by increasing ACA fund transfers. AHRQ's FY2015 request does not include any PPHF funds. The agency has received PPHF funding in each of the preceding years since the establishment of the fund in FY2010. Under the FY2015 request, most of the HCQO research program areas would see a decrease in their funding. The exceptions are Patient-Centered Health Research, which would receive an increase of $13 million as a result of the increased PCORTF transfer, and Patient Safety Research, which would receive a modest increase of $1 million over the FY2014 level.

Table 2. Agency for Healthcare Research and Quality (AHRQ)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015 req.
Health Costs, Quality and Outcomes (HCQO) Research	**276**	**266**	**272**	**300**	**331**	**306**
Health Information Technology Research	28	28	26	26	30	23
Patient Safety Research	91	66	66	67	72	73
Patient-Centered Health Research	21	29	41	68	93	106
PCORTF Transfer (non-add)	—	*(8)*	*(24)*	*(58)*	*(93)*	*(106)*
Health Services Research, Data, and Dissemination[a]	112	112	108	111	111	93
Value	4	4	4	4	3	—
Prevention/Care Management	21	28	28	26	23	11
PPHF Transfer (non-add)	*(6)*	*(12)*	*(12)*	*(6)*	*(7)*	—
Medical Expenditure Panel Surveys (MEPS)	**59**	**59**	**59**	**61**	**64**	**64**
Program Support	**68**	**68**	**74**	**68**	**69**	**70**
Total, Program Level	**403**	**392**	**405**	**429**	**464**	**440**
Less Funds From Other Sources						
PHS Evaluation Set-Aside	397	372	369	365	364	334
PCORTF Transfers	—	8	24	58	93	106
PPHF Transfers	6	12	12	6	7	—
Total, Discretionary Budget Authority	**0**	**0**	**0**	**0**	**0**	**0**

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 FY2015 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. Formerly "Crosscutting Activities;" also formerly "Research Innovations."

Centers for Disease Control and Prevention (CDC)

Agency Overview

According to CDC, its mission is "to protect America from health, safety and security threats, both foreign and in the [United States]."[29] 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).[30] 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.[31] 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.[32] The National Center on Birth Defects and Developmental Disabilities (NCBDDD) was established in PHSA Section 317C by the Children's Health Act of 2000.[33] 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.[34] ATSDR was established by the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA, the "Superfund" law).[35] Authorizations of appropriations for NCBDDD, NCHS, and ATSDR have expired, but the programs continue to receive annual appropriations.

CDC provides financial and technical assistance to state, local, municipal, tribal, and foreign governments, and to academic and non-profit entities. Nearly 85% of the agency's funding is spent on grants and contracts.[36] CDC has few regulatory responsibilities.

Table 3 presents funding levels for CDC programs for FY2010 through the FY2015 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;[37] (2) NIOSH activities to support the Energy Employees Occupational Illness Compensation Program Act (EEOICPA);[38] (3) the World Trade Center (WTC) Health Program;[39] and (4) appropriations provided under ACA, principally through the PPHF.[40] CDC also receives

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

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

[31] 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.

[32] 29 U.S.C. §671.

[33] 42 U.S.C. §247b-4.

[34] 42 U.S.C. §242k.

[35] 42 U.S.C. §9604(i).

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

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

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

[39] See CDC, World Trade Center Health Program, http://www.cdc.gov/niosh/topics/wtc/.

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

annual set-aside funds and authorized user fees, and may also receive funding through supplemental appropriations and other transfers.

FY2010-FY2014 Funding

While CDC's discretionary budget authority decreased from FY2010 to FY2014, reaching its lowest point in FY2013, the CDC/ATSDR program level generally held steady or increased during that period, with the exception of FY2013. Program levels have generally been sustained, despite the decreases in discretionary budget authority, by transfers from the PPHF. The decrease in program level for FY2013 was due both to sequestration of discretionary and nonexempt mandatory funding, which reduced CDC's program level by $293 million compared with FY2012,[41] and to a reduction in PPHF funding that year. As noted earlier in the report, almost half of the FY2013 PPHF funds were transferred to CMS for ACA implementation. As a result, CDC's allocation of PPHF funding was $346 million less than for FY2012. (See **Appendix C** for more discussion of the allocation of PPHF funds.) To partially offset the decrease in FY2013 PPHF funding, the HHS Secretary transferred $79 million to CDC from other HHS accounts, principally at NIH.[42]

FY2015 President's Budget Request

For FY2015, the Administration requests $5.400 billion in CDC budget authority and $397 million in set-aside funds, and proposes also to transfer $810 million from the PPHF. These three amounts provide CDC with its general operating budget, given that the remaining mandatory accounts each support narrow, specific activities. CDC notes that the FY2015 request would provide the second lowest general operating level since FY2010 (with FY2013 being the lowest).[43]

The FY2015 request would reduce funding for certain CDC "safety net" programs that deliver healthcare services, in light of the expansion of access to insurance coverage for these services under ACA. These programs include the National Breast and Cervical Cancer Early Detection Program, the Colorectal Cancer Screening Program, and the Section 317 Immunization Program.[44] In FY2014 appropriations, congressional appropriators asked the HHS Secretary to include with the FY2016 budget an analysis of how the ACA's requirements for private insurance coverage of preventive services, such as cancer screenings and immunizations, will impact eligibility for discretionary HHS programs such as these.[45] As with several previous years, the Administration proposes to eliminate the Preventive Health and Health Services block grant for FY2015, stating that PPHF funds serve the same purpose.[46]

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[41] CDC Office of the Chief Operating Officer, June 13, 2013.

[42] CDC Office of the Chief Operating Officer, June 13, 2013. See also John Reichard, "HHS to Use $454 Million From Prevention Fund for Health Insurance Enrollment," *CQ HealthBeat*, April 15, 2013.

[43] CDC, "CDC Overview," Budget Fact Sheet, p. 2, http://www.cdc.gov/fmo/topic/Budget%20Information/FY-2015-fact-sheets.html.

[44] See "Program Decreases and Eliminations" in FY2015 CDC congressional budget justification, p. 12, http://www.cdc.gov/fmo. However, CDC estimates an increase in mandatory funding for the Vaccine for Children Program (VFC), citing, among other things, increases in the cost of covered vaccines. See p. 9 in the justification.

[45] P.L. 113-76, Consolidated Appropriations Act, 2014, Division H, Title II, Section 226, January 17, 2014.

[46] FY2015 CDC congressional budget justification, p. 11.

The Administration requests new or increased FY2015 funding for several activities. These include, among others: $10 million for gun violence prevention research and $12 million to expand the National Violent Death Reporting System (NVDRS) to all 50 states; a $45 million increase to enhance global health security activities; a $30 million increase to combat antibiotic resistance; a $16 million increase to combat prescription drug overdoses; and a $10 million increase to improve foodborne illness detection.[47]

CDC's FY2015 budget implements the "Working Capital Fund," a revolving fund to be used by agency programs to "pay for" agency-wide services—such as human resources and procurement—that received direct appropriations in the past.[48] In order to implement the new fund, the Administration proposes to apply certain business services funds previously assigned to the Cross-cutting Activities and Program Support account across the various programmatic accounts instead. This has the effect of increasing the amounts in those accounts.

Table 3. 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 req.
Immunization and Respiratory Diseases	721	748	779	718	785	748
PHS Evaluation Set-Aside (non-add)	*(13)*	*(13)*	*(13)*	*(13)*	*(13)*	*(13)*
PPHF Transfer (non-add)	—	*(100)*	*(190)*	*(91)*	*(160)*	*(127)*
PHSSEF Transfer (non-add)	—	*(156)*	—	*(12)*	—	—
Vaccines for Children[b]	3,761	3,953	4,006	3,607	3,562	4,077
HIV/AIDS, Viral Hepatitis, STI and TB	1,119	1,116	1,110	1,095	1,121	1,128
PHS Evaluation Set-Aside (non-add)	—	—	—	*(4)*	—	*(3)*
PPHF Transfer (non-add)	*(30)*	—	*(10)*	—	—	—
Emerging & Zoonotic Infectious Diseases	281	304	304	341	390	445
PPHF Transfer (non-add)	*(20)*	*(52)*	*(52)*	*(44)*	*(52)*	*(52)*
Chronic Disease Prevention and Health Promotion	924	1,075	1,167	1,003	1,188	1,078
PPHF Transfer (non-add)	*(59)*	*(301)*	*(411)*	*(233)*	*(446)*	*(470)*
Birth Defects, Developmental Disabilities, Disability and Health	144	136	137	134	132	132
PPHF Transfer (non-add)	—	—	—	—	—	*(71)*
Environmental Health	181	170	140	142	180	169
PPHF Transfer (non-add)	—	*(35)*	*(35)*	*(21)*	*(13)*	*(37)*
Injury Prevention and Control	149	144	138	139	151	194
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	*(6)*

[47] Ibid, pp. 8 ff.

[48] Ibid, p. 16.

Program or Activity	2010	2011	2012	2013[a]	2014	2015 req.
Public Health Scientific Services	441	468	462	493	483	526
PHS Evaluation Set-Aside (non-add)	*(248)*	*(248)*	*(248)*	*(248)*	*(86)*	*(95)*
PPHF Transfer (non-add)	*(32)*	*(72)*	*(70)*	*(52)*	—	*(53)*
Occupational Safety and Health[c]	430	442	536	605	651	618
PHS Evaluation Set-Aside (non-add)	*(92)*	*(92)*	*(111)*	*(111)*	*(112)*	*(281)*
EEOICPA (non-add)	*(55)*	*(55)*	*(55)*	*(51)*	*(50)*	*(55)*
World Trade Ctr. Health Program (non-add)[d]	—	*(71)*	*(188)*	*(231)*	*(268)*	*(282)*
Global Health	354	340	348	363	417	464
Public Health Preparedness and Response	1,522	1,415	1,329	1,279	1,371	1,317
PPHF Transfer (non-add)	—	*(10)*	—	—	—	—
PHSSEF Transfer (non-add)	—	*(69)*	*(30)*	—	—	—
Crosscutting Activities and Program Support[e]	730[e]	605	659	251	299	124
PPHF Transfer (non-add)	*(50)*	*(41)*	*(41)*	*(23)*	*(160)*	—
Prevention Block Grant (non-add)	*(100)*	*(80)*	*(80)*	*(75)*	*(160)[f]*	—
ATSDR	100	77	76	72	75	95
Medical Monitoring (ACA Sec. 10323(b)) (non-add)	*(23)[g]*	—	—	—	—	*(20)[g]*
Childhood Obesity (ACA Sec. 4306)	25[h]	—	—	—	—	—
User Fees	2	2	2	2	2	2
Total, CDC/ATSDR Program Level	**10,884**	**10,995**	**11,193**	**10,243**	**10,806**	**11,117**
Less Funds From Other Sources						
Vaccines for Children	3,761	3,953	4,006	3,607	3,562	4,077
EEOICPA	55	55	55	51	50	55
PHSSEF Transfers	—	225	30	12	—	—
PHS Evaluation Set-Aside	352	352	371	375	211	397
ACA Mandatory Funds: PPHF Transfers	192	611	809	463	831	810
ACA Mandatory Funds: Other	48	—	—	—	—	20
World Trade Ctr. Health Program	—	71	188	231	268	282
User Fees	2	2	2	2	2	2
Total, CDC/ATSDR Discretionary BA	**6,474**	**5,726**	**5,732**	**5,503**	**5,882**	**5,474**
Less ATSDR Discretionary BA	77	77	76	72	75	75
Total, CDC Discretionary BA	**6,397**	**5,649**	**5,656**	**5,430**	**5,807**	**5,400**

Sources: CDC and ATSDR congressional budget justifications for FY2012 through FY2015, http://www.cdc.gov/fmo.

Notes: BA and program level amounts for FY2013, FY2014, and the FY2015 President's budget reflect a proposed 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. Individual amounts may not add to subtotals or totals due to rounding. PHSSEF is the Public Health and Social Services Emergency Fund, a fund used by appropriators to provide the Secretary with ongoing or one-time emergency funding, such as for the response to influenza epidemics. STI is sexually transmitted infection.

a. 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 and FY2015 are estimates.

c. Program levels for Occupational Safety and Health include Energy Employees and World Trade Center mandatory program funds.

d. 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.

e. Amounts for FY2010 include amounts previously designated as Public Health Leadership and Support, Business Services Support, Buildings and Facilities, and Preventive Health and Health Services Block Grant.

f. FY2014 funding for the Preventive Health and Health Services Block Grant ("Prevention Block Grant") was provided from the PPHF pursuant to P.L. 113-76, the FY2014 Consolidated Appropriations Act. Amounts for prior fiscal years were provided through annual discretionary appropriations.

g. ACA appropriated $23 million for the period FY2010-2014, 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.

h. ACA appropriated $25 million for a childhood obesity demonstration project, http://www.cdc.gov/obesity/childhood/researchproject.html.

Food and Drug Administration (FDA)

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

[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.

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.[51] 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 accounted for 42% of FDA's total FY2014 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 budget. After PDUFA, Congress added user fee authorities regarding medical devices, animal drugs, animal generic drugs, tobacco products, priority review, food reinspection, food recall, voluntary qualified food importer, generic drugs, biosimilars, and, most recently, outsourcing facilities (related to drug compounding) and some wholesale distributors and third-party logistics providers (related to pharmaceutical supply chain security).[52] 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.[53]

FY2010-FY2014 Funding

From FY2010 to FY2014, Congress increased FDA's annual appropriations by $192 million (8.1%), from $2.369 billion to $2.561 billion (see **Table 4**). However, because of a 144% increase in user fee revenue, the total program level for FDA increased by $1.269 billion (40.7%) over that period, from $3.118 billion to $4.387 billion. In addition to increasing collections from continuing user fee programs, FDA had also implemented several newly authorized user fees. Between FY2010 and FY2014, the proportion of the agency's budget that came from user fees increased from 30% to 42%.

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[51] For additional information on the history of the FDA budget, see CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

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

[53] User fees provide varying proportions of funding for several FDA programs (see **Table 4**). 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 FY2014, PDUFA revenues account for 63.8% of the human drugs program budget; fees provide 37.5% of the biologics budget, 25.0% of the devices and radiological health budget, 18.4% of the animal drugs and feeds budget, and 1.9% of the foods budget. **Appendix E** of this report presents additional detail.

FDA's statutory responsibilities have increased since FY2010, and new user fees do not cover all the new activities. The Food and Drug Administration Amendments Act of 2007 (FDAAA, P.L. 110-85), the Food Safety Modernization Act (FSMA, P.L. 111-353), the Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144), and the Drug Quality and Security Act (DQSA, P.L. 113-54) added requirements concerning food, drug, biologics, and device regulation.[54]

As noted earlier in the report, OMB determined that FDA user fees were fully sequestrable in FY2013 at the NDD percentage rate, along with the agency's discretionary appropriations. The FDA Commissioner estimated that FDA would lose about $83 million in user fees in FY2013 as a result of sequestration.[55] Congressional appropriators subsequently released those sequestered funds and made them available to the FDA in the FY2014 Agriculture appropriations act.[56]

FY2015 President's Budget Request

The President requested a FY2015 FDA total program level of $4.745 billion, including $2.584 billion (54.5%) in discretionary appropriations and $2.161 billion (45.5%) in user fees. As is customary, the request included $260 million in new user fees that Congress would have to authorize.[57] Without those proposed fees, which the appropriators cannot include in the FY2015 bill unless Congress and the President enact them into law, the total program level request is $4.485 billion, 2.2% above the FY2014 level (see **Table 4**). That total includes $2.584 billion (57.6%) in appropriations and $1.901 billion (42.4%) in authorized user fees; 0.9% and 4.1% above the FY2014 levels, respectively.

[54] See, for example, statement of Margaret A. Hamburg, Commissioner of Food and Drugs, FDA, before the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, "President's Fiscal Year 2014 Budget Request for the FDA," April 26, 2013; and Stephen Grossman, "Funding Cutbacks at FDA: A Sequester Primer," *FDA Matters*, March 7, 2013. For details of the additional responsibilities, see CRS Report RL34465, *FDA Amendments Act of 2007 (P.L. 110-85)*, by Susan Thaul; CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*, coordinated by Renée Johnson; CRS Report R42680, *The Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. 112-144)*, coordinated by Susan Thaul; and CRS Report R43290, *The Proposed Drug Quality and Security Act (H.R. 3204)*, by Susan Thaul.

[55] Remarks by Margaret A. Hamburg, Commissioner of Food and Drugs, 2013 FDLI Annual Conference, Washington, DC, April 23, 2013.

[56] Section 747 in Division A (Agriculture) of the Consolidated Appropriations Act, 2014 (P.L. 113-76) states that "[F]ees deposited under the heading 'Department of Health and Human Services—Food and Drug Administration—Salaries and Expenses' in fiscal year 2013 and sequestered pursuant to [the BBEDCA] shall be available until expended for the same purpose for which those funds were originally appropriated."

[57] Revenue from the five proposed new users fees is allocated across the following FDA program areas (foods, $210.5 million; human drugs, $0.5 million; animal drugs and feeds, $17.8 million; devices and radiological health, $3.8 million; headquarters and Office of the Commissioner, $15.6 million; GSA rent, $7.2 million; and other rent and rent-related activities, $4.1 million).

Table 4. Food and Drug Administration (FDA)

(Millions of Dollars, by Fiscal Year)

Program area	2010	2011	2012	2013	2014	2015 req.
Foods	**783**	**836**	**883**	**813**	**900**	**914**
BA	783	836	866	797	883	903
User Fees	—	—	17	17	17	10
Human drugs	**884**	**950**	**979**	**1,187**	**1,289**	**1,335**
BA	462	478	478	439	466	480
User Fees	421	472	501	748	823	856
Biologics	**291**	**302**	**329**	**308**	**338**	**343**
BA	206	212	212	195	211	210
User Fees	86	90	117	113	127	133
Animal drugs and feeds	**154**	**159**	**166**	**155**	**173**	**172**
BA	134	139	138	126	142	145
User Fees	20	20	28	29	32	27
Devices and radiological health	**370**	**379**	**376**	**384**	**428**	**437**
BA	314	322	323	296	321	318
User Fees	57	56	53	88	107	119
Tobacco products	**64**	**136**	**455**	**459**	**501**	**532**
BA	—	—	—	—	—	—
User Fees	64	136	455	459	501	532
Toxicological research	**59**	**61**	**60**	**55**	**62**	**59**
BA	59	61	60	55	62	59
User Fees	—	—	—	—	—	—
Headquarters/Commissioner's Office	**178**	**187**	**223**	**251**	**275**	**279**
BA	141	150	154	160	172	175
User Fees	37	37	69	91	103	104
GSA rent	**178**	**178**	**205**	**199**	**220**	**229**
BA	145	151	161	150	162	169
User Fees	32	27	45	49	58	60
Other rent and rent-related activities[a]	**124**	**129**	**132**	**157**	**178**	**164**
BA	103	100	106	118	133	116
User Fees	21	30	26	40	46	48
Export and color certification funds	**10**	**11**	**11**	**12**	**12**	**14**
BA	—	—	—	—	—	—
User Fees	10	11	11	12	12	14

Program area	2010	2011	2012	2013	2014	2015 req.
Buildings & Facilities	**22**	**13**	**9**	**5**	**9**	**9**
BA	22[b]	13	9	5	9	9
User Fees	—	—	—	—	—	—
Food and drug safety	—	—	—	**46**[c]	**0**	**0**
BA	—	—	—	46	0	0
User Fees	—	—	—	0	0	0
Total, Program Level	**3,118**	**3,339**	**3,832**	**4,031**	**4,387**	**4,485**
Less Funds From Other Sources						
User Fees	748	879	1,326	1,645	1,826	1,901
Total, Discretionary Budget Authority	**2,369**	**2,460**	**2,506**	**2,386**	**2,561**	**2,584**

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 request amounts are taken from the FY2015 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. Other rent and rent-related activities include White Oak consolidation.

b. The FY2010 Buildings & Facilities appropriation included about $7 million for the National Center for Natural Products Research, as directed by the Committee on Appropriations.

c. The FY2013 Sequestration Operating Plan notes food safety and drug safety items that had not been included in the program-level appropriations.

Health Resources and Services Administration (HRSA)

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.[58] HRSA also administers the health centers program, which provides grants to non-profit entities that provide primary care

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

services to people who experience financial, geographic, cultural, or other barriers to health care.[59]

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).[60]

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

FY2010-FY2014 Funding

As shown in **Table 5**, HRSA's discretionary budget authority decreased by 21.8% from $7.492 billion in FY2010 to $5.861 billion in FY2013. It then increased by 3.4% to $6.061 billion in FY2014. Overall, HRSA's discretionary budget authority in FY2014 was $1.431 billion (19.1%) below the FY2010 level. However, the agency's total program level over the five-year period

[59] For more information, see CRS Report R42433, *Federal Health Centers*, by Elayne J. Heisler.

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

[61] For more information, see CRS Report R42428, *The Maternal and Child Health Services Block Grant: Background and Funding*, by Carmen Solomon-Fears.

FY2010-FY2014 increased by $848 million (10.5%) from 8.067 billion to $8.915 billion due to the inclusion of significant amounts of ACA mandatory funding, primarily from the CHCF, as well as smaller amounts of set-aside funds and user fees.

Funding for the health centers program, administered by the Bureau of Primary Health Care, increased by $1.404 billion (65.6%) from $2.141 billion in FY2010 to $3.545 billion in FY2014. That increase was entirely due to CHCF mandatory funds, which increased from $1 billion to $2.145 billion over that period and provided a growing share of the total funding for the program. Other ACA funding for this bureau included $1.5 billion in FY2011 for health center construction, and four years of funding totaling $197 million for the School-Based Health Centers program.[62]

Total funding for health workforce programs decreased by $204 million (16.3%) from $1.249 billion in FY2010 to $1.045 billion in FY2014. Of particular note is the fact that the National Health Service Corps (NHSC) has received no discretionary funding since FY2012 and has been entirely funded by the CHCF. See **Appendix B** for more discussion of the CHCF.

Total funding for maternal and child health programs at HRSA increased $236 million (24%) from $984 million in FY2010 to $1.220 billion in FY2014. This increase was largely due to the ACA appropriation of mandatory funds for the Maternal, Infant, and Early Childhood Home Visiting program. Discretionary funding for the Maternal and Child Health Block Grant decreased from $661 million in FY2010 to $634 million in FY2014.[63] The ACA also appropriated $5 million for each of FY2010 through FY2012 for the Family-to-Family Health Information Centers program. Funding for the program was further extended first by the American Taxpayer Relief Act of 2012,[64] then by the Bipartisan Budget Act of 2013.[65]

While funding for the Ryan White HIV/AIDS programs has fluctuated over the past five years, the FY2014 level ($2.319 billion) is almost the same as the FY2010 level ($2.315 billion).[66] For each of FY2010 through FY2014, HRSA received a total of $25 million in set-aside funds, which have been used to help support Ryan White HIV/AIDS programs.

The Healthcare Systems Bureau received a one-time ACA appropriation of $100 million in FY2010 for hospital construction grants. FY2010 also was the final year of funding for the State Health Access Grant Program, which received $74 million that year. While funding for several of the programs administered by the Healthcare Systems Bureau (e.g., National Cord Blood Inventory, C.W. Bill Young Cell Transplantation Program) has remained relatively flat since FY2010, the 340B drug pricing program has seen its funding increase five-fold over the period FY2010-FY2014 from $2 million to $10 million. By comparison, funding for Poison Control Centers decreased $10 million (34.5%) from $29 million in FY2010 to $19 million in FY2014.

[62] The ACA appropriated $50 million for each of FY2010 through FY2013 for school-based health centers; however, the FY2013 amount was reduced by sequestration.

[63] Funding for the Maternal Child Health Block Grant was $605 million in FY2013 after sequestration.

[64] P.L. 112-240, 126 Stat. 2313.

[65] P.L. 113-67, Division B, 127 Stat. 1195.

[66] See CRS Report RL33279, *The Ryan White HIV/AIDS Program*, by Judith A. Johnson for more information on this program.

Rural health funding decreased from $185 million in FY2010 to $142 million in FY2014, largely due to the elimination of funding for the Delta Health Initiative and the Denali Project. Also of note is the elimination of HRSA's congressionally directed projects, or earmarks, in the FY2011 appropriations cycle. Congressional earmarks, which in the years prior to their elimination had become a significant component of HRSA's budget, totaled $337 million in FY2010.

FY2015 President's Budget Request

The President's Budget for FY2015 requested $10.753 billion in program level funding for HRSA, which is $1.838 billion (20.6%) above the FY2014 level. That amount is almost evenly split between discretionary budget authority and other, mostly mandatory, funding. Specifically, the FY2015 request includes $5.300 billion in discretionary budget authority and $5.453 billion from other funding sources: $3.910 billion in CHCF funding, $1.430 billion in proposed new mandatory funding, $87 million in set-aside funds, and $26 million in user fees (see **Table 5**).

The FY2015 budget request generally would fund HRSA programs at the FY2014 funding level, with some exceptions. It would reduce funding for Training for Diversity Programs, eliminate funding for the Children's Hospital Graduate Medical Education (GME), and reduce or eliminate funding for certain rural health programs. Specifically, it proposed to eliminate funding for Rural Emergency Devices and to reduce funding for Rural Hospital Flexibility Grants. The budget also would consolidate funding for Part C (Early Intervention Programs) and Part D (Children, Youth, and Families) of the Ryan White Program.[67]

The FY2015 budget request included three proposals for new mandatory funds to support HRSA-administered programs. First, it proposed a total of $3.950 billion over the six-year period FY2015-FY2020, including $400 million for FY2015, to continue funding for the NHSC. As already noted, the NHSC has been supported entirely by CHCF funds since FY2012. Those funds end in FY2015. The FY2015 budget provided a total of $810 million for the NHSC. That amount includes the final installment of $310 million from the CHCF, $400 million in proposed new mandatory funding, and $100 in discretionary appropriations. The health centers program also receives its final installment of CHCF funding ($3.6 billion) in FY2015. However, unlike the NHSC proposal, there are no new mandatory funds in the FY2015 budget for the health centers program. That program has seen its annual discretionary appropriation decline and be partially supplanted (replaced) by CHCF funding in the past few years.

Second, the FY2015 budget request proposed a total of $15 billion in new mandatory funds to extend and expand the Maternal, Infant, and Early Childhood Home Visiting program through FY2024, including $500 million for FY2015. ACA funding for this program ended in FY2014. However, the Protecting Access to Medicare Act of 2014 (P.L. 113-93), which was enacted shortly after the FY2015 budget request was released, appropriated $400 million for the home visiting program for FY2015.

Finally, the President's FY2015 budget proposed transferring a total of $5.230 billion from the Medicare Part A trust fund over the 10-year period FY2015-FY2024, including $530 million in FY2015, for the new Targeted Support for GME Program. This program would incorporate the existing Children's Hospital GME program, for which no FY2015 discretionary funds are

[67] For more information on the Ryan White Program, see CRS Report RL33279, *The Ryan White HIV/AIDS Program*, by Judith A. Johnson.

requested, and the Teaching Health Center GME program, which was created by the ACA. The budget proposes setting aside $100 million of the new mandatory funds in FY2015 for the Children's Hospital GME Program.

Table 5. Health Resources and Services Administration (HRSA)

(Millions of Dollars, by Fiscal Year)

Bureau or Activity	2010	2011	2012	2013	2014	2015 req.
Primary Care	**2,253**	**4,149**	**2,817**	**2,992**	**3,640**	**4,600**
Health Centers	2,141	2,481	2,672	2,856	3,545	4,511
CHCF Transfer (non-add)	—	*(1,000)*	*(1,200)*	*(1,465)*	*(2,145)*	*(3,600)*
Health Center Tort Claims	44	100	95	89	*95*	*89*
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[a]	18	18	—	—	—	—
Health Workforce[b]	**1,249**	**1,357**	**1,086**	**1,001**	**1,045**	**1,798**
National Health Service Corps (NHSC)	141	315	295	285	283	410
CHCF Transfer (non-add)	—	*(290)*	*(295)*	*(285)*	*(283)*	*(310)*
NHSC (New mandatory proposal)	—	—	—	—	—	400[c]
Faculty Loan Repayment Program	1	1	1	1	1	1
Training for Diversity[d]	96	95	85	80	81	67
Primary Care Training and Enhancement	237	39	39	37	37	37
PPHF Transfer (non-add)	*(198)*	—	—	—	—	—
Rural Physician Training Grants	—	—	—	—	—	4
Interdisciplinary, Community-Based Linkages[e]	72	72	73	62	72	51
PPHF Transfer (non-add)	—	—	*(12)*	*(2)*	—	—
Public Health Workforce Development	30[f]	30	33	8	18	18
PPHF Transfer (non-add)	*(21)*[f]	*(20)*	*(25)*	—	—	—
Nursing Workforce Development[g]	290	242	231	218	224	224
PPHF Transfer (non-add)	*(47)*	—	—	—	—	—
Children's Hospital GME Payments	317	268	265	251	265	—
GME Targeted Support (New mandatory proposal)	—	—	—	—	—	530[h]
Teaching Health Center GME Payments (ACA Sec.5508(c))	—	230	—	—	—	—
Other Health Workforce Programs[i]	41	41	35	34	37	37
National Practitioner Data Bank (User Fees)	24	24	28	27	27	19
Maternal and Child Health	**984**	**1,128**	**1,208**	**1,193**	**1,220**	**1,346**
Maternal and Child Health Block Grant	661	656	639	605	634	634
Healthy Start	105	104	104	98	101	101

Bureau or Activity	2010	2011	2012	2013	2014	2015 req.
Maternal, Infant Home Visiting (ACA Sec. 2951)	100	250	350	380	371	—
Home Visiting (New mandatory proposal)	—	—	—	—	—	500[i]
Family-to-Family Health Centers (ACA Sec. 5507)[k]	5	5	5	5	3	—
Other Maternal and Child Health Programs[l]	113	113	112	105	110	110
Ryan White HIV/AIDS	**2,315**	**2,337**	**2,392**	**2,249**	**2,319**	**2,323**
Health Care Systems	**267**	**87**	**101**	**95**	**103**	**111**
Health Care Systems Programs[m]	93	87	82	78	86	93
Hansen's Disease Programs	—	—	18	17	17	17
Health Center Infrastructure (ACA Sec. 10502)	100	—	—	—	—	—
State Health Access Grants	74	—	—	—	—	—
Rural Health	**185**	**138**	**138**	**131**	**142**	**125**
Other Activities	**813**	**467**	**460**	**436**	**446**	**451**
Congressional Earmarks	337	—	—	—	—	—
Family Planning	317	299	294	278	286	286
Program Management	147	162	160	151	153	157
Healthy Weight Collaborative (PPHF Transfer)	5	—	—	—	—	—
Vaccine Injury Compensation Program Operations	7	6	6	6	6	8
Total, Program Level	**8,067**	**9,662**	**8,202**	**8,097**	**8,915**	**10,753**
Less Funds From Other Sources						
PHS Evaluation Set-Aside	25	25	25	25	25	87
User Fees	24	24	28	27	27	26
ACA Mandatory Funds: PPHF Transfers	271	20	37	2	—	—
ACA Mandatory Funds: CHCF Transfers	—	1,290	1,495	1,750	2,428	3,910
ACA Mandatory Funds: Other	255	2,035	405	432	374	—
New Mandatory Proposals for FY2015	—	—	—	—	—	1,430
Total, Discretionary Budget Authority	**7,492**	**6,269**	**6,212**	**5,861**	**6,061**	**5,300**

Sources: The funding amounts for FY2010, FY2011, and FY2012 are taken from HRSA's FY2012 and FY2013 congressional budget justification documents. Funding amounts for FY2013, FY2014, and FY2015 are taken from HRSA's FY2015 congressional budget justification. These documents are available at http://www.hhs.gov/budget/.

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

a. Beginning in FY2012, funding for the Hansen's Disease Programs appears under the Health Care Systems budget account.

b. Health Workforce does not include the Home Health Aide Demonstration, which was authorized and funded by ACA Sec. 5507(a). The demonstration received an annual appropriation of $5 million for each of FY2010 through FY2012. [Note: The 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.]

c. The President's FY2015 budget proposed a total of $3.950 billion in new mandatory funds over the period FY2015-FY2020 to support the NHSC, including $400 million in FY2015.

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

e. Interdisciplinary, Community-Based Linkages includes the following programs: Area Health Education Centers (AHEC), Geriatric Programs, and Mental and Behavioral Health Education and Training.

f. Total includes $6 million for State Health Workforce Development grants.

g. 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.

h. The President's FY2015 budget proposed transferring a total of $5.230 billion from the Medicare Part A trust fund over the 10-year period FY2015-FY2024, including $530 million in FY2015, for the new Targeted Support for Graduate Medical Education Program. This program would incorporate the existing Children's Hospital GME program and the Teaching Health Center GME program (created by the ACA).

i. Other Health Workforce Programs include Health Care Workforce Assessment, Oral Health Training, and the Patient Navigator Program (funded through FY2011).

j. As shown in the table, the ACA funded the Maternal, Infant, and Early Childhood Home Visiting Program through FY2014. The President's FY2015 budget proposed a total of $15 billion in new mandatory funds to extend and expand the home visiting program through FY2024, including $500 million for FY2015. The Protecting Access to Medicare Act of 2014 (P.L. 113-93), which was enacted after the FY2015 budget was released, appropriated $400 million for the home visiting program for FY2015.

k. The ACA appropriated $5 million for each of FY2010 through FY2012 for Family-to-Family Health Information Centers. Subsequently, the American Taxpayer Relief Act of 2012 (P.L. 112-240) appropriated $5 million for FY2013, and the Pathway for SGR Reform Act of 2013 (P.L. 113-67, Division B) appropriated $2.5 million for the first half of FY2014. The Protecting Access to Medicare Act of 2014 (P.L. 113-93), which was enacted after the FY2015 budget was released, appropriated $2.5 million for the second half of FY2014 and $2.5 million for the first half of FY2015.

l. 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.

m. Health Care Systems Programs include Organ Transplantation, National Cord Blood Inventory, C.W. Bill Young Cell Transplantation Program, Poison Control Centers, and the 340B Drug Pricing Program.

Indian Health Service (IHS)

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.[68] IHS provides services to members of 566 federally recognized tribes either directly or through facilities and programs operated by Indian Tribes or Tribal Organizations through self-determination contracts and self-governance compacts authorized in the Indian Self-Determination and Education Assistance Act (ISDEAA).[69]

[68] For more information about the Indian Health Service (IHS), see CRS Report R43330, *The Indian Health Service (IHS): An Overview*, by Elayne J. Heisler.

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

The Snyder Act of 1921[70] provides general statutory authority for IHS.[71] In addition, specific IHS programs are authorized by two acts: the Indian Sanitation Facilities Act of 1959[72] and the Indian Health Care Improvement Act (IHCIA).[73] 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, not the Labor-HHS-ED appropriations act. Also, IHS funding is not subject to the PHS Program Evaluation Set-Aside.

FY2010-FY2014 Funding

Program level funding for the IHS increased by $318 million (6.2%) from $5.100 billion in FY2010 to $5.418 billion in FY2012. Funding declined in FY2013 by $111 million (2.1%) to $5.307 billion because of the sequestration of discretionary budget authority, but then increased by $454 million (8.6%) in FY2014 to $5.761 billion. Overall, IHS program level funding increased by $661 million (13%) between FY2010 and FY2014 (see **Table 6**).

The majority of these increases were used to fund additional clinical services, including providing additional funding for purchased/referred care. The purchased/referred care program—formerly the contract health service (CHS) program—purchases essential health services from local and community health care providers when IHS cannot provide medical care and specific services through its own system. In general, funding has not allowed the program to meet all requests, so IHS prioritizes payments based on relative medical need and denies other requests. Decreasing the number of denied requests has been a priority.[74]

The increase in IHS appropriations is also providing additional funding for contract support costs (CSCs). CSC funding goes to tribes to help pay for administering IHS-funded programs under

[70] P.L. 67-85, as amended; 25 U.S.C. §13.

[71] 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 the Department of Health and Human Services).

[72] P.L. 86-121; 42 U.S.C. §2004a.

[73] 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 as part of the ACA. See CRS Report R41630, *The Indian Health Care Improvement Act Reauthorization and Extension as Enacted by the ACA: Detailed Summary and Timeline*, by Elayne J. Heisler.

[74] See U.S. Dept. of Health and Human Services, Indian Health Service, *Fiscal Year 2014 Indian Health Service Justification of Estimates*, p. CJ-142, http://www.ihs.gov/BudgetFormulation/documents/FY2014BudgetJustification.pdf. The Senate Committee on Indian Affairs has also held hearings on this program and noted that IHS should work to reduce the number of denials. See U.S. Congress, Senate Committee on Indian Affairs, *Access to Contract Health Services in Indian Country*, 110th Cong., 2nd sess., June 26, 2008, S.Hrg.110-519 (Washington: GPO, 2008). GAO has also released reports on the CHS program. See, for example, GAO-13-272, *Indian Health Service: Capping Payments for Nonhospital Services Could Save Millions of Dollars for Contract Health Services*, 13-272, April 11, 2013, http://www.gao.gov/products/GAO-13-272.

self-determination contracts or self-governance compacts authorized by ISDEAA.[75] CSC funding pays for the costs that tribes incur for such items as financial management, accounting, training, and program start-up. Shortfalls in funding for the CSC program have resulted in reduced services or decreased administrative efficiency for tribes with contracts and compacts.[76] A 2012 Supreme Court decision in *Salazar v. Ramah Navajo*[77] found that a lack of sufficient appropriations does not release the federal government from its obligation to provide adequate contract support costs.[78] IHS works with Indian Tribes and Tribal Organizations to allocate the CSC increase, to determine appropriate CSC levels in future years, and to balance CSC priorities with any offsets in funding for direct health care services for IHS beneficiaries.

The IHS's FY2013 appropriation initially was above the FY2012 level. But the FY2013 sequestration reduced that appropriation to an amount that was $175 million (4.1%) below the FY2012 appropriation (see **Table 6**). This decrease was not expected because the BBEDCA sequestration rules include a 2% limit on cuts to IHS.[79] However, as noted earlier in this report, OMB determined that the 2% limit applied only to IHS's mandatory (i.e., diabetes) funding; the agency's discretionary appropriation was fully sequestrable, resulting in a 5% reduction (see **Table 1**).[80] Although IHS collected more in reimbursements in FY2013 than it did in FY2012—an additional $67 million—the increase in those funds, which are exempt from sequestration, was not sufficient to offset the amount reduced by the sequestration (see **Table 6**).

The FY2014 IHS budget increased funding for IHS above both the FY2013 and FY2012 operating levels. Specifically, it continued funding increases in clinical services—mainly allocated to increase funding for purchased/referred care—and CSCs. IHS also expects that the trend of increasing third-party collections will continue. As a result of the ACA's implementation, the IHS is expecting increased reimbursements from Medicare, Medicaid, CHIP, and other third-party insurers for services provided at IHS-funded facilities. Specifically, IHS is expecting that collections will increase by approximately $151 million because additional IHS beneficiaries will be eligible for Medicaid[81] and because some will enroll in private insurance offered through the exchanges established by the ACA.[82] IHS also is projecting increased collections from the VA. It estimates that it will receive $36 million from the VA in FY2014.

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[75] 25 U.S.C. §§450 et seq.

[76] See GAO, *Indian Self-Determination Act: Shortfalls in Indian Contract Support Costs Need to Be Addressed*, GAO/RCED-99-150, June 1999, http://www.gao.gov/archive/1999/rc99150.pdf.

[77] *Salazar v. Ramah Navajo*, No. 11-551, slip op. (June 18, 2012), available at http://www.supremecourt.gov/opinions/11pdf/11-551.pdf.

[78] CRS Report WSLG119, *Supreme Court Holds the Government Liable for Contract Support Costs in Indian Self-Determination Contracts Even When Congress Fails to Appropriate Adequate Funds*, by Jane M. Smith.

[79] Rob Carpiccioso, "A Miscalculation on the Sequester Has Already Harmed Indian Health," *Indian Country*, March 11, 2013, http://indiancountrytodaymedianetwork.com/2013/03/11/miscalculation-sequester-has-already-harmed-indian-health-148110.

[80] See CRS Report R42050, *Budget "Sequestration" and Selected Program Exemptions and Special Rules*, coordinated by Karen Spar.

[81] This would only occur in states where the Medicaid program is expanded. See CRS Report R41210, *Medicaid and the State Children's Health Insurance Program (CHIP) Provisions in ACA: Summary and Timeline*, by Evelyne P. Baumrucker et al.

[82] IHS beneficiaries are exempt from the ACA requirement to have insurance coverage; however, ACA included provisions that would make it easier for IHS beneficiaries who choose to participate in a health insurance plan through the exchanges. Specifically, IHS beneficiaries have a special enrollment period for health insurance plans offered through the exchanges and, if their incomes are not more than 300% of the federal poverty level, are exempt from cost-

(continued...)

FY2015 President's Budget Request

The FY2015 President's Budget would increase the IHS's program level funding by $228 million (4.0%) from $5.761 billion to $5.989 billion (see **Table 6**). This is primarily due to the agency's request for more appropriations. But is also reflects continued growth in third-party collections. The agency's discretionary budget authority would increase by $199 million (4.6%) to $4.634 billion from the FY2014 level of $4.435 billion. The additional funds would be mainly used to increase funding for clinical services, including purchased/referred care. Additional funds also would be allocated for preventive health services, CSCs, and for staffing and operations at newly constructed IHS facilities.

Under the President's Opportunity, Growth, and Security Initiative,[83] IHS would receive an additional $200 million for construction projects. These amounts are not included in **Table 6**.

Table 6. Indian Health Service (IHS)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015 req.
Clinical and Preventive Services	**4,139**	**4,171**	**4,335**	**4,277**	**4,566**	**4,746**
Clinical Services	3,845[a]	3,877[b]	4,038[c]	3,987[d]	4,271[e]	4,440[f]
Purchased/Referred Care (non-add)[g]	*(779)*	*(780)*	*(844)*	*(801)*	*(879)*	*(929)*
Preventive Health	144	144	147	143	148	156
Special Diabetes Program for Indians[h]	150	150	150	147	147	150
Other Health Services	**560**	**559**	**636**	**603**	**735**	**772**
Urban Health Projects	43	43	43	41	41	41
Indian Health Professions	41	41	41	38	33	38
Tribal Management/Self-Governance	9	9	9	8	6	8
Direct Operations	69	69	72	68	68	68
Contract Support Costs	398	398	471	448	587	617
Health Facilities	**401**	**411**	**448**	**427**	**460**	**470**
Maintenance and Improvement	60[i]	60[i]	61[i]	59[i]	62[k]	62[k]
Sanitation Facilities Construction	96	96	80	75	79	79
Health Care Facilities Construction	29	39	85	77	85	85
Facilities/Environmental Health Support	193	193	199	194	211	221

(...continued)

sharing when enrolled in a plan offered through an exchange. In addition, IHS beneficiaries, like the general population, are eligible for income-determined subsidies to purchase insurance. See CRS Report R41152, *Indian Health Care: Impact of the Affordable Care Act (ACA)*, by Elayne J. Heisler.

[83] This $56 billion discretionary spending initiative, split evenly between defense and nondefense spending, was proposed in the President's FY2015 Budget. It would provide additional funding in, and investments for, a broad range of programs designed to spur economic growth and strengthen national security. The cost would be offset by a mix of spending and tax reforms. For more information, see http://www.whitehouse.gov/omb/budget.

Program or Activity	2010	2011	2012	2013	2014	2015 req.
Medical Equipment	23	23	23	21	23	23
Total, Program Level	**5,100**	**5,140**	**5,418**	**5,307**	**5,761**	**5,989**
Less Funds from Other Sources						
Collections	891	915	954	1,021	1,172	1,197
Rental of Staff Quarters	6	6	8	8	8	8
Special Diabetes Program for Indians[h]	150	150	150	147	147	150
Total, Discretionary Budget Authority	**4,052**	**4,069**	**4,306**	**4,131**	**4,435**	**4,634**

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. 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 $1,172 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.

f. Includes an estimated $1,197 million in collections from Medicare, Medicaid, CHIP, the Department of Veterans Affairs, private insurance, and other programs.

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

h. PHSA Sec. 330C provides an annual appropriation of $150 million through FY2015 for this program. These mandatory funds are subject to a 2% sequestration.

i. Includes $6 million that IHS received from rental of staff quarters.

j. Includes $8 million that IHS received from rental of staff quarters.

k. Includes $8 million that IHS estimates the agency will receive from rental of staff quarters.

National Institutes of Health (NIH)

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.[84] 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.

As shown in **Table 7**, the annual Labor-HHS-ED appropriations act provides separate appropriations to 24 of the ICs, the OD, and the Buildings and Facilities account. NIH receives additional funds from the Interior/Environment appropriations act and from a mandatory appropriation for type 1 diabetes research.

FY2010-FY2014 Funding

In program level funding, the FY2010 total of $31.243 billion for NIH was higher than funding in each of the four following years (see **Table 7**). Program level funding declined by $317 million (1.0%) from FY2010 to FY2011 and further decreased by $66 million (0.2%) to $30.860 billion in FY2012. As a result of the FY2013 sequestration of discretionary funding and other adjustments, NIH's program level funding for that fiscal year was $1.709 billion (5.5%) below FY2012.[85] The Consolidated Appropriations Act, 2014, (P.L. 113-76) provided NIH with a program level total of $30.150, a $1 billion increase over the FY2013 post-sequestration level but still almost $1 billion below the FY2010 program level.

The ICs have shared about equally in the increases and decreases each year. A few programs that were moved in the NCATS/NCRR reorganization have received additional emphasis, and an HHS initiative on Alzheimer's disease research has brought additional funding to the National Institute

[84] 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.

[85] The FY2010 and FY2011 appropriations included about $300 million each that did not remain with NIH. Funds for the U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis, and Malaria were appropriated to NIH (in the account for NIAID, the National Institute of Allergy and Infectious Diseases) but were then transferred to non-HHS agencies that manage overseas assistance programs. Since FY2012 Congress has appropriated Global Fund money directly to the relevant agencies.

on Aging (NIA). In FY2013, the initial enacted appropriation gave NIH a slight increase over FY2012 by adding funding for the OD. The FY2013 sequestration, however, reduced each NIH account by about 5%, and an HHS transfer under the Secretary's authority resulted in a further reduction of $173 million (about 0.55% from each IC and a larger amount from OD).

The main funding mechanism for supporting extramural research is research project grants (RPGs), which are competitive, peer-reviewed, and largely investigator-initiated. In FY2013, NIH supported a total of 34,840 RPGs, including 8,234 in the "new and competing awards" category. In FY2014, NIH expects to support 34,213 RPGs, including 8,997 competing awards.[86]

FY2015 President's Budget Request[87]

The FY2015 President's Budget requested a program level total of $30.362 billion for NIH, $211 million (0.7%) more than the comparable FY2014 amount of $30.151 billion (see **Table 7**). In FY2015 NIH estimates that it will be able to support 34,197 RPGs, including 9,326 new and competing awards. Most of the institutes and ICs would receive essentially level funding in the request compared to FY2014 with very few exceptions such as a $50 million (9%) increase for the Common Fund and a $25 million (4%) increase for NCATS. The Common Fund supports research in emerging areas of scientific opportunity, public health challenges, or knowledge gaps that might benefit from collaboration between two or more institutes or centers.

Under the President's Opportunity, Growth, and Security Initiative,[88] NIH would receive an additional $970 million, increasing the NIH budget to a total program level of $31.3 billion in FY2015 (these amounts are not reflected in **Table 7**). The additional funds would provide support for 650 new grants in FY2015 as well as added resources for certain specific topic areas, such as the multi-agency Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative, sharing and analysis of complex data sets, and Alzheimer's disease research and vaccine development.[89]

[86] U.S. Department of Health and Human Services, *FY2015 Budget in Brief*, March 4, 2014, p. 43, http://www.hhs.gov/budget/fy2015/fy-2015-budget-in-brief.pdf.

[87] For additional details, see the NIH section of CRS Report R43086, *Federal Research and Development Funding: FY2014*, coordinated by John F. Sargent Jr.

[88] This $56 billion discretionary spending initiative, split evenly between defense and nondefense spending, was proposed in the President's FY2015 Budget. It would provide additional funding in, and investments for, a broad range of programs designed to spur economic growth and strengthen national security. The cost would be offset by a mix of spending and tax reforms. For more information, see http://www.whitehouse.gov/omb/budget.

[89] For further background on NIH, see CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Judith A. Johnson, and for current funding information, see the NIH section of CRS Report R43086, *Federal Research and Development Funding: FY2014*, coordinated by John F. Sargent Jr.

Table 7. National Institutes of Health (NIH)

(Millions of Dollars, by Fiscal Year)

Institutes and Centers (ICs)	2010[a]	2011[b]	2012[c]	2013	2014	2015 req.
Cancer (NCI)	5,098	5,059	5,067	4,783	4,923	4,931
Heart/Lung/Blood (NHLBI)	3,094	3,070	3,076	2,900	2,983	2,988
Dental/Craniofacial Research (NIDCR)	413	410	410	387	397	397
Diabetes/Digestive/Kidney (NIDDK)[d]	1,959	1,942	1,945	1,835	1,881	1,893
Neurological Disorders/Stroke (NINDS)	1,634	1,622	1,625	1,532	1,586	1,608
Allergy/Infectious Diseases (NIAID)[e]	4,815	4,776	4,486	4,230	4,393	4,423
General Medical Sciences (NIGMS)	2,048	2,034	2,428	2,291	2,362	2,369
Child Health/Human Development (NICHD)	1,327	1,318	1,320	1,245	1,281	1,283
Eye (NEI)	706	701	702	656	674	675
Environmental Health Sciences (NIEHS)	695	684	685	646	665	665
NIEHS, Interior/Environment[f]	79	79	79	75	77	77
Aging (NIA)	1,108	1,100	1,121	1,039	1,169	1,171
Arthritis/Musculoskeletal/Skin (NIAMS)	538	534	535	505	519	520
Deafness/Communication Disorders (NIDCD)	418	415	416	392	403	404
Mental Health (NIMH)	1,494	1,477	1,479	1,394	1,417	1,440
Drug Abuse (NIDA)	1,067	1,051	1,052	992	1,016	1,023
Alcohol Abuse/Alcoholism (NIAAA)	462	458	459	433	445	446
Nursing Research (NINR)	145	144	145	136	140	140
Human Genome Research (NHGRI)	524	511	513	483	497	498
Biomedical Imaging/Bioengineering (NIBIB)	316	314	338	319	326	329
Minority Health/Health Disparities (NIMHD)	211	210	276	260	268	268
Complementary/Alternative Med (NCCAM)	129	128	128	121	124	125
[former] Ctr for Research Resources (NCRR)	1,267	1,258	—	—	—	—
Advancing Translational Sciences (NCATS)	—	—	575	542	632	657
Fogarty International Center (FIC)	70	69	70	66	67	68
National Library of Medicine (NLM)[g]	349	345	346	360	375	381
Office of Director (OD)	1,177	1,167	1,459	1,411	1,400	1,452
Buildings & Facilities (B&F)	100	50	125	118	129	129
Total, Program Level	**31,243**	**30,926**	**30,860**	**29,151**	**30,151**	**30,362**
Less Funds From Other Sources						
PHS Evaluation Set-Aside (NLM)	8	8	8	8	8	8
Type 1 Diabetes Research (NIDDK)[d]	150	150	150	142	139	150
Total, Discretionary Budget Authority	**31,084**	**30,767**	**30,702**	**29,001**	**30,003**	**30,203**

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, FY2014 and FY2015 are from the FY2015 HHS Budget in Brief, http://www.hhs.gov/budget/fy2015/fy-2015-budget-in-brief.pdf.

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.

a. 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).

b. FY2011 reflects real transfer of almost $1 million from HHS Office of the Secretary to NIMH for the Interagency Autism Coordinating Committee.

c. 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.

d. NIDDK program level includes mandatory funds for type 1 diabetes research appropriated in PHSA Sec. 330B (provided by P.L. 110-275, P.L. 111-309, and P.L. 112-240). Funds have been appropriated through FY2014 and are proposed for reauthorization in FY2015. The FY2013 and FY2014 amounts are post-sequestration levels.

e. 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); see report footnote 85. FY2010 amount includes BioShield transfer of $304 million; for more information, see CRS Report R43607, *The Project BioShield Act: Issues for the 113th Congress*, by Frank Gottron.

f. This is a separate account in the Interior/Environment appropriations act for NIEHS research activities related to Superfund.

g. NLM program level includes $8 million in set-aside funds each year.

Substance Abuse and Mental Health Services Administration (SAMHSA)

Agency Overview

SAMHSA is the lead federal agency for increasing access to behavioral health services.[90] 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 numerous competitive grant programs that fund states, territories, tribal organizations, local communities, and private entities. Under SAMHSA' s charitable choice provisions, religious organizations are eligible to receive funding in order to provide substance abuse services without altering their religious character. The agency also collects information on the incidence and prevalence of mental illness and substance abuse at the national and state levels.

SAMHSA and most of its programs and activities are authorized under Title V of the PHSA. However, the agency's two largest programs, the Substance Abuse Prevention and Treatment (SAPT) block grant and the Community Mental Health Services (CMHS) block grant, which together accounted for 63.5% of SAMHSA's program-level funding in FY2014, are separately authorized under PHSA Title XIX, Part B.

[90] Unless otherwise noted, information in this section is summarized from CRS Report R41477, *Substance Abuse and Mental Health Services Administration (SAMHSA): Agency Overview and Reauthorization Issues*, by C. Stephen Redhead.

Under PHSA Title V, SAMHSA is organized into three centers: the Center for Mental Health Services (CMHS), the Center for Substance Abuse Treatment (CSAT), and the Center for Substance Abuse Prevention (CSAP). 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. PRNS authorizes each center to fund projects that (1) translate promising new research findings to community-based prevention and treatment services; (2) provide training and technical assistance; and (3) target resources to increase service capacity where it is most needed. In addition, PHSA Title V authorizes a number of specific grant programs, referred to as categorical grants. The PHSA also directs SAMHSA to conduct data collection and analysis activities related to mental health and substance abuse. The agency administers the National Survey on Drug Use and Health (an annual survey that collects information about substance use and related health topics) and publishes analyses of the survey data.

Most SAMHSA programs are administered by one of the three centers and focus on mental health, substance abuse treatment, or substance abuse prevention. Some programs receive support from more than one center. For example, CMHS and CSAT both support SAMHSA's Behavioral Health Treatment Court Collaboratives. Additional activities that fall outside the three centers (e.g., collecting information on the incidence and prevalence of mental illness and substance abuse) are categorized under Health Surveillance and Program Support.

Congress has not taken up comprehensive legislation to reauthorize SAMHSA since 2000, when the agency and its programs were last reauthorized as part of the Children's Health Act.[91] However, Congress has added some new authorities to Title V and otherwise expanded a few SAMHSA programs and activities in the past decade. 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.

FY2010-FY2014 Funding

From FY2010 through FY2014, SAMHSA's program-level funding increased slightly from $3.583 billion to $3.631 billion, an increase of $48 million (1.3%). SAMHSA's discretionary budget authority, excluding set-aside funds and PPHF transfers, was virtually unchanged over that period, increasing by just $4 million (0.1%) from $3.431 billion to $3.435 billion (see **Table 8**). The agency's discretionary appropriations declined each year—reaching a low point in FY2013 as a result of sequestration—before rebounding in FY2014 primarily as a result of increased funding for mental health and the SAPT block grant.

In the Consolidated Appropriations Act, 2012 and the accompanying conference report,[92] Congress rejected changes SAMHSA proposed to its budget structure in the FY2012 budget request. Among other proposed changes, the FY2012 budget request would have combined most of the existing PRNS activities and programs in the three centers into a single account for Innovation and Emerging Issues. Congress directed that future budget requests reflect the structure of the three centers, as well as an account labeled Health Surveillance and Program Support to fund "program support and cross-cutting activities that supplement activities funded

[91] P.L. 106-310, Titles XXXI-XXXIV, 114 Stat. 1168.

[92] P.L. 112-74, Division F, Title II, 125 Stat. 1073; H.Rept. 112-331, pp. 1139-1142.

under [the three centers, and] ... to carry out national surveys on drug abuse and mental health, to collect and analyze program data, and to conduct public awareness and technical assistance activities."[93] SAMHSA's FY2013 and FY2014 budget requests reflected the structure requested by Congress in P.L. 112-74.

FY2015 President's Budget Request

The FY2015 request provides SAMHSA with $3,298 million in discretionary budget authority, which is $137 million (4.0%) below the FY2014 amount of $3,435 million (see **Table 8**). The request provides level funding for the mental health and SAPT block grants and other formula grants, but reduces funding for PRNS activities and programs in the three centers. Those reductions in discretionary budget authority are partially offset by an increase in set-aside funds. Overall, the FY2015 request gives SAMHSA a program level total of $3,568 million, which is $63 million (1.7%) below the FY2014 amount.

Table 8. Substance Abuse and Mental Health Services Administration (SAMHSA)

(Millions of Dollars, by Fiscal Year)

Program or Activity	2010	2011	2012	2013	2014	2015 req.
Center for Mental Health Services (CMHS)	**1,005**	**1,022**	**994**	**910**	**1,080**	**1,057**
Mental Health Block Grant	421	420	460	437	484	484
PHS Evaluation Set-Aside (non-add)	*(21)*	*(21)*	*(21)*	*(21)*	*(21)*	*(21)*
Programs of Regional & National Significance	361	384	316	267	378	355
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	*(5)*
PPHF Transfer (non-add)	*(20)*	*(45)*	*(45)*	—	*(12)*	*(38)*
Children's Mental Health Services	121	118	117	111	117	117
PATH Homeless Formula Grant	65	65	65	61	65	65
Protection & Advocacy Formula Grant	36	36	36	34	36	36
Center for Substance Abuse Treatment	**2,253**	**2,214**	**2,229**	**2,114**	**2,181**	**2,117**
Substance Abuse Block Grant	1,799	1,783	1,800	1,710	1,820	1,820
PHS Evaluation Set-Aside (non-add)	*(79)*	*(79)*	*(79)*	*(79)*	*(79)*	*(79)*
Programs of Regional & National Significance	452	431	429	404	361	297
PHS Evaluation Set-Aside (non-add)	*(9)*	*(2)*	*(2)*	*(2)*	*(2)*	*(30)*
PPHF Transfer (non-add)	—	*(25)*	*(29)*	—	*(50)*	—
Prescription Drug Monitoring (NASPER)[a]	2	—	—	—	—	—
Center for Substance Abuse Prevention	**202**	**186**	**186**	**176**	**176**	**186**
Programs of Regional & National Significance	202	186	186	176	176	186
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	*(16)*
Health Surveillance and Program Support	**102**	**177**	**160**	**154**	**194**	**208**
Health Surveillance and Program Support	102	171	124	123	120	122
PHS Evaluation Set-Aside (non-add)	*(23)*	*(29)*	*(27)*	*(27)*	*(30)*	*(29)*
PPHF Transfer (non-add)	—	*(18)*	*(18)*	*(15)*	—	*(20)*

[93] P.L. 112-74; 125 Stat. 1074.

Program or Activity	2010	2011	2012	2013	2014	2015 req.
Public Awareness and Support	—	—	14	14	14	16
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	*(16)*
Performance & Quality Information Systems	—	—	13	9	13	13
PHS Evaluation Funds (non-add)	—	—	—	—	—	*(13)*
Agency-Wide Initiatives	—	5	9	8	46	56
PHS Evaluation Set-Aside (non-add)	—	—	—	—	—	*(1)*
Data Request and Publications User Fees[b]	—	—	—	—	2	2
St. Elizabeths Hospital[c]	1	—	—	—	—	—
Total, Program Level	**3,583**	**3,599**	**3,569**	**3,354**	**3,631**	**3,568**
Less Funds From Other Sources						
PHS Evaluation Set-Aside	132	132	130	130	133	211
PPHF Transfers	20	88	92	15	62	58
Data Request and Publications User Fees	—	—	—	—	2	2
Total, Discretionary Budget Authority	**3,431**	**3,380**	**3,347**	**3,210**	**3,435**	**3,298**

Sources: The funding amounts for FY2010 are taken from SAMHSA's FY2011 operating plan and FY2012 congressional budget justification document. The amounts for FY2011 are taken from the FY2013 HHS Budget in Brief. The amounts for FY2012 are taken from SAMHSA's FY2013 operating plan. The amounts for FY2013, FY2014 and the FY2015 request are taken from the agency's FY2015 congressional budget justification documents. These documents are 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 Kristin Finklea, Lisa N. Sacco, and Erin Bagalman.

b. SAMHSA has received authority to collect Data Request and Publications User Fees for extraordinary requests that SAMHSA would not otherwise be able to fulfill using existing resources.

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).[94] Generally, the discretionary funds appropriated under ARRA were intended to be time-limited. 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.[95]

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.

[94] 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 Clinton T. Brass et al.

[95] 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. As briefly discussed earlier in the report, OMB determined that sequestration of CHCF funding for community health centers and migrant health centers is capped at 2%. 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 1**).

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 earlier discussion in the HRSA section of the report).

Table B-1. Community Health Center Fund, FY2011-FY2015

(Millions of Dollars, by Fiscal Year)

Program	2011	2012	2013	2014	2015	Total
Health Center Program	1,000	1,200	1,500	2,200	3,600	9,500
Post-sequestration (non-add)			*(1,465)*	*(2,145)*	*TBD*[a]	
National Health Service Corps	290	295	300	305	310	1,500
Post-sequestration (non-add)			*(285)*	*(283)*	*(287)*	
Total	**1,290**	**1,495**	**1,800**	**2,505**	**3,910**	**11,000**

Source: Prepared by CRS based on ACA Section 10503 and the HHS *FY2015 Budget in Brief*, available at http://www.hhs.gov/budget/.

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

a. The post-sequestration amount of FY2015 CHCF funding for health centers will depend on the specific allocation of funds to the various types of health centers.

Appendix C. Prevention and Public Health Fund (PPHF)

Authority and Funding Allocation

ACA Section 4002 established the Prevention and Public Health Fund (PPHF), administered by the HHS Secretary, and provided it with a permanent annual appropriation. Under the law, PPHF's annual appropriation increases from $500 million in FY2010 to $2 billion in FY2015 and in each fiscal year thereafter. However, the Middle Class Tax Relief and Job Creation Act of 2012[96] 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. The PPHF annual appropriation is now $1 billion through FY2017 and will increase to $2 billion in FY2022 and in 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 funds, Congress explicitly directed the Secretary to distribute PPHF funds according to the FY2014 Consolidated Appropriation.[97]

As discussed earlier in the report, the PPHF appropriation is fully sequestrable at the applicable percentage rate for nonexempt nondefense mandatory spending (see **Table 1**). 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 FY2015 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.[98]

Scope of PPHF-Funded Activities

The terms "prevention," "wellness," and "public health activities," which describe allowable PPHF-funded activities, are not defined in the PHSA, ACA, or elsewhere in federal law. ACA was not accompanied by committee reports in either chamber. Finally, HHS has not published regulations, guidance, or other information to clarify the department's views about the types of activities that are within scope for PPHF funding.[99]

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[96] P.L. 112-96, Section 3205, 126 Stat. 194.

[97] "Explanatory Statement Submitted by Mr. Rogers of Kentucky ... Regarding ... H.R. 3547, Consolidated Appropriations Act, 2014," *Congressional Record*, vol. 160, part 9 (January 15, 2014), pp. H-1041-H1042.

[98] 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 Angela Napili and Kirsten J. Colello.

[99] For more information about federal prevention activities and how they may be defined, see Government Accountability Office, *Available Information on Federal Spending, Cost Savings, and International Comparisons Has Limitations*, GAO-13-49, December 6, 2012, http://gao.gov/products/GAO-13-49.

HHS published an annual report to Congress on PPHF spending for FY2012, as required by law.[100] The report notes spending (typically through grants or contracts) on the following types of activities, among others: (1) *community prevention activities* to improve health and reduce chronic disease risk factors, to reduce tobacco use, and to improve fitness and reduce obesity; (2) *clinical prevention activities* to improve access to important preventive services and definitive care for a variety of health needs; (3) *behavioral health* screening and integration with primary care; (4) *public health infrastructure*, workforce, and training; and (5) *public health research* and data collection. As shown in **Table C-1**, more than two-thirds of PPHF funds have been distributed to CDC.

Table C-1. PPHF Transfers to HHS Agencies

(Millions of Dollars, by Fiscal Year)

Agency	2010	2011	2012	2013	2014	2015 Proposal[a]	Agency Total 2010-2014	Agency Total (%) 2010-2014
ACL	0	0	20	9	28	28	57	1.3
AHRQ	6	12	12	7	7	0	43	1.0
CDC	192	611	809	463	831	810	2,906	68.4
CMS	0	0	0	454[b]	0	0	454[b]	10.7
HRSA	271	20	37	2	0	0	330	7.8
OS	12	19	30	0	0	105	61	1.4
SAMHSA	20	88	92	15	62	58	277	6.5
Sequestered	—	—	—	51	72	—	—	—
Total	**500**	**750**	**1,000**	**1,000**	**1,000**	**1,000**	**4,250**	**100**

Sources: Prepared by Congressional Research Service based on HHS agency congressional budget justifications for FY2012 through FY2015, 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 7.3% sequestration (i.e., $73 million) for FY2015 required under current law; see **Table 1**.

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

Relationship to Annual Appropriations

In some cases, the Secretary has used, or proposed to use, PPHF funds to augment funds from annual discretionary appropriations. For example, for FY2013, the Administration proposed using the PPHF to fund almost the entire budget of the CDC Center on Birth Defects and Developmental Disabilities.[101] If PPHF funds were to become unavailable, appropriators would

[100] HHS, "The Affordable Care Act and the Prevention and Public Health Fund: Report to Congress for FY2012," undated, http://www.hhs.gov/open/recordsandreports/prevention/fy2012_aca_rpt_to_congress.pdf.

[101] CDC, *Justification of Estimates for Congressional Committees*, FY2013, February, 2012, p. 153, http://www.cdc.gov/fmo.

face a need to provide additional regular appropriations in order to sustain programmatic activities.[102]

Recent funding trends for the CDC Chronic Disease Prevention and Health Promotion account illustrate this point. This account has received sizeable PPHF distributions since funds first became available for FY2010. As shown in **Figure C-1**, budget authority for the account has decreased from its highest level in FY2009, before PPHF funds were available. However, the program level increased from FY2010 through FY2012, due to the increasing transfers of PPHF funds. The program level then decreased for FY2013, in part due to the decrease in budget authority (BA) as a result of rescission and sequestration, but in larger part to the reduced PPHF amount that resulted from a large PPHF transfer to CMS for ACA implementation, as shown in **Table C-1**.[103] Ultimately, the CMS transfer and its effect on the PPHF transfer to CDC had a greater effect on the FY2013 operating budget for CDC Chronic Disease Prevention and Health Promotion activities than did sequestration.[104] In directing the allocation of FY2014 PPHF funds, Congress in most cases provided PPHF funds to pre-existing programs and activities rather than to programs and activities newly authorized under ACA.

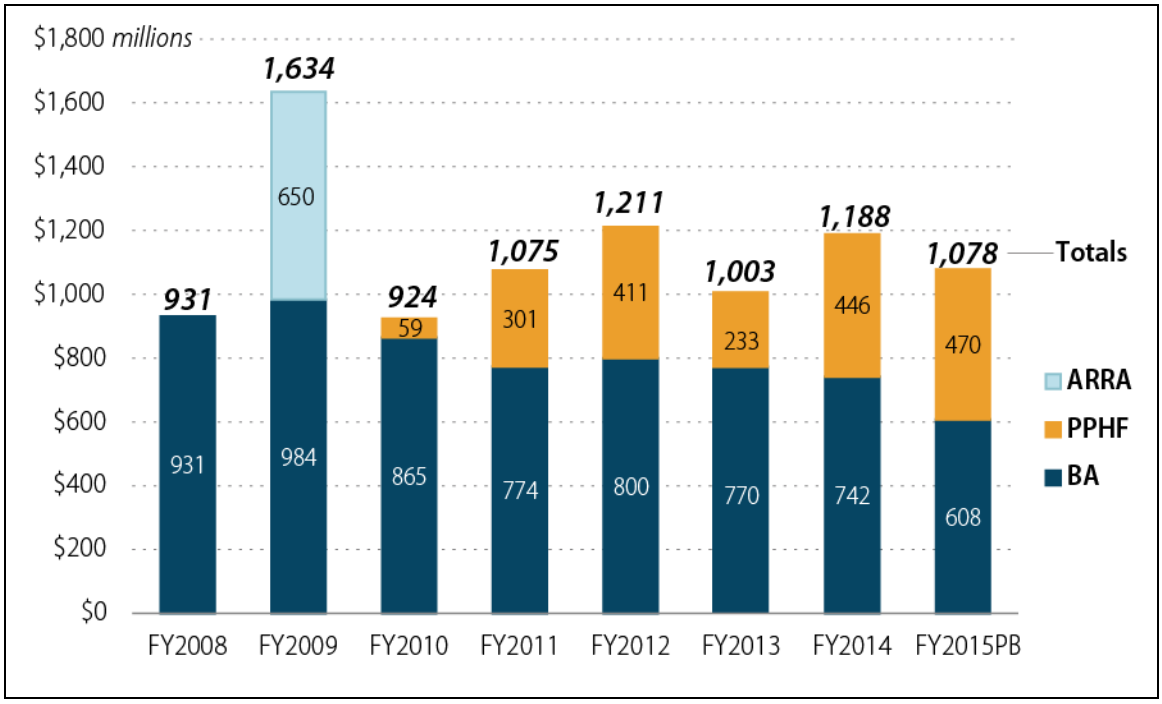
[102] John Reichard, "Advocates: CDC, Other Agencies Face Big Cuts Fast if Prevention Fund Ends," *CQ HealthBeat*, June 18, 2012.

[103] Rachana Dixit, "HHS Sets Aside $454 Million in Prevention Funds for Insurance Enrollment Support," *InsideHealthPolicy*, April 16, 2013.

[104] 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.

Figure C-1. Funding for CDC Chronic Disease Prevention and Health Promotion, FY2008-FY2015

Dollars in millions



Source: Prepared by Congressional Research Service from CDC, *Justification of Estimates for Congressional Committees*, FY2013, p. 120; FY2014, p. 138; and FY2015, p. 129, all at http://www.cdc.gov/fmo.

Notes: ARRA is the American Recovery and Reinvestment Act of 2009 (see **Appendix A**). PPHF is the ACA Prevention and Public Health Fund. BA is discretionary budget authority. PB is President's budget. FY2012, FY2013, FY2014, and FY2015 amounts have been made comparable to reflect a planned budget realignment for the CDC Working Capital Fund. These amounts are not strictly comparable to amounts for earlier fiscal years. Amounts for FY2013 and FY2014 reflect sequestration, which affected both BA and PPHF funds for FY2013, and PPHF funds for FY2014.

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).[105] 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.[106] Of the total amount transferred to HHS, 80% is to be distributed to AHRQ. **Table D-1** shows the allocation of PCORTF funds through FY2015.

Table D-1. Distribution of PCORTF Funding

(Millions of Dollars, by Fiscal Year)

Funding Recipient	2010	2011	2012	2013	2014 est.	2015 est.
PCORI	10	40	120	289	543	528
HHS	—	10	30	72	136	132
AHRQ (non-add)	—	*(8)*	*(24)*	*(58)*	*(109)*	*(106)*
Office of the Secretary (non-add)	—	*(2)*	*(6)*	*(14)*	*(27)*	*(26)*
Total	**10**	**50**	**150**	**361**	**679**	**660**

Source: CRS calculations using data provided in Office of Management and Budget, *Fiscal Year 2015, Appendix, Budget of the U.S. Government, p. 1358.*

[105] 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.

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

Appendix E. FDA User Fee Authorizations

Table E-1. FDA User Fee Authorizations and Revenue

(Dollars in Millions, In Order of FY2014 Anticipated Revenue)

User Fee	Initial Authorizing Legislation and Year	FY2014 Revenue
Prescription drug	Prescription Drug User Fee Act (PDUFA), 1992 (P.L. 102-300)	760
Tobacco product	Family Smoking Prevention and Tobacco Control Act, 2009 (P.L. 111-31)	534
Generic drug	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	306
Medical device	Medical Device User Fee and Modernization Act (MDUFMA), 2002 (P.L. 107-250)	115
Animal drug	Animal Drug User Fee Act (ADUFA), 2003 (P.L. 108-130)	24
Biosimilars	Food and Drug Administration Safety and Innovation Act (FDASIA), 2012 (P.L. 112-144)	21
Mammography	Mammography Quality Standards Act (MQSA), 1992 (P.L. 102-539)	19
Food reinspection	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	15
Food recall	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	13
Color certification	Color Additive Amendments of 1960 (P.L. 86-618)	7
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA), 2008 (P.L. 110-316)	7
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
Priority review with voucher[a]	Food and Drug Administration Amendments Act (FDAAA), 2007 (P.L. 110-85)	0
Voluntary qualified importer (VQIP)[b]	Food Safety Modernization Act (FSMA), 2011 (P.L. 111-353)	0
Total		**1,826**

Source: Prepared by CRS.

a. The appropriations act for FY2009 was the first to authorize priority review user fees to be assessed when a sponsor submitted an application using a priority review voucher that FDA had issued after it approved an New Drug Application (from the same or another sponsor) for a tropical disease. Congress added a second opportunity for a priority review voucher in return for an approved NDA for a rare pediatric disease. FDA collected a priority review fee only once, in 2012.

b. No appropriations have yet been authorized for VQIP.

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