

An hourglass-shaped graphic with a globe inside. The top bulb is dark blue, and the bottom bulb is light blue. The globe is a darker shade of blue. The hourglass is centered on the page.

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*Public Health Service (PHS) Agencies: Background and  
Funding*

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March 26, 2008

**Abstract.** Funding for the PHS agencies is provided through three different appropriations acts. Total discretionary appropriations to these agencies for FY2008 totaled \$50.6 billion. For each of the PHS agencies, this report describes the mission, organization, key programs, history, and legislative authorities, and provides budget tables for FY2007 through the FY2009 request.

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# Public Health Service (PHS) Agencies: Background and Funding

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## Summary

The U.S. Public Health Service (PHS) originated in an act of July 16, 1798, that authorized marine hospitals for the care of American merchant seamen. Over the years, the scope and responsibilities of the act and the service have broadened. The Public Health Service Act of July 1, 1944, revised and consolidated into one law all legislation existing at that time relating to programs and activities of the PHS. The act, codified at 42 U.S.C. § 201 et seq., has been amended and extended nearly every year since 1944 and currently includes 29 titles.

The PHS Act is administered by the Department of Health and Human Services (HHS) through eight operating agencies. Those agencies are

- the Agency for Healthcare Research and Quality (AHRQ),
- the Agency for Toxic Substances and Disease Registry (ATSDR),
- the Centers for Disease Control and Prevention (CDC),
- the Food and Drug Administration (FDA),
- the Health Resources and Services Administration (HRSA),
- the Indian Health Service (IHS),
- the National Institutes of Health (NIH), and
- the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Agency for Toxic Substances and Disease Registry is administered by the Director of the CDC, and the two agencies are discussed together in this report. Together, the PHS agencies administer more than 300 programs that cover a wide spectrum of health-related activities.

Funding for the PHS agencies is provided through three different appropriations acts. Total discretionary appropriations to these agencies for FY2008 totaled \$50.6 billion.

For each of the PHS agencies, this report describes the mission, organization, key programs, history, and legislative authorities, and provides budget tables for FY2007 through the FY2009 request. It will be updated as legislative and other events warrant.

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## Overview and History of the Public Health Service

The Public Health Service Act (PHS Act) authorizes programs for the conduct, support, and coordination of “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams.”<sup>1</sup> The Department of Health and Human Services (HHS) is the executive branch department responsible for carrying out the provisions of the PHS Act.

The Public Health Service originated in an act of July 16, 1798. That act authorized marine hospitals to care for American merchant seamen. Over the years, the scope and responsibilities of the PHS Act and the Service have broadened. The Public Health Service Act of July 1, 1944, revised and consolidated into one law all legislation existing at that time relating to programs and activities of the PHS. The act has been amended and extended nearly every year since 1944 and currently includes 29 titles. A list of titles in the act is provided in **Table 1**. A compilation of the PHS Act, as amended through December 31, 2004, is available at [http://energycommerce.house.gov/108/pubs/109\\_health.pdf](http://energycommerce.house.gov/108/pubs/109_health.pdf).

**Table 1. Titles in the Public Health Service Act**

<b>Title I</b>	<b>Short Title and Definitions</b>
Title II	Administration and Miscellaneous Provisions
Title III	General Powers and Duties of Public Health Service
Title IV	National Research Institutes
Title V	Substance Abuse and Mental Health Services Administration
Title VI	Assistance for Construction and Modernization of Hospitals and Other Medical Facilities
Title VII	Health Professions Education
Title VIII	Nursing Workforce Development
Title IX	Agency for Healthcare Research and Quality
Title X	Population Research and Voluntary Family Planning Programs
Title XI	Genetic Diseases, Hemophilia Programs, and Sudden Infant Death Syndrome
Title XII	Trauma Care
Title XIII	Health Maintenance Organizations
Title XIV	Safety of Public Water Systems
Title XV	Preventive Health Measures with Respect to Breast and Cervical Cancers
Title XVI	Health Resources Development
Title XVII	Health Information and Health Promotion
Title XVIII	President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
Title XIX	Block Grants

<sup>1</sup> Section 301 of the PHS Act, codified at 42 U.S.C. § 241(a).

Title I	Short Title and Definitions
Title XX	Adolescent Family Life Demonstration Projects
Title XXI	Vaccines
Title XXII	Requirements for Certain Group Health Plans for Certain State and Local Employees
Title XXIII	Research with Respect to Acquired Immune Deficiency Syndrome
Title XXIV	Health Services with Respect to Acquired Immune Deficiency Syndrome
Title XXV	Prevention of Acquired Immune Deficiency Syndrome
Title XXVI	HIV Health Care Services Program
Title XXVII	Assuring Portability, Availability, and Renewability of Health Insurance Coverage
Title XXVIII	National Preparedness for Bioterrorism and Other Public Health Emergencies
Title XXIX	Lifespan Respite Care

**Sources:** Compiled by CRS from U.S. House of Representatives, Committee on Energy and Commerce, *Compilation of Selected Acts Within the Jurisdiction of the Committee on Energy and Commerce: Health Law*, August 2005 [http://energycommerce.house.gov/108/pubs/109\\_health.pdf](http://energycommerce.house.gov/108/pubs/109_health.pdf), and P.L. 109-442, Lifespan Respite Care Act of 2006.

Reorganization Plan No. 3 of 1966 transferred all statutory power and functions of the Surgeon General and other officers and agencies of the PHS to the Secretary of Health, Education, and Welfare (HEW).<sup>2</sup> In 1979, the Department of Education Organization Act (P.L. 96-88) provided for a separate Department of Education, and HEW was officially redesignated as HHS on May 4, 1980. HHS has designated eight agencies as Public Health Service operating divisions.<sup>3</sup> Those agencies are

- the Agency for Healthcare Research and Quality (AHRQ),
- the Agency for Toxic Substances and Disease Registry (ATSDR),
- the Centers for Disease Control and Prevention (CDC),
- the Food and Drug Administration (FDA),
- the Health Resources and Services Administration (HRSA),
- the Indian Health Service (IHS),
- the National Institutes of Health (NIH), and
- the Substance Abuse and Mental Health Services Administration (SAMHSA).

The Agency for Toxic Substances and Disease Registry is administered by the Director of the CDC, and the two agencies are discussed together in this report.

The missions and key functions of the PHS agencies vary. Two of them principally conduct and support *research*: NIH conducts and supports basic, clinical, and translational medical research,

<sup>2</sup> The House and Senate held hearings on President Johnson's reorganization plan, but no further legislative action was taken. The plan became effective June 25, 1966, 80 Stat. 1610.

<sup>3</sup> The HHS "family of agencies" also includes the following, which are not part of the PHS: Office of the Secretary, Administration for Children and Families, Administration on Aging, and Centers for Medicare and Medicaid Services. See links at <http://www.hhs.gov/>.

and AHRQ conducts and supports research on the quality and effectiveness of health care services and systems. One agency, IHS, provides or directly funds *health care services* for members of the nation's federally recognized Indian tribes. Two agencies support the provision of *health care services, or the systems that provide them*, for a number of other special populations: 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, and SAMHSA funds programs and systems that provide mental health and substance abuse prevention and treatment services. CDC/ATSDR develops and supports *public health* prevention programs and systems, such as disease surveillance and provider education programs, for a full spectrum of acute and chronic diseases and injuries, including public health emergencies such as bioterrorism. Although the agencies above have limited regulatory responsibilities, if any, the FDA's mission is almost entirely *regulatory*, ensuring the safety of foods and the safety and effectiveness of drugs, vaccines, medical devices, and other health products.

**Table 2** presents total budgets for each of the agencies for FY2007 through the FY2009 request. Detailed budget tables are provided with each agency discussion. Five of the agencies (AHRQ, CDC, HRSA, NIH, and SAMHSA) receive the bulk of their funding through the annual appropriations act for the Departments of Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS-ED). ATSDR and IHS funds are provided through the Interior, Environment, and Related Agencies appropriation, and FDA receives its funding through the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriation. As part of the President's annual budget proposal, HHS presents a common request for all of its components. Documents supporting the HHS budget request for FY2009, including a summary called the *Budget in Brief* and links to the "Congressional justification" materials prepared for the Appropriations Committees, may be found at <http://www.hhs.gov/budget/docbudget.htm>.

The PHS Evaluation Set-Aside, also called the PHS Evaluation Tap, is a unique budget transfer feature for agencies and offices authorized by the PHS Act and funded by the Labor-HHS-ED appropriations act. Section 241 of the PHS Act (42 U.S.C. § 238j) authorizes the Secretary to use a portion of eligible appropriations to assess the effectiveness of federal health programs and to identify ways to improve them. Funds are also used for activities that support the infrastructure for evaluation of health programs, such as data-gathering and analysis. Although the PHS Act 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 maximum amount of funds that may be set aside for evaluation (currently 2.4% of the eligible portions of agency budgets).<sup>4</sup>

HHS identifies the amount of set-aside funds to be "tapped," primarily from the appropriations of NIH, HRSA, CDC, and SAMHSA, and determines the amount of funding to be made available to each "recipient" agency or program, including several offices within the Office of the HHS Secretary. Many of the recipient programs are specified by Congress in the appropriations act.

<sup>4</sup> The current provision is found in § 206 of the FY2008 Labor-HHS-ED appropriations act, P.L. 110-161, Division G. Most of the funds appropriated for CDC, HRSA, NIH, and SAMHSA are subject to the PHS evaluation tap. Exceptions, by HHS convention, include funds appropriated for certain block grants (Prevention, Substance Abuse, and Mental Health), for program management activities, and for Buildings and Facilities, as well as some programs not authorized by the PHS Act, such as the Maternal and Child Health Block Grant in HRSA. For further details, see *Use of Public Health Service Evaluation Set-Aside Authority for FY 2005*, available at <http://aspe.hhs.gov/rcc/SetAsideReport/FY2005.pdf>, and *Evaluation in the Department of Health and Human Services*, available at <http://aspe.hhs.gov/pic/perfimp/2002/appendixa.htm>.



The entire budget of AHRQ is funded through the evaluation set-aside, and selected programs in the other four agencies also receive funds through this transfer mechanism. See the individual agency budget tables for specifics.

For each of the PHS agencies, this report describes the mission, organization, key programs, history, and legislative authorities, and provides budget tables for FY2007 through the FY2009 request. It will be updated as legislative and other events warrant.

**Table 2. Public Health Service (PHS) Agency Budgets: Summary Table**

(dollars in millions)

Agencies	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
<b>Agency for Healthcare Research and Quality (AHRQ)</b>				
Discretionary budget authority	0	0	0	0.0%
Total program level	319	335	326	-2.7%
<b>Centers for Disease Control and Prevention (CDC)/ Agency for Toxic Substances and Disease Registry (ATSDR)</b>				
Discretionary budget authority	6,060	6,124	5,691	-7.1%
Total program level	9,116	9,209	8,797	-4.5%
<b>Food and Drug Administration (FDA)</b>				
Discretionary budget authority	1,583	1,720	1,771	2.9%
Total program level	1,974	2,270	2,400	5.7%
<b>Health Resources and Services Administration (HRSA)</b>				
Discretionary budget authority	6,398	6,864	5,872	-14.5%
Total program level	6,447	6,917	5,922	-14.4%
<b>Indian Health Service (IHS)</b>				
Discretionary budget authority	3,180	3,346	3,325	-0.6%
Total program level	4,103	4,282	4,261	-0.5%
<b>National Institutes of Health (NIH)</b>				
Discretionary budget authority	28,978	29,307	29,307	0.0%
Total program level	29,038	29,171	29,165	0.0%
<b>Substance Abuse and Mental Health Services Administration (SAMHSA)</b>				
Discretionary budget authority	3,206	3,234	3,025	-6.5%
Total program level	3,327	3,356	3,159	-5.9%
<b>Total for PHS Agencies<sup>a</sup></b>				
Discretionary budget	49,405	50,596	48,991	-3.2%

Agencies	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
authority				

**Source:** Derived from agency tables in this report (**Table 3** through **Table 9**).

**Note:** Totals and percentages may not compute exactly due to rounding.

- a. AHRQ is financed through PHS evaluation funds, which come from the appropriations of other agencies. Therefore, AHRQ is not included in the total for discretionary budget authority. (A total program level for PHS agencies cannot be calculated without additional information on the distribution of PHS evaluation funds across multiple HHS agencies.)

## Agency for Healthcare Research and Quality (AHRQ)

### Mission

The Agency for Healthcare Research and Quality (AHRQ) is the lead agency charged with supporting research designed to improve the quality of health care, to increase the efficiency of its delivery, and to broaden access to the most essential health services. To accomplish these goals, it funds, conducts, and disseminates research aimed at reducing the costs of care, promoting patient safety, and increasing the effectiveness of health care services.

### Organization and Key Programs

The agency is divided into nine major functional components, consisting of four offices and five research centers. The offices, centers, and key program areas are described below.<sup>5</sup> Unlike the National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC), which each have separate funding streams for major organizational entities such as centers or institutes, AHRQ funds are targeted to specific programs or objectives (e.g., comparative effectiveness, patient safety, and health disparities). Budget dollars are then allocated to AHRQ's centers by the Director, according to research priorities identified by Congress or the Department of Health and Human Services. Therefore, **Table 3**, which describes AHRQ's budget, does not provide funding stream data for the separate research centers at AHRQ. Instead, budget figures are displayed according to several broad program categories, also described below.

### Offices and Research Centers

The Office of the Director is charged with ensuring that AHRQ's strategic objectives are achieved. The Office of Performance Accountability, Resources, and Technology coordinates agency-wide program planning and administrative operations. The Office of Extramural Research, Education, and Priority Populations (OEREP) directs the scientific review process, manages AHRQ's research training programs, monitors and evaluates ongoing research, and supports or conducts studies on priority populations and health disparity populations. The Office

<sup>5</sup> For additional information, see <http://www.ahrq.gov/about/offcntrs.htm>.

of Communications and Knowledge Transfer implements and manages programs for disseminating the results of AHRQ activities and AHRQ-funded research.

The Center for Outcomes and Evidence (COE) conducts and supports research, assessments, and demonstrations on safety, quality, effectiveness, and cost-effectiveness. It serves as a repository for evidence-based information on therapeutics, technologies, and health care practices. COE summarizes these findings and provides an array of tools and products to promote and facilitate evidence-based clinical decisions. The Center for Primary Care, Prevention, and Clinical Partnerships (CP3) focuses on research addressing the effectiveness and quality of primary and preventive health care services. CP3 serves as a locus for research on health information technology. It also supports work on the preparedness of the health care system to deal with bioterrorism, natural disasters, and pandemic flu. The Center for Delivery, Organization, and Markets (CDOM) conducts and supports qualitative and quantitative studies on how organizational dynamics in the health sector affect access and costs. For instance, its research examines how market forces influence payment methods, financial and non-financial incentives, safety net funding, and employer purchasing strategies. The Center for Financing, Access, and Cost Trends (CFACT) manages studies of the cost and financing of health care, including research analyzing trends and patterns of health expenditures, public and private insurance coverage, utilization of care, and access to care for various subsets of the general population. CFACT's work includes modeling and projections of health care use, population health status, and overall health care expenditures. The Center for Quality Improvement and Patient Safety (CQuIPS) supports research addressing patient safety, including studies on health care quality measurement and medical error reporting. In addition, it develops and disseminates reports aimed at decreasing medical errors, risks, and hazards in health care settings.

### Program Areas

The AHRQ budget, presented in **Table 3**, is organized according to program areas. These are (1) Research on Healthcare Costs, Quality and Outcomes (HQCO), which consists of patient safety research, and non-patient safety research; (2) the Medical Expenditure Panel Survey; and (3) program support.

Medical errors result in considerable morbidity, mortality, and costs to the health care system. With the increased focus on patient safety stimulated by the release of the Institute of Medicine's 1999 report, *To Err Is Human*, and with a substantial budget increase from Congress directed toward patient safety, AHRQ embarked on a strategic approach to develop a large, targeted *patient safety research* initiative. The ongoing objectives of this effort include developing public-private partnerships to build capacity for medical error reduction activities, examining the effect of working conditions on patient safety, and reviewing different methods of reporting medical errors.

Among its patient safety research programs, AHRQ is actively involved with researching the advantages and disadvantages associated with *health information technology* (HIT). HIT broadly refers to the use of computers and computer programs to store, protect, retrieve, and transfer clinical, administrative, and financial information electronically within health care settings. Clinicians and researchers believe that electronic health records could play an important role in coordinating care, especially for people with chronic conditions, such as diabetes or asthma, who frequently see multiple providers. An AHRQ priority is the dissemination of new knowledge and best practices from pioneers in this field.

Nearly 60% of AHRQ's budget is awarded as grants and contracts to researchers at universities and other research institutions for the purpose of studying issues other than patient safety. Recently, AHRQ has placed a high priority on research regarding the care of individuals with chronic conditions and/or multiple co-morbidities. It has expressed a particular interest in funding studies of *patient-centered care* that evaluate different efforts to redesign structural processes to target sicker individuals. This includes interventions that empower patients, improve patient-provider communication, and facilitate the coordination of care, such as telehealth, electronic health records, disease-management programs, medication therapy compliance programs, and Web-based applications for patients and health care providers. AHRQ has also devoted considerable resources to *eliminating health disparities*, investigating strategies to reduce racial, ethnic, and socioeconomic inequities in access to health care services. To this end, it produces an annual report to Congress, the *National Healthcare Disparities Report*.<sup>6</sup>

The *comparative effectiveness* program, which helps policy makers, clinicians, and patients determine which medical treatments work best for certain health conditions, grew out of Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173). The program supports the development of new scientific information through research on the outcomes of health care services and therapies, including pharmaceuticals, and by comparing different therapies used to treat the same condition.<sup>7</sup>

Cosponsored by AHRQ and the National Center for Health Statistics in CDC, the *Medical Expenditure Panel Survey (MEPS)* is a survey of health care use by the civilian population living in the United States. MEPS produces nationally representative statistics on health care utilization and expenditures. It also collects data on health conditions, health insurance, and coverage. MEPS is composed of three different but related surveys: the Household Component (HC), the Medical Provider Component (MPC), and the Insurance Component (IC). The MEPS HC Survey collects detailed data on demographic characteristics, health conditions, health status, access to care, satisfaction with care, and health insurance coverage. The MPC Survey supplements and validates information on medical care events reported in the MEPS HC by contacting medical providers and pharmacies identified by household respondents. Lastly, the IC Survey collects data on health insurance plans obtained through private and public-sector employers.<sup>8</sup>

## History and Legislative Authorities

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 Title IX to the PHS Act 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 it through FY2005. The new name was intended to underscore that

<sup>6</sup> See <http://www.ahrq.gov/qual/nhdr06/nhdr06.htm>.

<sup>7</sup> For more information, see <http://www.effectivehealthcare.ahrq.gov>.

<sup>8</sup> For more information about MEPS, see <http://www.meps.ahrq.gov/mepsweb>.

AHRQ is a scientific research agency, not an entity that determines federal health care policies and regulations. The word “Quality” was added to the agency’s name to emphasize its lead role in coordinating all federal health care quality improvement efforts.

**Table 3** presents funding levels for AHRQ programs for FY2007 through FY2009. As described in the introduction to this report, AHRQ receives all of its funding through the PHS Evaluation Set-Aside, rather than through provision of new budget authority in appropriations.

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

(dollars in millions)

Activities	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
<b>Research on Health Costs, Quality, and Outcomes (HCQO)</b>				
Budget Authority	0	0	0	0.0%
PHS Evaluation Tap funding <sup>a</sup>	261	277	268	-3.3%
Patient Safety Research (non-add) <sup>b</sup>	(34)	(34)	(32)	-6.0%
Health Information Technology (non-add) <sup>b</sup>	(50)	(45)	(45)	0.0%
Total AHRQ patient safety program (non-add) <sup>b</sup>	(84)	(79)	(77)	-2.7%
Comparative Effectiveness (non-add)	(15)	(30)	(30)	0.0%
<b>Medical Expenditure Panel Surveys (MEPS)</b>				
Budget Authority	0	0	0	0.0%
PHS Evaluation Tap funding <sup>a</sup>	55	55	55	0.0%
<b>Program Support</b>				
Budget Authority	0	0	0	0.0%
PHS Evaluation Tap funding <sup>a</sup>	3	3	3	0.0%
<b>Total, AHRQ discretionary budget authority</b>	0	0	0	0.0%
Total, PHS Evaluation Tap funding <sup>a</sup>	319	335	326	-2.7%
<b>Total, AHRQ program level</b>	<b>319</b>	<b>335</b>	<b>326</b>	<b>-2.7%</b>

**Source:** Adapted by CRS from AHRQ, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, at <http://www.ahrq.gov/about/cj2009/cj2009.pdf>.

**Note:** Totals and percentages may not compute exactly due to rounding.

- a. AHRQ receives its entire funding through transfers from other PHS agencies under the PHS Evaluation Set-Aside (§ 241 of the PHS Act).
- b. AHRQ’s patient safety program includes both Patient Safety Research and Health Information Technology.

# Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR)

## Mission

According to the Centers for Disease Control and Prevention (CDC), its mission is “to promote health and quality of life by preventing and controlling disease, injury, and disability.”<sup>9</sup> CDC is the nation’s principal public health agency, providing coordination and support for a variety of population-based disease and injury control activities. Approximately 75% of the agency’s funding is spent extramurally through grants, contracts, and cooperative agreements to various stakeholders, including state, local, municipal, and foreign governments, non-profit organizations, academic institutions, and others. Upon the request and under the authority of a state or foreign government, CDC provides technical assistance, including workforce support, specialized laboratory services, data management, and other services to support public health investigations. The agency does not directly deliver either health care or public health services to individuals.

CDC coordinates, analyzes, and disseminates public health information derived from a number of health surveys and disease surveillance systems that it manages. The information may be used to develop public health recommendations, such as immunization schedules for children. CDC also publishes several peer-reviewed journals, including *Morbidity and Mortality Weekly Report (MMWR)*, a weekly journal reporting on public health investigations and surveillance findings.

CDC performs many of the administrative functions for the Agency for Toxic Substances and Disease Registry (ATSDR), and the Director of CDC serves as the Administrator of ATSDR. Congress established ATSDR in 1980 in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, P.L. 96-510, the “Superfund” law) to investigate and reduce the harmful effects of exposure to hazardous substances on human health.<sup>10</sup>

## Organization and Key Programs

The current structure of CDC was implemented in April 2005 in a reorganization called “The Futures Initiative.”<sup>11</sup> The agency has more than 8,500 permanent employees and approximately 6,000 contract employees.<sup>12</sup> CDC occupies several main campuses in Atlanta, GA, and several other sites, including locations in Colorado, Maryland, Ohio, West Virginia, and Washington, DC. The agency’s organizational components are described below.

- The **Office of the Director** manages and directs agency activities.

<sup>9</sup> See the CDC website at <http://www.cdc.gov/>.

<sup>10</sup> See “Public Health Issues and the Agency for Toxic Substances and Disease Registry,” in CRS Report 97-312, *Superfund Fact Book*, by Mark Reisch and David M. Bearden.

<sup>11</sup> See <http://www.cdc.gov/futures/> and the CDC organizational chart at <http://www.cdc.gov/about/organization/orgChart.htm>.

<sup>12</sup> See CDC’s current annual report, *The State of CDC, FY2006*, p. 35, at <http://www.cdc.gov/about/stateofcdc/cdrom/SOCD/SOCD2006.pdf>.

- The **Coordinating Center for Environmental Health and Injury Prevention** houses two operating divisions. The *National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH-ATSDR)* provides national leadership in preventing and controlling disease and death resulting from the interactions between people and their environment. The *National Center for Injury Prevention and Control (NCIPC)* works to prevent death and disability from non-occupational injuries, including those that are unintentional (e.g., falls, fires, drowning, poisoning, and motor vehicle crashes) and those that result from violence (e.g., homicide, suicide, and domestic violence).
- The **Coordinating Center for Health Information and Service** houses three operating divisions. The *National Center for Health Statistics (NCHS)* provides statistical information that guides public health policy and activities. The *National Center for Public Health Informatics (NCPHI)* provides leadership in the application of information technology to public health. The *National Center for Health Marketing (NCHM)* provides leadership in health marketing science and in its application to public health.
- The **Coordinating Center for Health Promotion** houses three operating divisions. The *National Center on Birth Defects and Developmental Disabilities (NCBDDD)* provides national leadership for preventing birth defects and developmental disabilities and for improving the health and wellness of people with disabilities. The *National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)* works to prevent premature death and disability from chronic diseases such as heart disease, cancer, diabetes, and arthritis, and promotes healthy personal behaviors. The *Office of Genomics and Disease Prevention* provides national leadership in fostering understanding of human genomic discoveries and how they can be used to improve health and prevent disease.
- The **Coordinating Center for Infectious Diseases** houses four operating divisions. The *National Center for Immunization and Respiratory Diseases (NCIRD)* supports research and programs for vaccine-preventable diseases. The *National Center for Zoonotic, Vector-Borne, and Enteric Diseases (NCZVED)* works to prevent illness, disability, and death caused by infectious diseases domestically and globally. The *National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)* provides national leadership in preventing and controlling human immunodeficiency virus (HIV) infection, sexually transmitted diseases, and tuberculosis. The *National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID)* focuses on improving preparedness and response capacity for new and complex infectious disease outbreaks.
- The **Coordinating Office for Global Health** provides national leadership, coordination, and support for CDC's global health activities, in collaboration with global health partners.
- The **Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)** provides strategic direction for CDC to support terrorism preparedness and emergency response efforts.

- The **National Institute for Occupational Safety and Health (NIOSH)** ensures safety and health for all people in the workplace through research and prevention.

## History and Legislative Authorities

In 1946, the Communicable Disease Center was created from the Office of Malaria Control in War Areas, in Atlanta, GA. The original agency was established in 1942 to control malaria and other mosquito-borne diseases in U.S. military personnel training in the southeastern United States. In 1970, CDC was renamed the Center for Disease Control to reflect its added responsibilities for noncommunicable diseases. CDC's mission continued to expand to include programs in occupational and environmental health, family planning and reproductive health, and chronic diseases. A major reorganization in 1980, and its renaming to the Centers for Disease Control, emphasized the importance of health promotion and education in the agency's mission. In 1992, Congress added the words "and Prevention" to the agency's name, to recognize its role in the prevention of disease, injury, and disability. In enacting the change, Congress specified that the agency may continue to use the acronym "CDC" because of its recognition within the public health community and among the public.<sup>13</sup>

Many of CDC's activities are not specifically authorized but are based in broad, permanent authorities in the PHS Act. For example, Section 301 authorizes the Secretary of HHS to conduct research and investigations as necessary to control disease; Section 307 authorizes the Secretary to cooperate with and provide assistance to foreign nations; and Section 317 authorizes the Secretary to award grants to states for preventive health programs. Some other CDC programs (e.g., lead poisoning prevention) are explicitly authorized in the PHS Act, primarily in Title III.

Four CDC operating divisions are explicitly authorized in statute. *NIOSH* was established in permanent authority in the Occupational Safety and Health Act of 1970.<sup>14</sup> The *National Center on Birth Defects and Developmental Disabilities* was established in Section 317C of the PHS Act by the Children's Health Act of 2000. Its appropriations authority expired in 2007.<sup>15</sup> The *National Center for Health Statistics* was established in Section 306 of the PHS Act by the Health Services Research, Health Statistics, and Medical Libraries Act of 1974. Its appropriations authorities expired in FY2002 and FY2003. *ATSDR* was established in the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA).<sup>16</sup> Its appropriations authority expired in 1994.<sup>17</sup> *NCBDDD*, *NCHS*, and *ATSDR* have continued to receive annual appropriations despite their expired authorities.

CDC has few regulatory authorities. Public health regulatory authorities, such as professional licensing, facility inspection, quarantine, and contact tracing, are generally based in state law. CDC's limited regulatory authorities include certain authorities to regulate laboratories in which

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<sup>13</sup> Information on CDC history is available in Centers for Disease Control and Prevention, "CDC: The Nation's Prevention Agency," *MMWR*, vol. 41, no. 44 (November 6, 1992), p. 834.

<sup>14</sup> 29 U.S.C. § 671.

<sup>15</sup> 42 U.S.C. § 247b-4.

<sup>16</sup> 42 U.S.C. § 9604(i).

<sup>17</sup> 42 U.S.C. § 9611(m).



potential bioterrorism agents are handled, and authority for disease control functions concerning entries of persons, goods, and conveyances from other countries.<sup>18</sup>

Most CDC programs are funded through the Departments of Labor, Health and Human Services, Education, and Related Agencies (L-HHS-ED) annual appropriation. ATSDR is funded separately from other CDC programs, in the Interior, Environment, and Related Agencies annual appropriation. **Table 4** presents funding levels for CDC programs for FY2007 through FY2009. Occasionally, upon the request of the chairman of a Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, the CDC Director will submit directly to the chairman a “professional judgment” budget, outside of the usual budget request published by the White House Office of Management and Budget in February of each year. A CDC “professional judgment” budget for FY2008 requested almost \$1 billion above the agency’s FY2007 level.<sup>19</sup>

**Table 4. Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR)**

(dollars in millions)

Programs	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
Infectious Diseases, budget authority (BA)	1,797	1,892	1,857	-1.8%
<i>Pandemic and seasonal influenza (non-add)<sup>a</sup></i>	(73)	(157)	(160)	1.8%
PHS Evaluation Tap funding <sup>b</sup>	13	13	13	0.0%
Infectious Diseases, program level	1,810	1,905	1,870	-1.8%
Health Promotion, BA	947	961	932	-3.0%
Health Information and Service, BA	136	90	133	48.0%
PHS Evaluation Tap funding <sup>b</sup>	134	187	151	-19.0%
Health Information and Service, program level	270	277	284	2.7%
Environmental Health and Injury, BA	283	289	271	-6.4%
Occupational Safety and Health, BA	228	287	184	-36.0%
PHS Evaluation Tap funding <sup>b</sup>	87	95	87	-7.9%
Occupational Safety and Health, program level	315	382	271	-29.0%
Global Health, BA	307	302	302	0.1%
Public Health Research, BA	0	0	0	0.0%
PHS Evaluation Tap funding <sup>b</sup>	31	31	31	0.0%
Public Health Research, program level	31	31	31	0.0%

<sup>18</sup> For more information, see CRS Report RL34144, *Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation*, by Kathleen S. Swendiman and Nancy Lee Jones.

<sup>19</sup> See [http://www.fundcdc.org/documents/CDCFY2008PJ\\_000.pdf](http://www.fundcdc.org/documents/CDCFY2008PJ_000.pdf).

Programs	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
Public Health Improvement and Leadership, BA	203	225	182	-19.0%
Prev. Health and Health Services Block Grant, BA	99	97	0	-100.0%
Buildings and Facilities, BA	134	55	0	-100.0%
Business Services Support, BA	378	372	338	-9.1%
Terrorism, BA	1,473	1,479	1,419	-4.1%
<b>Subtotal, Labor-HHS-ED discretionary BA</b>	<b>5,985</b>	<b>6,050</b>	<b>5,618</b>	<b>-7.1%</b>
ATSDR, BA (Interior/Environment appropriations)	75	74	73	-1.6%
<b>Subtotal, CDC/ATSDR discretionary BA</b>	<b>6,060</b>	<b>6,124</b>	<b>5,691</b>	<b>-7.1%</b>
Total, PHS Evaluation Tap funding <sup>b</sup>	265	326	283	-13.2%
Vaccines for Children (VFC) <sup>c</sup>	2,736	2,702	2,766	2.4%
EEOICPA <sup>d</sup> (proposed)	52	55	55	0.0%
User fees <sup>e</sup>	2	2	2	0.0%
<b>Total, CDC/ATSDR program level</b>	<b>9,116</b>	<b>9,209</b>	<b>8,797</b>	<b>-4.5%</b>

**Source:** Adapted by CRS from CDC, *Budget Request Summary, Fiscal Year 2009*, FY2009 Discretionary All-Purpose Table, pp. 16-18, at <http://www.cdc.gov/fmo/fmofybudget.htm>.

**Note:** Totals and percentages may not compute exactly due to rounding. BA is budget authority, the discretionary appropriation for the program. Program level is the total available funding for the program.

- Levels reflect a proposed consolidation of influenza funding. For the FY2009 request, CDC has consolidated all funding for pandemic and seasonal influenza within the Infectious Diseases budget rather than displaying it within several budget categories. FY2007 and FY2008 amounts reflect comparable funding.
- Funds from PHS Evaluation Set-Aside (§ 241 of the PHS Act).
- The Vaccines for Children (VFC) program provides free pediatric vaccines to doctors who serve eligible children. The VFC program is funded entirely by federal Medicaid appropriations and is administered by CDC's National Center for Immunization and Respiratory Diseases.
- EEOICPA is the Energy Employees Occupational Illness Compensation Program Act. The FY2009 request includes an additional \$55 million in mandatory funding to support required activities that are carried out by NIOSH. Prior to FY2009, funding for these activities was provided by the Department of Labor through an interagency agreement. The FY2007 and FY2008 amounts reflect comparable funding.
- CDC is authorized to collect fees from researchers and others who use certain of the agency's databases.

## Food and Drug Administration

### Mission

The Food and Drug Administration (FDA) website, at <http://www.fda.gov>, has a brief statement of its mission:

- To promote and protect the public health by helping safe and effective products reach the market in a timely way.
- To monitor products for continued safety after they are in use.
- To help the public get the accurate, science-based information needed to improve health.

## Organization and Key Programs

FDA regulates more than \$1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers. It regulates the safety of foods (including animal feeds) and the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices.

The organization charts of FDA overall and its components are available at <http://www.fda.gov/opacom/7org.html>. Six centers within FDA represent the broad program areas for which the agency has responsibility; other offices have agency-wide responsibilities:

- **The Office of the Commissioner** is responsible for agency-wide management of policies and activities. <http://www.fda.gov/oc/default.htm>
- **The Center for Biologics Evaluation and Research (CBER)** is responsible for the safety of the nation's blood supply and routinely examines blood bank operations for record keeping and testing for contaminants. It also ensures the safety, purity, and effectiveness of biologics (medical preparations made from living organisms and their products), such as insulin and vaccines. <http://www.fda.gov/cber/>.
- **The Center for Devices and Radiological Health (CDRH)** regulates medical devices. The marketing approval process varies based on two criteria: (1) whether a device is new, which requires demonstration of safety and effectiveness, or substantially equivalent to an approved device, and (2) which of three classes of risk to the public that FDA assigns to it. <http://www.fda.gov/cdrh/>
- **The Center for Drug Evaluation and Research (CDER)** evaluates new drug applications; no prescription drug can enter interstate commerce unless and until FDA determines, based on data from clinical trials, that it is safe and effective when used for the population and clinical condition described in its labeling. In addition to this premarket review, FDA is responsible for the postmarket safety and effectiveness of approved products. It has some authority to influence direct-to-consumer advertising; review adverse event reports from manufacturers, clinicians, consumers, and studies described by manufacturers or in peer-reviewed journals; and alert clinicians or the public to newly identified possible risks. FDA follows similar procedures for changes in labeling and dosage or other modifications to an approved product, and for nonprescription drugs. In addition to direct appropriations, user fees paid by pharmaceutical companies support CDER's premarket review and, to a lesser extent, postmarket safety activities. <http://www.fda.gov/cder/>
- **The Center for Food Safety and Applied Nutrition (CFSAN)** is responsible for protecting the safety and wholesomeness of the human food supply, except for meat and poultry products, which are regulated by the U.S. Department of Agriculture. It preapproves for safety the addition of certain chemicals to food

products (such as food and color additives). CFSAN tests food samples to determine whether any substances, such as pesticide residues or heavy metals, are present in unacceptable amounts. It also sets standards for label information to assist consumers in knowing what is present in the foods they are buying. In addition, CFSAN regulates the safety and labeling of cosmetics.  
<http://www.cfsan.fda.gov/list.html>

- **The Center for Veterinary Medicine (CVM)** regulates animal drugs and devices to ensure safety and effectiveness, and regulates the safety of animal feeds, including pet food. <http://www.fda.gov/cvm/default.html>
- **The National Center for Toxicological Research (NCTR)**, located in Arkansas, conducts research on the biological effects of widely used chemicals. NCTR does not have regulatory responsibilities. <http://www.fda.gov/nctr/index.html>
- **The Office of Regulatory Affairs** conducts FDA's compliance activities, including inspection and enforcement. <http://www.fda.gov/ora/>

## History and Legislative Authorities

Until the beginning of the 20<sup>th</sup> century, charlatans peddled adulterated and mislabeled medicines throughout the United States without penalty. In 1902, Congress passed the Biologics Control Act after 13 children died from a diphtheria vaccine contaminated with tetanus. In 1906, Congress passed the Food and Drugs Act. These were the first in a series of laws intended to assure Americans that the medicines they used did no harm and actually worked—that they are, in other words, *safe and effective*.

Over the next 60 years, Congress passed two major pieces of legislation expanding FDA authority in pursuit of those goals. It passed the Federal Food, Drug, and Cosmetic Act (FFDCA) in 1938, which authorized FDA food-related activities and required that drugs be proven safe before they could be sold in interstate commerce. Then, in 1962, in the wake of the thalidomide tragedy, Congress amended the law to require that drugmakers prove the effectiveness of their products as well.<sup>20</sup> Since 1962, FDA's authority and regulatory scope have continued to evolve.

As an agency, FDA and its predecessors have had several administrative homes in the federal government. The box below tracks the highlights of its organizational moves.<sup>21</sup>

### FDA Organizational Timeline

1862	New Bureau of Chemistry in the new U.S. Dept. of Agriculture (USDA)
1927	Bureau of Chemistry became the Food, Drug, and Insecticide Administration
1931	Renamed: the USDA Food and Drug Administration (FDA)
1940	FDA transferred from USDA to the Federal Security Agency (FSA)
1953	FSA became the Dept. of Health, Education, and Welfare (HEW)
1968	FDA (remaining in HEW) became part of the Public Health Service (PHS)

<sup>20</sup> Kefauver-Harris Drug Amendments to the FFDCA, P.L.87-781 (1962).

<sup>21</sup> See FDA and USDA Web pages at <http://www.fda.gov/opacom/backgrounders/miles.html> and [http://www.fsis.usda.gov/About\\_FSYS/Agency\\_History/index.asp](http://www.fsis.usda.gov/About_FSYS/Agency_History/index.asp).

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1980 HEW (without Education) became the Dept. of Health and Human Services (HHS)

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The FFDCA is the principal source of FDA's authority.<sup>22</sup> The Act consists of the following chapters, governing the majority of FDA's activities:

### FFDCA Chapters

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<b>Chapter I:</b>	Short Title.
<b>Chapter II:</b>	Definitions.
<b>Chapter III:</b>	Prohibited Acts and Penalties.
<b>Chapter IV:</b>	Food. Pursuant to the definition in Section 201, food is defined to include foods for humans, as well as animal feeds, including pet food.
<b>Chapter V:</b>	Drugs and Devices. Includes provisions regarding the regulation of human drugs and medical devices, and animal drugs; certain provisions regarding biological products; and certain special provisions such as those regarding pediatric drug studies.
<b>Chapter VI:</b>	Cosmetics.
<b>Chapter VII:</b>	General Authority. Includes, among other things, authority to promulgate regulations, and to conduct inspections and investigations. <sup>23</sup>
<b>Chapter VIII:</b>	Imports and Exports.
<b>Chapter IX:</b>	Miscellaneous.

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FDA is also responsible for certain provisions in other laws, most notably the Public Health Service (PHS) Act.<sup>24</sup> The PHS Act contains certain specific provisions that are implemented by FDA, such as mammography quality standards.<sup>25</sup> The Act also contains certain broad provisions that are implemented by FDA. An example is FDA's enforcement of a ban on the interstate sale of baby turtles, which can cause Salmonella infections, as an exercise of the HHS Secretary's broad authority under the PHS Act to control diseases.<sup>26</sup>

FDA's authority to regulate most human biologics—products such as vaccines, blood and blood components—flows from provisions in the PHS Act (Section 351) and in specific sections of the FFDCA.<sup>27</sup> Furthermore, different types of biologics may be regulated by either CDER or CBER.<sup>28</sup> Veterinary biologics, such as animal vaccines, are not regulated by FDA. They fall under a separate law, the Virus, Serum, and Toxin Act, which is administered by USDA.

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<sup>22</sup> The FFDCA is codified at 21 U.S.C. § 301 et seq. The FDA website offers the text of FFDCA chapters (current through December 2004); a cross-reference to corresponding sections in Title 21, Chapter 9 of the U.S. Code; and significant amendments to the FFDCA, at <http://www.fda.gov/opacom/laws/>.

<sup>23</sup> In general, FDA's regulations are found in Title 21 of the Code of Federal Regulations. FDA maintains a current searchable version of Title 21 on its website at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>.

<sup>24</sup> A listing of the many other laws containing provisions for which FDA is responsible is available at <http://www.fda.gov/opacom/laws/#other>.

<sup>25</sup> Public Health Service Act, Sec. 354, 42 U.S.C. § 263b.

<sup>26</sup> Public Health Service Act, Sec. 361, 42 U.S.C. § 264.

<sup>27</sup> See FDA, Center for Biologics Evaluation and Research, "Frequently Asked Questions," at <http://www.fda.gov/cber/faq.htm>.

<sup>28</sup> See FDA, "Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research," at <http://www.fda.gov/oc/combinatiion/transfer.html>.

**Budget.** FDA has a total budget of nearly \$2.3 billion for FY2008. **Table 5** presents FDA funding levels for FY2007 through FY2009. FDA's budget has two funding streams: direct appropriations (budget authority, or BA) and industry user fees. In FDA's annual appropriation, Congress sets both the total amount of appropriated funds and the level of user fees to be collected that year. Appropriated funds are largely for salaries and expenses (\$1.714 billion in FY2008), with a much smaller amount for buildings and facilities (\$6 million in FY2008). User fees (\$549 million in FY2008) come from several programs: the three major user fee programs provide support for FDA's prescription drug, medical device, and animal drug activities, whereas smaller amounts come from mammography clinic certification fees and export and color certification fees. The FY2008 total for FDA—the program level—was \$2.270 billion, 15.0% above the FY2007 actual level.

Although the FDA's authorizing committees in Congress are the committees with jurisdiction over public health issues—the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce—FDA's assignment within the appropriations committees reflects its origin within the Department of Agriculture. The 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.

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

**Table 5. Food and Drug Administration (FDA)**

(dollars in millions)

Program area	Funds	FY2007 actual	FY2008 enacted	FY2009 request <sup>a</sup>	% change FY09 vs. FY08
Foods	BA	457	510	543	6.4%
Human drugs	BA	315	353	358	1.3%
	Fees	228	327	381	16.4%
	Total	544	680	739	8.6%
Biologics	BA	146	155	158	1.9%
	Fees	56	81	87	8.2%
	Total	202	236	245	4.0%
Animal drugs and feeds	BA	95	97	104	6.7%
	Fees	11	12	16	37.0%
	Total	106	109	119	9.9%
Devices and radiological health <sup>b</sup>	BA	231	238	242	1.6%
	Fees	37	46	49	7.1%
	Total	268	284	291	2.5%
Toxicological research (NCTR)	BA	42	44	46	4.1%
Headquarters and Office of the Commissioner <sup>b</sup>	BA	92	97	99	2.0%
	Fees	20	36	40	10.8%

Program area	Funds	FY2007 actual	FY2008 enacted	FY2009 request <sup>a</sup>	% change FY09 vs. FY08
	Total	111	133	139	4.3%
GSA rent	BA	127	131	131	0.0%
	Fees	12	29	25	-11.4%
	Total	139	159	156	-2.0%
Other rent and rent-related (including White Oak consolidation)	BA	68	89	89	0.0%
	Fees	18	10	20	92.9%
	Total	86	99	109	9.8%
Export and color certification funds	Fees	10	10	10	8.4%
<b>Subtotal, Salaries &amp; Expenses</b>	<b>BA</b>	<b>1,572</b>	<b>1,714</b>	<b>1,769</b>	<b>3.2%</b>
	<b>Fees</b>	<b>391</b>	<b>549</b>	<b>628</b>	<b>14.4%</b>
	<b>Total</b>	<b>1,964</b>	<b>2,264</b>	<b>2,397</b>	<b>5.9%</b>
Buildings & Facilities	BA	10	6	2	-60.5%
<b>Total, FDA Budget Authority</b>	<b>BA</b>	<b>1,583</b>	<b>1,720</b>	<b>1,771</b>	<b>2.9%</b>
<b>Total, FDA User Fees</b>	<b>Fees</b>	<b>391</b>	<b>549</b>	<b>628</b>	<b>14.4%</b>
<b>Total, FDA Program Level</b>	<b>Total</b>	<b>1,974</b>	<b>2,270</b>	<b>2,400</b>	<b>5.7%</b>

**Source:** Adapted by CRS from FDA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, at <http://www.fda.gov/oc/oms/ofm/budget/documentation.htm>.

**Notes:** Totals and percentages may not compute exactly due to rounding. BA = budget authority, also referred to as direct appropriations. Fees = collected user fees. Total program level = budget authority plus user fees.

- a. The FY2009 request includes a total of \$35.5 million in new or proposed user fees: Direct to Consumer advertising (\$14.0 million), proposed Generic Drug User Fee Act (\$16.6 million), and proposed Animal Generic Drug User Fee Act (\$4.8 million).
- b. Includes mammography user fees.

## Health Resources and Services Administration (HRSA)

### Mission

The Health Resources and Services Administration (HRSA)—“the access agency”—provides leadership and support for health services and resources for people who are uninsured, isolated, or medically vulnerable. According to HRSA, its programs target, for example, the 47 million Americans who lack health insurance, over 50 million Americans who live in rural and poor urban areas where health care services are scarce, more than 1 million people living with HIV/AIDS, and over 94,000 Americans who are waiting for an organ transplant.<sup>29</sup>

<sup>29</sup> HRSA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, p. 3, available at (continued...)

HRSA funds projects to support health services through grants to community-based organizations; colleges and universities; hospitals; state, local, and tribal governments; associations; national groups; and foundations. These grantees provide various services that include the identification of recruitment and training needs for the state and national health workforce; recruitment and retention of qualified health professionals to serve in the primary care workforce; administration of programs relating to implementation of state maternal and child health service programs; development of integrated information systems to enhance quality of and access to health services in underserved populations; and management of the federal response to health care needs for persons living with HIV/AIDS. In addition, HRSA administers the program for health centers, which provides grants for basic primary medical services to people who live in rural and urban areas and experience financial, geographic, cultural, or other barriers to health care.

## Organization and Key Programs

HRSA is headquartered in Rockville, MD, and is organized into six bureaus, 13 offices, and one center. The agency, restructured several times between 2003 and 2007 by the Bush Administration, currently has the following organizational components:

- The **Bureau of Primary Health Care** aims to increase access to primary and preventive health care and improve the health status of underserved and vulnerable populations. Its largest program, Health Centers, provides grants to over 4,000 health centers and clinics that provide routine access to health care for over 17 million people living in inner city and rural areas.
- The **Bureau of Clinician Recruitment and Service** administers programs authorized under various titles of the PHS Act. In 2007, HHS announced creation of the new Bureau of Clinician Recruitment and Service and transfer of the following programs from the Bureau of Health Professions: National Health Service Corps, Nursing Scholarship Program, Nursing Education Loan Repayment Program, Faculty Loan Repayment Program, and the Native Hawaiian Scholarship Program (which has not been funded in recent years). These programs attract and recruit individuals from all backgrounds to study and work in medicine, nursing, dentistry, mental and behavioral health services, and other allied health fields.
- The **Bureau of Health Professions** aims to provide national leadership in the development, distribution, and retention of a diverse, culturally competent health workforce. Grants to institutions target education and training opportunities at all academic levels, from elementary through post-graduate education. Individuals who are specializing in primary care medicine and dentistry, geriatrics, and allied health professions, among others, benefit from these grants. Many of these programs are authorized in Title VII, Health Professions Education and Title VIII, Nursing Workforce Development.
- The **Maternal and Child Health Bureau** seeks to strengthen the infrastructure for maternal and child health services. The Maternal and Child Health Block

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<ftp://ftp.hrsa.gov/about/budgetjustification09.pdf#page=10>.



Grant, Healthy Start, and Emergency Medical Services for Children, offered by state and local health agencies, are among its larger programs.

- The **HIV/AIDS Bureau** administers programs consolidated by the Ryan White HIV/AIDS Treatment Modernization Act.<sup>30</sup> The programs provide life-saving and life-extending services for people living with HIV/AIDS. According to HRSA, these programs reach more than 500,000 individuals throughout the country each year, making it the federal government's largest discretionary grant program for people living with HIV/AIDS.
- The **Healthcare Systems Bureau** provides leadership and direction in the development of national programs and services for health emergency preparedness, vaccine injury compensation, bone marrow transplantation, organ transplantation and procurement, and poison control centers, among other functions.

Among HRSA's 13 offices, some focus on specific populations or health care issues, while others are involved with the agency's management. The Office of Rural Health Policy (ORHP) is significant in its mission to promote access to health care services in rural populations. ORHP is responsible for informing and advising the Secretary of HHS on matters affecting rural health care. Other offices address issues related to minority health and health disparities, international health, health information technology, federal assistance management, financial management, legislation, communications, and performance review, among other things. A new Center for Quality coordinates activities related to strengthening and improving the quality of health care in HRSA programs and on behalf of its service populations.<sup>31</sup>

## History and Legislative Authorities

In 1935, Congress authorized the first programs for maternal and child health services and general health grants to states in various sections of the Social Security Act. Around 1940, these programs were transferred to the newly created Federal Security Agency (FSA) and later administered in the Bureau of Medical Services and Bureau of State Services. In 1953, the Department of Health, Education and Welfare (HEW) was created at cabinet level and replaced the FSA. Federal support for health services continued to evolve in HEW, and new targets for service focused on migrant health, health workforce development, and hospital and health facility construction. Within HEW, two new agencies, the Health Services Administration and the Health Resources Administration, were created in 1973. In 1982, the Secretary of HHS merged the two agencies into the present-day HRSA.

Currently, HRSA supports a variety of programs established under various authorities. Although the majority of programs are authorized in the PHS Act, a few are authorized in the Social Security Act. For example, in the PHS Act, Title III authorizes the Community Health Centers Program, National Health Service Corps, Children's Hospitals Graduate Medical Education Program, Organ Transplant and Bone Marrow Programs, Telehealth Program, and State Offices of Rural Health. Title VII authorizes programs for health workforce development, and Title VIII authorizes programs for nursing workforce development. Title XXVI consolidates all Ryan White

<sup>30</sup> P.L. 109-415 was signed on December 19, 2006.

<sup>31</sup> See more information at HRSA's website, at <http://www.hrsa.gov/about/default.htm>.

HIV/AIDS programs. Various sections of the Social Security Act authorize Maternal and Child Health Block Grants and the Rural Health Policy Development Programs. Finally, 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.

**Table 6** presents funding levels for HRSA programs for FY2007 through FY2009. For detailed appropriations on programs in Title VII and Title VIII, see CRS Report RS22438, *Health Professions Programs in Title VII and Title VIII of the Public Health Service (PHS) Act: Appropriations History (FY2002-FY2009)*, by Bernice Reyes-Akinbileje and Mary Vennetta Wright.

**Table 6. Health Resources and Services Administration (HRSA)**

(dollars in millions)

Bureaus, Offices, and Programs	FY2007 actual	FY2008 enacted	FY2009Pres. request	% change FY09 vs. FY08
Health Centers	1,988	2,065	2,092	1.3%
Other BPHC Programs	18	18	18	2.1%
<b>Subtotal, Bureau of Primary Health Care (BPHC)</b>	<b>2,006</b>	<b>2,083</b>	<b>2,110</b>	<b>1.3%</b>
National Health Service Corps	126	123	121	-2.0%
Loan Repayment/Fellowships (Sec. 738) <sup>a</sup>	1	1	0	-100%
Nursing Scholarships/Loan Repayment (Sec. 846) <sup>b</sup>	31	31	44	41.9%
<b>Subtotal, Bureau of Clinician Recruitment and Service (BCRS)</b>	<b>158</b>	<b>155</b>	<b>165</b>	<b>6.1%</b>
Health Professions <sup>a</sup>	183	193	0	-100.0%
Nursing Workforce Development <sup>b</sup>	119	126	66	-47.3%
Children's Hospitals Graduate Medical Education	297	302	0	-100.0%
Pt. Navigator Outreach/Chronic Disease Prevent	0	3	0	-100.0%
<b>Subtotal, Bureau of Health Professions (BHP)</b>	<b>599</b>	<b>623</b>	<b>66</b>	<b>-89.4%</b>
Maternal and Child Health Block Grant	693	666	666	0.0%
Healthy Start	102	100	100	0.0%
Other MCHB Programs	41	79	39	-51.2%
Subtotal, Maternal and Child Health Bureau (MCHB) <sup>c</sup>	<b>835</b>	<b>845</b>	<b>804</b>	<b>-4.8%</b>
<b>Subtotal, HIV/AIDS Bureau<sup>d</sup></b>	<b>2,113</b>	<b>2,142</b>	<b>2,143</b>	<b>0.1%</b>
<b>Subtotal, Healthcare Systems Bureau</b>	<b>75</b>	<b>82</b>	<b>68</b>	<b>-16.9%</b>
<b>Subtotal, Rural Health Programs</b>	<b>168</b>	<b>175</b>	<b>25</b>	<b>-85.9%</b>
Health Care-Related Facilities and Activities	0	304	0	-100.0%
Parklawn Building Lease Replacement	0	0	36	na

Bureaus, Offices, and Programs	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
Telehealth + Program Management	153	148	148	0.1%
Family Planning	283	300	300	0.0%
<b>Subtotal, Other HRSA Programs</b>	<b>436</b>	<b>752</b>	<b>484</b>	<b>-35.7%</b>
<b>Total, Health Resources and Services account, discretionary</b>	<b>6,391</b>	<b>6,856</b>	<b>5,865</b>	<b>-14.5%</b>
Health Education Assistance Loans (HEAL)	3	3	3	2.1%
Vaccine Injury Compensation Program direct operations	4	5	5	-16.2%
<b>Total, HRSA discretionary budget authority</b>	<b>6,398</b>	<b>6,864</b>	<b>5,872</b>	<b>-14.5%</b>
National Practitioner Data Bank (User Fees) <sup>e</sup>	16	19	19	1.8%
Health Care Integrity and Protection Data Bank (User Fees) <sup>e</sup>	4	4	0	-100.0%
Family to Family Health Information Centers (mandatory) <sup>f</sup>	3	4	5	25.0%
PHS Evaluation Tap fundings <sup>g</sup>	25	25	25	0.0%
HEAL Liquidating Account	1	1	1	0.0%
<b>Total, HRSA program level</b>	<b>6,447</b>	<b>6,917</b>	<b>5,922</b>	<b>-14.4%</b>

**Source:** Adapted by CRS from HRSA, *Justification of Estimates for Appropriations Committees, FY2009*, All-Purpose Table, p. 7, at <ftp://ftp.hrsa.gov/about/budgetjustification09.pdf#page=14>.

**Notes:** Totals and percentages may not compute exactly due to rounding.

- a. Total appropriations for Title VII programs are obtained by adding the appropriation for Sec. 738, administered by the BCRS, to the appropriations for the various health professions programs administered by the BHP. Total appropriations for Title VII programs are as follows: FY2007, \$185 million; FY2008, \$194 million; and FY2009 request, \$0.
- b. Total appropriations for Title VIII programs are obtained by adding the appropriation for Sec. 846, administered by the BCRS, to the appropriations for the various nursing workforce development programs administered by the BHP. Total appropriations for Title VIII programs are as follows: FY2007, \$150 million; FY2008, \$156 million; and FY2009 request, \$110 million.
- c. Excludes mandatory funding for Family to Family Health Information Centers.
- d. Excludes the amount for PHS Evaluation Tap funding (\$25 million).
- e. User fees available for Bureau of Health Professions.
- f. Mandatory funds for Maternal and Child Health Bureau appropriated in the Deficit Reduction Act of 2005 (P.L. 109-171).
- g. Additional funds for Ryan White AIDS programs from PHS Evaluation Set-Aside (§ 241 of PHS Act).

## Indian Health Service (IHS)

### Mission

The Indian Health Service (IHS) provides, or funds the provision of, direct health care services to members of the nation's 562 federally recognized Indian<sup>32</sup> tribes (totaling about 1.8 million Indians in 35 states) who are in IHS service delivery areas.<sup>33</sup> Services are provided through IHS-funded clinics, hospitals, health centers, and other facilities, operated by IHS itself, Indian tribes, tribal organizations, or urban Indian organizations. Health care services are also provided through contracts with private health services providers. Besides services, IHS also funds the construction, equipping, operation, and maintenance of health care and sanitation facilities.

IHS health care services cover almost the entire range of clinical health services, including ambulatory, inpatient, preventive, mental health, and dental care. IHS's public health services include home and community sanitation facilities, public health nurses, and epidemiology. Besides providing general clinical health services, IHS also focuses on special Indian health problems, such as fetal alcohol syndrome, diabetes prevention and treatment, alcoholism and mental health, hepatitis B, and maternal and child health.

Eligible Indians receive free IHS health services regardless of their ability to pay. The federal government considers its provision of these health services to be based on its trust responsibility for Indian tribes, a responsibility derived from federal statutes, treaties, court decisions, executive actions, and the Constitution (which assigns authority over Indian relations to Congress). IHS programs are not entitlement programs, but rather are funded through discretionary appropriations, plus reimbursements from third parties, including Medicare and Medicaid. Available funding is not sufficient to cover all Indian health services needs, however, so IHS does not provide the same health care services in all areas. Services vary from place to place and from time to time.

### Organization and Key Programs

To carry out its roles for health care services and health care facilities, the IHS is organized into a headquarters office, 12 regions (each directed by an area office), and 163 service units (each assigned to an area office).<sup>34</sup> At the headquarters level, and within area offices and service units where relevant, there are programmatic offices for the following activities:

- clinical and preventive health services, including clinical and community services, behavioral health, nursing services, oral health, and diabetes treatment and prevention;

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<sup>32</sup> In this report, the term "Indian" means American Indians and Alaska Natives. The latter term includes the Eskimos (Inuit and Yupik), Aleuts, and American Indians of Alaska.

<sup>33</sup> IHS also funds limited health services to Indians in certain urban areas.

<sup>34</sup> A service unit is an administrative entity within a defined geographical area, through which services are directly or indirectly provided to eligible Indians. A service unit may cover a number of small reservations, or, conversely, a large reservation may be covered by several service units.

- public health support, including disease prevention and epidemiology, and health professions recruitment and scholarship programs; and
- environmental health and engineering, including health facilities planning and construction, sanitation facilities construction, facilities operation, engineering, and environmental health services.

Direct clinical health care is provided through 46 inpatient hospitals and 633 ambulatory facilities (which include 304 health clinics, 143 health stations, 166 Alaska village clinics, and 20 school health centers). Fifteen of the hospitals and 550 of the ambulatory facilities are operated by tribes and tribal organizations, under contracts and compacts pursuant to the Indian Self-Determination and Education Assistance Act of 1975.<sup>35</sup> The remaining facilities are operated by the IHS. In addition, IHS funds 34 urban Indian health projects in 41 urban sites through federal contracts and grants.<sup>36</sup>

The IHS offers information on its programs through its website at <http://www.ihs.gov>.

## History and Legislative Authorities

Health care services for Indians developed gradually over the course of the 19<sup>th</sup> century, pursuant to congressional appropriations but without an explicit statutory establishment of an Indian medical agency. What health services were provided were under the War Department before 1849, and under the Department of the Interior after 1849, when the Bureau of Indian Affairs (BIA) was transferred to Interior. While the number of BIA hospitals and physicians gradually increased in the late 19<sup>th</sup> and early 20<sup>th</sup> centuries, BIA did not have a bureau-wide medical supervisor until 1908. The Snyder Act of 1921<sup>37</sup> authorized federal programs for Indians within the BIA, including health care, but did not establish an Indian medical agency. In 1954, Congress passed the Transfer Act, directing that Interior's and the BIA's responsibilities, functions, and facilities for Indian health care be transferred to the Surgeon General of the Public Health Service in the Department of Health, Education, and Welfare.<sup>38</sup> The transfer occurred on July 1, 1955, and since then, IHS has been a part of the PHS.

Besides general statutory authority under the Snyder Act and the Transfer Act, specific IHS programs are authorized by the Indian Sanitation Facilities Act of 1959,<sup>39</sup> authorizing the PHS to construct sanitation facilities for Indian communities and homes; the Indian Health Care Improvement Act (IHICIA) of 1976,<sup>40</sup> which established many specific IHS programs, such as urban health, professions recruitment, and mental health, and which also amended the Social Security Act to authorize IHS to make direct collections from Medicare/Medicaid and third-party insurers; and the Indian Self-Determination and Education Assistance Act of 1975,<sup>41</sup> which

<sup>35</sup> P.L. 93-638, act of January 4, 1975, 88 Stat. 2203, as amended; 25 U.S.C. § 450 et seq.

<sup>36</sup> Statistics in this paragraph are from U.S. Department of Health and Human Services, Indian Health Service, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, pp. CJ-123 and CJ-218.

<sup>37</sup> Act of November 2, 1921, 42 Stat. 208, as amended; 25 U.S.C. § 13.

<sup>38</sup> P.L. 83-568, act of August 5, 1954, 68 Stat. 674, as amended; 42 U.S.C. § 2001 et seq.

<sup>39</sup> P.L. 86-121, act of July 31, 1959, 73 Stat. 267; 42 U.S.C. § 2004a.

<sup>40</sup> P.L. 94-437, act of September 30, 1976, 90 Stat. 1400, as amended; 25 U.S.C. § 1601 et seq., and 42 U.S.C. § 1395qq, § 1396j (and amending other sections).

<sup>41</sup> P.L. 93-638, act of January 4, 1975, 88 Stat. 2203, as amended; 25 U.S.C. § 450 et seq.

provides for tribal administration of federal Indian programs, especially BIA and IHS programs, under self-determination contracts and self-governance compacts.

Unlike most other PHS agencies, the IHS receives its appropriations under the Interior, Environment, and Related Agencies Appropriations Act, not under the Labor-HHS-Education Appropriations Act.

The Snyder Act, as it currently stands, can be considered a permanent, general authorization for IHS. The IHCA's authorizations of appropriations, however, which are more program-specific, expired at the end of FY2001. Congress continues to appropriate funds for IHS and has been considering IHCA reauthorization bills since the 106<sup>th</sup> Congress. In the 110<sup>th</sup> Congress, the Senate's IHCA reauthorization bill (S. 1200) was passed by the Senate on February 26, 2008, and forwarded to the House, while the House bill (H.R. 1328) has been ordered reported from one committee and must be considered by two other committees of jurisdiction.

**Table 7** presents funding levels for IHS programs for FY2007 through FY2009. For further information on IHS, see CRS Report RL33022, *Indian Health Service: Health Care Delivery, Status, Funding, and Legislative Issues*, by Roger Walke.

**Table 7. Indian Health Service (IHS)**

(dollars in millions)

Programs	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
<b>Health Services</b>				
<b>Clinical Services</b>				
Hospitals and Health Clinics	1,411	1,484	1,522	2.6%
Dental Health	125	134	138	3.2%
Mental Health	61	64	66	3.6%
Alcohol and Substance Abuse	148	173	162	-6.5%
Contract Health Care	543	553	563	1.9%
Catastrophic Health Emergency Fund	N/A	27	25	-6.0%
<b>Subtotal, Clinical Services</b>	<b>2,289</b>	<b>2,434</b>	<b>2,476</b>	<b>1.7%</b>
<b>Preventive Health</b>				
Public Health Nursing	52	56	58	4.2%
Health Education	14	15	25	1.6%
Community Health Reps.	55	55	56	1.6%
Immunization (Alaska)	2	2	2	1.6%
<b>Subtotal, Preventive Health</b>	<b>123</b>	<b>128</b>	<b>131</b>	<b>2.7%</b>
<b>Other Health Services</b>				
Urban Health Projects	34	35	0	-100.0%
Indian Health Professions	31	36	22	-39.7%
Tribal Management	2	2	3	1.6%
Direct Operations	64	64	63	-1.6%

Programs	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
Self-Governance	6	6	6	1.6%
Contract Support Costs	270	267	272	1.6%
<b>Subtotal, Other Health Services</b>	<b>407</b>	<b>410</b>	<b>365</b>	<b>-11.1%</b>
<b>Subtotal, Health Services</b>	<b>2,819</b>	<b>2,972</b>	<b>2,972</b>	<b>0.0%</b>
<b>Health Facilities</b>				
Maintenance and Improvement	55	53	53	0.0%
Sanitation Facilities Construction	94	94	94	0.0%
Health Care Facilities Construction	26	37	16	-56.8%
Facilities/Environmental Health Support	165	170	169	-0.3%
Equipment	22	21	21	0.0%
<b>Subtotal, Health Facilities</b>	<b>361</b>	<b>375</b>	<b>353</b>	<b>-5.7%</b>
<b>Total, IHS discretionary budget authority</b>	<b>3,180</b>	<b>3,346</b>	<b>3,325</b>	<b>-0.6%</b>
Collections	773	786	786	0.0%
Special Diabetes Program for Indians <sup>a</sup>	150	150	150	0.0%
<b>Total, IHS program level</b>	<b>4,103</b>	<b>4,282</b>	<b>4,261</b>	<b>-0.5%</b>

**Source:** Adapted by CRS from IHS, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009, All-Purpose Table, p. Cj-3*, at [http://www.ihs.gov/NonMedicalPrograms/BudgetFormulation/bf\\_cong\\_justifications.asp](http://www.ihs.gov/NonMedicalPrograms/BudgetFormulation/bf_cong_justifications.asp).

**Note:** Totals and percentages may not compute exactly due to rounding.

a. Funds available to IHS for Special Diabetes Program for Indians (P.L. 105-33, P.L. 106-554, P.L. 107-360, and P.L. 110-173; 42 U.S.C. 254c-3).

## National Institutes of Health (NIH)

### Mission

The National Institutes of Health is the primary agency of the federal government charged with conducting and supporting biomedical and behavioral research. It also has major roles in research training and health information dissemination. According to the NIH website, “Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.”<sup>42</sup>

NIH is the largest of the PHS agencies, with a budget of \$29.2 billion in FY2008 (see **Table 9**) and total employment of more than 18,000 people. Over 80% of NIH’s annual funding goes out through grant, contract, and training awards to extramural scientists working in universities,

<sup>42</sup> See <http://www.nih.gov/about/>.

academic health centers, hospitals, and independent research institutions in the United States and abroad. The NIH intramural research program, accounting for about 10% of the budget, includes more than 6,500 scientists and technical support staff who are government employees, and several thousand additional scientific fellows, guest researchers, and contractors. The remainder of the budget is for research management, administration, and physical infrastructure.

## Organization and Key Programs

The agency's organization consists of the Office of the NIH Director and 27 institutes and centers. The Office of the Director (OD) sets overall policy for NIH and coordinates the programs and activities of all NIH components, particularly trans-institute research initiatives and issues. The individual institutes and centers (ICs), each of which focuses on particular diseases, areas of human health and development, or aspects of research support, plan and manage their own research programs in coordination with the Office of the Director. As shown in **Table 9**, Congress provides separate appropriations to 24 of the 27 ICs, to OD, and to a buildings and facilities account. (The remaining three centers, not included in the table, are funded through the NIH Management Fund, financed by taps on other NIH appropriations.) NIH occupies a 317-acre main campus in Bethesda, MD, as well as numerous off-campus sites, including locations in Maryland, North Carolina, and Montana.

The institutes and centers, listed in the order found in appropriations acts, are briefly described below.<sup>43</sup> Each leads a national research and information program in the research areas indicated.

- **Office of the Director** (OD) has charge of overall NIH leadership, and liaison with HHS. It includes special offices for research on AIDS, women's health, behavioral and social sciences, and disease prevention (including rare diseases and dietary supplements).
- **National Cancer Institute** (NCI, established 1937). All aspects of cancer—cause, diagnosis, prevention, treatment, rehabilitation, and continuing care of patients.
- **National Heart, Lung, and Blood Institute** (NHLBI, established 1948). Diseases of the heart, blood vessels, lungs, and blood; sleep disorders; and blood resources management. It also administers the NIH Woman's Health Initiative.
- **National Institute of Dental and Craniofacial Research** (NIDCR, established 1948). Infectious and inherited oral, dental, and craniofacial diseases and disorders.
- **National Institute of Diabetes and Digestive and Kidney Diseases** (NIDDK, established 1948). Diabetes, endocrinology, metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases.
- **National Institute of Neurological Disorders and Stroke** (NINDS, established 1950). Convulsive, neuromuscular, demyelinating, and dementing disorders; fundamental neurosciences; stroke, trauma.

<sup>43</sup> For further information on each component, see <http://www.nih.gov/icd/>. See also the *NIH Almanac, 2006-2007*, at <http://www.nih.gov/about/almanac/about.htm>.



- **National Institute of Allergy and Infectious Diseases** (NIAID, established 1948). Infectious, immunologic, and allergic diseases.
- **National Institute of General Medical Sciences** (NIGMS, established 1962). Research and research training in basic biomedical sciences (cellular and molecular biology, genetics, pharmacology, physiology). Special focus on minority researchers.
- **National Institute of Child Health and Human Development** (NICHD, established 1962). Reproductive biology; population issues; embryonic development; maternal, child, and family health; medical rehabilitation.
- **National Eye Institute** (NEI, established 1968). Eye diseases, visual disorders, visual function, preservation of sight, health problems of the visually impaired.
- **National Institute of Environmental Health Sciences** (NIEHS, established 1969). Interrelationships of environmental factors, individual genetic susceptibility, and age as they affect health.
- **National Institute on Aging** (NIA, established 1974). Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged.
- **National Institute of Arthritis and Musculoskeletal and Skin Diseases** (NIAMS, established 1986). Arthritis; bone, joint, connective tissue and muscle disorders; skin diseases.
- **National Institute on Deafness and Other Communication Disorders** (NIDCD, established 1988). Normal mechanisms and disorders of hearing, balance, smell, taste, voice, speech, and language.
- **National Institute of Nursing Research** (NINR, established 1986). Management of acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics.
- **National Institute on Alcohol Abuse and Alcoholism** (NIAAA, established 1970). Causes of alcoholism, how alcohol damages the body, prevention and treatment strategies.
- **National Institute on Drug Abuse** (NIDA, established 1973). Social, biological, behavioral, and neuro-scientific bases of drug abuse and addiction; causes, prevention, and treatment strategies.
- **National Institute of Mental Health** (NIMH, established 1949). Brain research, mental illness, and mental health.
- **National Human Genome Research Institute** (NHGRI, established 1989). Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research.
- **National Institute of Biomedical Imaging and Bioengineering** (NIBIB, established 2000). Research, training and coordination in biomedical imaging, bioengineering and related technologies and modalities, including biomaterials and informatics.

- **National Center for Research Resources** (NCRR, established 1962). Extramural and intramural research resources and technologies, including general clinical research centers, computers, instrument systems, animal resources and facilities, and nonmammalian research models.
- **National Center for Complementary and Alternative Medicine** (NCCAM, established 1999). Identifies, evaluates, and researches unconventional health care practices.
- **National Center on Minority Health and Health Disparities** (NCMHD, established 1993). Research, training, and coordination on minority health conditions and populations with health disparities.
- **John E. Fogarty International Center** (FIC, established 1968). Focal point for NIH's international collaboration activities and scientific exchanges; provides leadership in global health.
- **National Library of Medicine** (NLM, established 1956). Collects, organizes, and makes available biomedical information; sponsors programs to improve biomedical communications and U.S. medical library services.
- **NIH Clinical Center** (CC, established 1953). NIH's hospital and outpatient facility for clinical research.
- **Center for Scientific Review** (CSR, established 1946). Receives, assigns, and reviews research and training grant applications.
- **Center for Information Technology** (CIT, established 1964). Provides, coordinates, and manages information technology for NIH; research to advance computational science.

## History and Legislative Authorities

NIH traces its roots to 1887, when a one-room Laboratory of Hygiene was established at the Marine Hospital in Staten Island, New York. Relocated to Washington, DC, in 1891, and renamed the Hygienic Laboratory, it operated for its first half century as an intramural research lab for the Public Health Service. Congress designated the lab the National Institute of Health in 1930 (P.L. 71-251). It moved to donated land in the Maryland suburbs in 1938. By 1948, several new institutes and divisions had been created, and the agency became the National Institutes of Health (P.L. 80-655). As indicated in the list above, Congress continued to add new institutes and centers for several decades, most recently in 2000.

Section 301 of the Public Health Service Act (42 U.S.C. § 241) grants the Secretary of HHS broad permanent authority to conduct and sponsor research. In addition, Title IV, "National Research Institutes" (42 U.S.C. § 281-290b), authorizes in greater detail various activities, functions, and responsibilities of the NIH Director and the institutes and centers. All of the institutes and centers are covered by specific provisions in the PHS Act. Prior to passage of the NIH Reform Act of 2006 (P.L. 109-482), nine of the ICs and a variety of individual programs had time-and-dollar limits on their authorizations of appropriations. Most of the authorizations had expired, but § 301 provided authority for the programs. The other institutes and centers and most NIH programs did not require periodic reauthorization by Congress, and there was no overall authorization for the agency. The NIH Reform Act added a number of authorities for the NIH

Director, authorized total funding levels for NIH appropriations for FY2007 to FY2009, and eliminated all of the other specific authorizations in Title IV.

For additional information on NIH, see CRS Report RL33695, *The National Institutes of Health (NIH): Organization, Funding, and Congressional Issues*, by Pamela W. Smith, and the NIH section of CRS Report RL34048, *Federal Research and Development Funding: FY2008*, by John F. Sargent Jr. et al.

**Table 8. National Institutes of Health (NIH)**

(dollars in millions)

Institutes and Centers (ICs)	FY2007 actual <sup>a</sup>	FY2008 enacted <sup>b</sup>	FY2009 Pres. request	% change FY09 vs. FY08
Cancer (NCI)	4,795	4,805	4,810	0.1%
Heart/Lung/Blood (NHLBI)	2,919	2,922	2,925	0.1%
Dental/Craniofacial Research (NIDCR)	390	390	391	0.1%
Diabetes/Digestive/Kidney (NIDDK)	1,706	1,707	1,708	0.1%
Neurological Disorders/Stroke (NINDS)	1,535	1,544	1,545	0.1%
Allergy/Infectious Diseases (NIAID) <sup>c,d</sup>	4,366	4,561	4,569	0.2%
General Medical Sciences (NIGMS)	1,936	1,936	1,938	0.1%
Child Health/Human Development (NICHD)	1,254	1,255	1,256	0.1%
Eye (NEI)	667	667	668	0.1%
Environmental Health Sciences (NIEHS)	642	642	643	0.1%
Aging (NIA)	1,047	1,047	1,048	0.1%
Arthritis/Musculoskeletal/Skin (NIAMS)	508	509	509	0.1%
Deafness/Communication Disorders (NIDCD)	394	394	395	0.2%
Nursing Research (NINR)	137	137	138	0.1%
Alcohol Abuse/Alcoholism (NIAAA)	436	436	437	0.1%
Drug Abuse (NIDA)	1,000	1,001	1,002	0.1%
Mental Health (NIMH) <sup>e</sup>	1,404	1,405	1,407	0.1%
Human Genome Research (NHGRI)	486	487	488	0.2%
Biomedical Imaging/Bioengineering (NIBIB)	298	299	300	0.5%
Research Resources (NCRR)	1,144	1,149	1,160	1.0%
Complementary/Alternative Med (NCCAM)	121	122	122	0.1%
Minority Health/Health Disparities (NCMHD)	199	200	200	0.1%
Fogarty International Center (FIC)	66	67	67	0.1%
Library of Medicine (NLM)	320	321	323	0.8%

Institutes and Centers (ICs)	FY2007 actual <sup>a</sup>	FY2008 enacted <sup>b</sup>	FY2009 Pres. request	% change FY09 vs. FY08
Office of Director (OD) <sup>d</sup>	1,047	1,109	1,057	-4.7%
Common Fund (non-add)	(483)	(496)	(534)	7.7%
Buildings & Facilities (B&F)	81	119	126	5.6%
<b>Subtotal, Labor/HHS Appropriation</b>	<b>28,899</b>	<b>29,230</b>	<b>29,230</b>	<b>0.0%</b>
Superfund (Interior approp to NIEHS) <sup>f</sup>	79	78	78	0.0%
<b>Total, NIH discretionary budget authority</b>	<b>28,978</b>	<b>29,307</b>	<b>29,307</b>	<b>0.0%</b>
Pre-appropriated Type I diabetes funds <sup>g</sup>	150	150	150	0.0%
PHS Evaluation Tap funding <sup>h</sup>	8	8	8	0.0%
Global Fund transfer (AIDS/TB/Malaria) <sup>c</sup>	-99	-295	-300	1.8%
<b>Total, NIH program level</b>	<b>29,038</b>	<b>29,171</b>	<b>29,165</b>	<b>0.0%</b>

**Source:** Adapted by CRS from NIH, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, Tabular Data, p. TD-1, at <http://officeofbudget.od.nih.gov/UI/2008/tabular%20data.pdf>.

**Note:** Totals and percentages may not compute exactly due to rounding.

- FY2007 reflects the transfer of \$99 million from NIH to the Office of the Secretary, as mandated by the FY2007 supplemental appropriations act, P.L. 110-28 (see note d). FY2007 also reflects comparative transfers to HHS (\$0.542m) and among NIH ICs.
- The FY2008 program level is an increase of \$133 million (0.5%) over FY2007. FY2008 includes comparative IC transfers from NHLBI to NIDDK (\$0.816 million) and from NLM to NIDCR (\$0.455 million).
- NIAID totals include funds for transfer to the Global Fund to Fight HIV/AIDS, TB, and Malaria.
- For FY2007, the war/emergency supplemental appropriations act (P.L. 110-28, May 25, 2007) transferred funding for the Advanced Development of Medical Countermeasures to the Assistant Secretary for Preparedness and Response (\$49.5m from NIAID and \$49.5m from OD).
- FY2008 amount reflects transfer of \$0.983 million from Office of the Secretary to NIMH to administer the Interagency Autism Coordinating Committee.
- Separate account in the Interior/Environment/Related Agencies appropriation for NIEHS research activities related to Superfund.
- Funds available to NIDDK for diabetes research under PHS Act § 330B (authorized by P.L. 106-554, P.L. 107-360, and P.L. 110-173).
- Additional funds for NLM from PHS Evaluation Set-Aside (§ 241 of PHS Act).

## Substance Abuse and Mental Health Services Administration (SAMHSA)

### Mission

SAMHSA supports states' efforts to enhance prevention and treatment programs for substance abuse and mental health disorders. SAMHSA provides federal support for these services by administering two block grants (one for substance abuse prevention and treatment services, the

other for mental health services), two other formula grants, and discretionary grants to local communities, states, and private entities to address the public health issues of substance abuse and mental illness. SAMHSA funds a wide range of activities, including strategic planning, education and training, prevention programs, early intervention, and treatment services.

In April 2006, SAMHSA published a matrix of the priority mental health and substance abuse issues addressed by the agency, along with the agency's cross-cutting principles.<sup>44</sup> The priority issue areas include individual health concerns such as co-occurring mental health and substance abuse disorders, suicide, and behavioral health issues for individuals with hepatitis and HIV/AIDS; societal issues such as homelessness and criminal justice; and systems-level issues such as treatment capacity and workforce development. In addition, SAMHSA has identified principles to guide program, policy, and resource allocation within the agency. These principles include use of evidence-based practices, evaluation, collaboration, cultural competence, stigma reduction, and cost-effectiveness.

## Organization and Key Programs

For FY2008, SAMHSA has a total budget of nearly \$3.4 billion and a staff of approximately 534.<sup>45</sup> For a breakdown of the agency's budget, see **Table 9**. SAMHSA is composed of three centers of operation, as described below. Each center has a director who reports to SAMHSA's Administrator. Each center has general authority to fund states and communities to address priority substance abuse and mental health needs. This authority, called Programs of Regional and National Significance (PRNS), authorizes SAMHSA to fund projects that (1) translate promising new research findings into 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. SAMHSA determines its funding priorities in consultation with states and other stakeholders. SAMHSA offers information on its programs through its website at <http://www.samhsa.gov>.

SAMHSA centers are as follows:

- **Center for Mental Health Services (CMHS).**<sup>46</sup> CMHS supports mental health services provided by the states and local governments through its mental health block grant and discretionary grant programs. CMHS is authorized to prevent mental illness and promote mental health by providing funds to evaluate, improve, and implement effective treatment practices, address violence among children, provide technical assistance to state and local mental health agencies, and collect data.
- **Center for Substance Abuse Prevention (CSAP).**<sup>47</sup> CSAP aims to improve the quality of substance abuse prevention practices nationwide. Through its discretionary grant programs, CSAP provides states, communities, organizations,

<sup>44</sup>

SAMHSA, *Matrix of Priorities*, April 2006, at [http://www.samhsa.gov/Matrix/Matrix\\_Brochure\\_2006.pdf](http://www.samhsa.gov/Matrix/Matrix_Brochure_2006.pdf).

<sup>45</sup> SAMHSA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2009*, available at [http://www.samhsa.gov/Budget/FY2009/SAMHSA\\_CJ2009.pdf](http://www.samhsa.gov/Budget/FY2009/SAMHSA_CJ2009.pdf).

<sup>46</sup> See <http://mentalhealth.samhsa.gov/cmhs/>.

<sup>47</sup> See <http://prevention.samhsa.gov/>.

and families with tools to promote protective factors and to reduce risk factors for substance abuse. CSAP also supports the National Clearinghouse for Alcohol and Drug Information (NCADI), the largest federal source of information about substance abuse research, treatment, and prevention available to the public.

- **Center for Substance Abuse Treatment (CSAT).**<sup>48</sup> CSAT aims to promote the quality and availability of community-based substance abuse treatment services for individuals and families who need them. CSAT works with states and community-based groups to improve and expand existing substance abuse treatment services under the formula-based substance abuse prevention and treatment block grant. CSAT also supports SAMHSA's free treatment referral service to link people with the community-based substance abuse services they need.

## History and Legislative Authorities

SAMHSA's predecessor agency, the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), was established in 1974. In 1992, Congress passed the ADAMHA Reorganization Act (P.L. 102-321), which, among other things, established SAMHSA as a services agency with programs focused on people with or at risk for mental or substance abuse disorders. The Act also moved the three research institutes—National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and National Institute on Alcohol Abuse and Alcoholism (NIAAA)—to NIH, and renamed ADAMHA as SAMHSA to reflect its focus on funding community-based services.

SAMHSA is authorized under Title V of the PHS Act, as amended (42 U.S.C. § 290aa—290kk-3). In PHS Act Title XIX, SAMHSA's block grants are authorized under Part B (42 U.S.C. § 300x-1—300x-66) and some additional programs are authorized under Part C (42 U.S.C. § 300y—300y-11). SAMHSA was last reauthorized in 2000, as part of the Children's Health Act.<sup>49</sup> At the time of that reauthorization, most of the agency's programs were extended for three years, through FY2003, and the block grant funding formula was not modified. The 2000 reauthorization focused on improving mental health and substance abuse services for children and adolescents, implementing proposals to give states more flexibility in the use of block grant funds, and replacing some existing categorical grant programs with general authority to give the Secretary of HHS more flexibility to respond to those who require mental health and substance abuse services.

Currently, authorizations for all of SAMHSA programs have expired. For additional information on SAMHSA, see CRS Report RL33997, *Substance Abuse and Mental Health Services Administration (SAMHSA): Reauthorization Issues*, by Ramya Sundararaman.

<sup>48</sup> See <http://csat.samhsa.gov/>.

<sup>49</sup> P.L. 106-310, Titles XXXI-XXXIV.

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

(dollars in millions)

Centers	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
<b>Center for Mental Health Services (CMHS)</b>				
Programs of Regional and National Significance	263	299	155	-48.1%
Mental Health Block Grant	407	400	400	0.0%
<i>PHS Evaluation Tap funding (non-add)<sup>a</sup></i>	<i>(21)</i>	<i>(21)</i>	<i>(21)</i>	<i>0.0%</i>
<i>Mental Health Block Grant, program level (non-add)</i>	<i>(428)</i>	<i>(421)</i>	<i>(421)</i>	<i>0.0%</i>
Children's Mental Health	104	102	114	12.0%
Projects for Assistance in Transition from Homelessness (PATH formula grant)	54	53	60	12.0%
Protection and Advocacy for Individuals with Mental Illness (PAIMI formula grant)	34	35	34	-2.5%
<b>Subtotal, CMHS budget authority</b>	<b>862</b>	<b>889</b>	<b>763</b>	<b>-14.2%</b>
PHS Evaluation Tap funding <sup>a</sup>	21	21	21	0.0%
<b>Subtotal CMHS program level</b>	<b>884</b>	<b>911</b>	<b>784</b>	<b>-13.9%</b>
<b>Center for Substance Abuse Treatment (CSAT)</b>				
Programs of Regional and National Significance	395	396	326	-17.7%
<i>PHS Evaluation Tap funding (non-add)<sup>a</sup></i>	<i>(4)</i>	<i>(4)</i>	<i>(11)</i>	<i>160.3%</i>
<i>PRNS, program level (non-add)</i>	<i>(399)</i>	<i>(400)</i>	<i>(337)</i>	<i>-15.8%</i>
Substance Abuse Prevention and Treatment (SAPT) Block Grant	1,679	1,680	1,699	1.1%
<i>PHS Evaluation Tap funding (non-add)<sup>a</sup></i>	<i>(79)</i>	<i>(79)</i>	<i>(79)</i>	<i>0.0%</i>
<i>SAPT Block Grant, program level (non-add)</i>	<i>(1,759)</i>	<i>(1,759)</i>	<i>(1,779)</i>	<i>1.1%</i>
<b>Subtotal, CSAT budget authority</b>	<b>2,074</b>	<b>2,076</b>	<b>2,025</b>	<b>-2.5%</b>
Subtotal, PHS Evaluation Tap funding <sup>a</sup>	84	84	90	17.5%
<b>Subtotal, CSAT program level</b>	<b>2,158</b>	<b>2,159</b>	<b>2,115</b>	<b>-2.0%</b>
<b>Center for Substance Abuse Prevention (CSAP)</b>				
Programs of Regional and National Significance	193	194	158	-18.6%
<b>Subtotal, CSAP budget authority</b>	<b>193</b>	<b>194</b>	<b>158</b>	<b>-18.6%</b>
<b>Subtotal, Program Management budget authority</b>	<b>77</b>	<b>75</b>	<b>75</b>	<b>0.0%</b>
PHS Evaluation Tap funding <sup>a</sup>	16	18	22	22.5%
<b>Subtotal, Program Management program level</b>	<b>93</b>	<b>93</b>	<b>97</b>	<b>4.3%</b>
<b>St. Elizabeths Hospital Buildings &amp; Facilities</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>na</b>
<b>Data Evaluation</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>na</b>
<b>Total, SAMHSA budget authority</b>	<b>3,206</b>	<b>3,234</b>	<b>3,025</b>	<b>-6.5%</b>

Centers	FY2007 actual	FY2008 enacted	FY2009 Pres. request	% change FY09 vs. FY08
Total, PHS Evaluation Tap funding <sup>a</sup>	121	122	133	8.9%
<b>TOTAL, SAMHSA program level</b>	3,327	3,356	3,158	-5.9%

**Source:** Adapted by CRS from SAMHSA, Justification of Estimates for Appropriations Committees, Fiscal Year 2009, p. Executive Summary-4.

**Note:** Totals and percentages may not compute exactly due to rounding.

a. Additional funds from PHS Evaluation Set-Aside (§ 241 of PHS Act).

## Additional Congressional Research Service (CRS) Reports

Agency Overview Reports CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by Judith A. Johnson.

CRS Report RL33022, *Indian Health Service: Health Care Delivery, Status, Funding, and Legislative Issues*, by Roger Walke.

CRS Report RL33695, *The National Institutes of Health (NIH): Organization, Funding, and Congressional Issues*, by Pamela W. Smith.

CRS Report RL33997, *Substance Abuse and Mental Health Services Administration (SAMHSA): Reauthorization Issues*, by Ramya Sundararaman.

### Appropriations Reports

CRS Report RL34132, *Agriculture and Related Agencies: FY2008 Appropriations*, by Jim Monke.

CRS Report RL34448, *Federal Research and Development Funding: FY2009*, by John F. Sargent Jr. et al.

CRS Report RL34461, *Interior, Environment, and Related Agencies: FY2009 Appropriations*, by Carol Hardy Vincent et al.

CRS Report RL34076, *Labor, Health and Human Services, and Education: FY2008 Appropriations*, by Pamela W. Smith, Gerald Mayer, and Rebecca R. Skinner.

## Links to Selected Reports on Current Legislative Issues

*Biomedical Research Policy and Funding:*

[http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2257&from=3&fromId=13](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2257&from=3&fromId=13).

Drugs, Biologics, and Medical Devices:



[http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2678&from=3&fromId=13](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2678&from=3&fromId=13).

Food Safety and Nutrition:

[http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2621&from=3&fromId=13](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2621&from=3&fromId=13).

Public Health and Emergency Preparedness:

[http://apps.crs.gov/cli/cli.aspx?PRDS\\_CLI\\_ITEM\\_ID=2628&from=3&fromId=13](http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=2628&from=3&fromId=13).

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<http://wikileaks.org/wiki/CRS-RL34098>