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

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Prepared for Members and Committees of Congress

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

## 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 appropriations to these agencies for FY2007 totaled more than \$49.5 billion. (This report does not yet reflect the effects of FY2007 supplemental appropriations.)

For each of the PHS agencies, this report describes the mission, organization, key programs, history, and legislative authorities, and provides budget tables for FY2006 through the FY2008 request. It will be updated as legislative and other events warrant.

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

# **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].

Title I	Short Title and Definitions
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

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

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

-	-
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
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
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], 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

 $<sup>^2</sup>$  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.

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, 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 FY2006 through the FY2008 request. Detailed budget tables are provided with each agency discussion. (This report does not yet reflect the effects of FY2007 supplemental appropriations.) 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 from the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriation.

<sup>&</sup>lt;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/].

A unique budget feature for the agencies funded under the Labor-HHS-ED appropriation and authorized by the PHS Act is the PHS "Evaluation Set-Aside" Fund, authorized by PHS Act § 241 (42 U.S.C. § 238j). This funding is available to the five PHS agencies mentioned, as well as several offices within the Office of the HHS Secretary, to assess the effectiveness of federal health programs and to identify ways to improve them. The annual Labor-HHS-ED appropriations act specifies the 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 available to each PHS agency. 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.

For each of the PHS agencies, this report describes the mission, organization, key programs, history, and legislative authorities, and provides budget tables for FY2006 through the FY2008 request. It will be updated as legislative and other events warrant.

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

Agencies	FY2006	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07		
Agency for Healthcare Research and Quality (AHRQ) <sup>a</sup>						
Discretionary budget authority	\$0.0	\$0.0	\$0.0	0.0%		
Total program level	\$318.7	\$319.0	\$329.6	3.3%		
Centers for Disease Control and Prevention (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR)						
Discretionary budget authority	\$6,389.9	\$6,012.7	\$5,791.7	-3.7%		
Total program level	\$8,631.6	\$9,185.4	\$8,821.9	-4.0%		
Food and Drug Administration (FDA	)					
Discretionary budget authority	\$1,494.7	\$1,574.2	\$1,640.7	4.2%		
Total program level	\$1,876.5	\$2,007.7	\$2,068.9	3.0%		
Health Resources and Services Administration (HRSA)						
Discretionary budget authority	\$6,630.3	\$6,458.6	\$5,859.8	-9.3%		
Total program level	\$6,679.0	\$6,510.6	\$5,908.7	-9.2%		

(dollars in millions)

<sup>&</sup>lt;sup>4</sup> Most of the funds appropriated for CDC, HRSA, NIH, and SAMHSA are available for PHS evaluations except, by HHS convention, for 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* at [http://aspe.hhs.gov/pic/perfimp/2002/appendixa.htm].

Agencies	FY2006	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07		
Indian Health Service (IHS)						
Discretionary budget authority	\$3,045.3	\$3,180.2	\$3,270.7	2.8%		
Total program level	\$3,843.5	\$3,978.4	\$4,121.0	3.6%		
National Institutes of Health (NIH)	National Institutes of Health (NIH)					
Discretionary budget authority	\$28,409.0	\$29,078.0	\$28,699.7	-1.3%		
Total program level	\$28,468.2	\$29,137.2	\$28,557.9	-2.0%		
Substance Abuse and Mental Health Services Administration (SAMHSA)						
Discretionary budget authority	\$3,203.2	\$3,206.1	\$3,046.4	-5.0%		
Total program level	\$3,324.5	\$3,327.0	\$3,167.6	-4.8%		
Total for PHS Agencies <sup>a</sup>				-		
Discretionary budget authority	\$49,172.4	\$49,509.8	\$48,309.0	-2.4%		

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

 a. AHRQ is financed through PHS evaluation funds, which are included in 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

<sup>&</sup>lt;sup>5</sup> For additional information, see [http://www.ahrq.gov/about/offcntrs.htm].

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 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 costeffectiveness. 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

<sup>&</sup>lt;sup>6</sup> See [http://www.ahrq.gov/qual/nhdr06/nhdr06.htm].

<sup>&</sup>lt;sup>7</sup> For more information, see [http://www.effectivehealthcare.ahrq.gov].

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 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 FY2006 through FY2008. 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	FY2006	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07		
Research on Health Costs, Quality, and Outcomes (HCQO)						
Budget Authority	0.0	0.0	0.0	0.0		
Evaluation Tap funding <sup>a</sup>	\$260.7	\$261.0	\$271.6	4.1%		
Patient Safety Research (non-add)	(84.0)	(84.0)	(93.9)	11.8%		
Health Information Technology (non-add) <sup>b</sup>	(49.9)	(49.9)	(44.8)	-10.2%		

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

Activities	FY2006	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07		
Comparative Effectiveness (non-add)	(15.0)	(15.0)	(15.0)	0.0		
Medical Expenditure Panel Surveys (MEPS)						
Budget Authority	0.0	0.0	0.0	0.0		
Evaluation Tap funding <sup>a</sup>	55.3	55.3	55.3	0.0		
Program Support	Program Support					
Budget Authority	0.0	0.0	0.0	0.0		
Evaluation Tap funding <sup>a</sup>	2.7	2.7	2.7	0.0		
Total, AHRQ budget authority	0.0	0.0	0.0	0.0		
Evaluation Tap Funding <sup>a</sup>	318.7	319.0	329.6	3.3%		
Total, AHRQ program level	\$318.7	\$319.0	\$329.6	3.3%		

**Sources:** Adapted by CRS from AHRQ Operating Plan for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007; House Appropriations Committee table (April 17, 2007); and AHRQ FY2008 Justification of Estimates for Appropriations Committees, at [http://www.ahrq.gov/about/cj2008/cj2008.pdf].

Note: Numbers may not add due to rounding.

a. AHRQ receives its entire funding through transfers from other PHS agencies under the PHS program evaluation set-aside (§ 241 of the PHS Act).

b. Patient safety research includes 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.

<sup>&</sup>lt;sup>9</sup> See the CDC website at [http://www.cdc.gov/].

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 *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.
- 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*

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

<sup>&</sup>lt;sup>12</sup> See CDC's current annual report, *The State of CDC, FY2006*, (employment statistics are on p. 35) at [http://www.cdc.gov/about/stateofcdc/cdrom/SOCDC/SOCDC2006.pdf].

*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.
- 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 and is authorized through FY2007.<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. The Center's 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> NCHS and ATSDR have continued to receive annual appropriations despite their expired authorities.

<sup>&</sup>lt;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>&</sup>lt;sup>14</sup> 29 U.S.C. § 671.

<sup>&</sup>lt;sup>15</sup> 42 U.S.C. § 247b-4.

<sup>&</sup>lt;sup>16</sup> 42 U.S.C. § 9604(I).

<sup>&</sup>lt;sup>17</sup> 42 U.S.C. § 9611(m).

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

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 FY2006 through FY2008. 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 requests almost \$1 billion above the agency's FY2007 level.<sup>18</sup>

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

Programs	FY2006 <sup>a</sup>	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07
Infectious Diseases, budget authority	\$1,682.4	\$1,791.4	\$1,781.6	-0.5%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	(12.8)	(12.8)	(12.8)	
Infectious Diseases, program level	1,695.2	1,804.2	1,794.4	-0.5%
Health Promotion	958.0	959.7	958.7	-0.1%
Health Information and Service, budget authority	84.7	88.4	108.4	22.6%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	(134.2)	(134.2)	(135.1)	0.7%
Health Information and Service, program level	218.9	222.7	243.5	9.3%
Environmental Health and Injury	287.5	288.1	287.7	-0.1%
Occupational Safety and Health, budget authority	175.8°	167.0	165.9	-0.7%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	(87.1)	(87.1)	(87.1)	
Occupational Safety and Health, program level	262.9 <sup>c</sup>	254.1	253.0	-0.4%

(dollars in millions)

<sup>&</sup>lt;sup>18</sup> See [http://www.fundcdc.org/documents/CDCFY2008PJ\_000.pdf].

Programs	FY2006ª	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07
Global Health	379.6 <sup>d</sup>	334.0	379.7	13.7%
Terrorism	1,631.2 <sup>e</sup>	1,541.3	1,504.4	-2.4%
Public Health Research, budget authority	0.0	0.0	0.0	
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	(31.0)	(31.0)	(31.0)	
Public Health Research, program level	31.0	31.0	31.0	0.0%
Public Health Improvement and Leadership	264.1 <sup>f</sup>	189.8	190.4	0.3%
Preventive Health and Health Services Block Grant	98.9	99.0	0.0	-100.0%
Buildings and Facilities	158.3	134.4	20.0	-85.1%
Business Services Support	317.6	344.3	319.9	-7.1%
Pandemic Influenza supplemental appropriations	277.0 <sup>g</sup>	0.0	0.0	
Subtotal, Labor-HHS-ED appropriation	\$6,315.0	\$5,937.5	\$5,716.7	-3.7%
ATSDR (Interior/Environment appropriation)	74.9	75.2	75.0	-0.3%
Total, CDC/ATSDR budget authority	\$6,389.9	\$6,012.7	\$5,791.7	-3.7%
Total, PHS Program Evaluation Set-Aside <sup>b</sup>	265.1	265.1	266.0	0.3%
Vaccines for Children (VFC), <sup>h</sup> current law	1,974.3	2,905.3	2,762.0	-4.9%
User fees <sup>i</sup>	2.2	2.2	2.2	
Total, CDC/ATSDR program level	\$8,631.6	\$9,185.4	\$8,821.9	-4.0%

**Sources:** Adapted by CRS from CDC FY2007 Joint Resolution Detail Table, reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007, and FY2008 Congressional Justifications for CDC and ATSDR, at [http://www.cdc.gov/fmo/fmofybudget.htm].

Note: Numbers may not add due to rounding.

- a. FY2006 reflects 1% rescission and HHS internal transfer.
- b. Funds from PHS program evaluation set-aside (§ 241 of the PHS Act).
- c. Includes \$10 million in supplemental funding for mining safety.
- d. Includes \$68 million in FY2006 emergency supplemental appropriations.
- e. Includes \$55 million in FY2006 emergency supplemental appropriations.
- f. Includes \$75 million in FY2006 emergency supplemental appropriations.
- g. Amounts from P.L. 109-148 and P.L. 109-234.
- h. 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.
- i. CDC is authorized to collect fees from researchers and others who use certain of the agency's databases.

# Food and Drug Administration (FDA)

#### 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 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. [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>19</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>20</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)				
1980	HEW (without Education) became the Dept. of Health and Human Services (HHS)				

The FFDCA is the principal source of FDA's authority.<sup>21</sup> The Act consists of the following chapters, governing the majority of FDA's activities:

Chapter I:	Short Title.
Chapter II:	Definitions.
Chapter III:	Prohibited Acts and Penalties.
Chapter IV:	Food. Pursuant to the definition in Section 201, food is defined to include foods for humans, as well as animal feeds, including pet food.
Chapter V:	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.
Chapter VI:	Cosmetics.

<sup>&</sup>lt;sup>19</sup> Kefauver-Harris Drug Amendments to the FFDCA, P.L. 87-781 (1962).

<sup>&</sup>lt;sup>20</sup> See FDA and USDA Web pages at [http://www.fda.gov/opacom/backgrounders/ miles.html] and [http://www.fsis.usda.gov/About\_FSIS/Agency\_History/index.asp].

<sup>&</sup>lt;sup>21</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/].

Chapter VII:	General Authority. Includes, among other things, authority to
	promulgate regulations, and to conduct inspections and
	investigations. <sup>22</sup>
Chapter VIII:	Imports and Exports.
Chapter IX:	Miscellaneous.

FDA is also responsible for certain provisions in other laws, most notably the Public Health Service (PHS) Act.<sup>23</sup> The PHS Act contains certain specific provisions that are implemented by FDA, such as mammography quality standards.<sup>24</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>25</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>26</sup> Furthermore, different types of biologics may be regulated by either CDER or CBER.<sup>27</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.

**Budget.** FDA has an annual budget of about \$2 billion. **Table 5** presents FDA funding levels for FY2006 through FY2008. 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 (\$1.569 billion in FY2007), with a much smaller amount for buildings and facilities (\$5 million in FY2007). User fees (\$433.5 million in FY2007) 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 FY2007 total for FDA — the program level — was \$2.008 billion, 7% above the level enacted for FY2006.

<sup>&</sup>lt;sup>22</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>&</sup>lt;sup>23</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>&</sup>lt;sup>24</sup> Public Health Service Act, Sec. 354, 42 U.S.C. § 263b.

<sup>&</sup>lt;sup>25</sup> Public Health Service Act, Sec. 361, 42 U.S.C. § 264.

<sup>&</sup>lt;sup>26</sup> See FDA, Center for Biologics Evaluation and Research, "Frequently Asked Questions," June 4, 2007, at [http://www.fda.gov/cber/faq.htm].

<sup>&</sup>lt;sup>27</sup> See FDA, "Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research," June 30, 2003, at [http://www.fda.gov/oc/combination/transfer.html].

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.

			FY2007 final	FY2008 Pres.	% change FY08 vs.
Program area	Funds	FY2006	enacted	request <sup>a</sup>	FY2007
Foods	BA	\$438.7	\$457.1	\$466.7	2.1%
	Fees			—	—
	Total	438.7	457.1	466.7	2.1%
Human drugs	BA	297.7	315.1	324.4	3.0%
	Fees	219.8	255.2	232.4	-9.0%
	Total	517.6	570.4	556.8	-2.4%
Biologics	BA	139.0	144.5	155.1	7.3%
	Fees	56.5	65.7	60.8	-7.6%
	Total	195.5	210.3	215.8	2.6%
Animal drugs and feeds	BA	89.6	94.7	94.8	0.1%
	Fees	9.3	9.5	11.5	20.8%
	Total	98.9	104.3	106.3	2.0%
Devices and radiological health <sup>b</sup>	BA	220.6	230.7	240.1	4.1%
	Fees	39.9	42.2	45.3	7.1%
	Total	260.5	272.9	285.4	4.6%
Toxicological research (NCTR)	BA	40.7	42.1	36.5	-13.3%
	Fees			—	—
	Total	40.7	42.1	36.5	-13.3%
Headquarters and Office of the	BA	86.9	90.5	88.6	-2.2%
Commissioner <sup>b</sup>	Fees	30.5	32.1	32.9	2.3%
	Total	117.4	122.6	121.4	-1.0%
GSA rent	BA	116.4	126.9	131.5	3.7%
	Fees	17.3	19.1	26.9	40.5%
	Total	133.7	146.0	158.4	8.5%
Other rent and rent-related	BA	57.2	67.6	98.0	45.0%
(including White Oak	Fees	0.8	1.1	9.1	766.9%
consolidation)	Total	57.9	68.6	107.1	56.1%
Export and color certification	BA	_	_	—	—
funds	Fees	7.6	8.5	9.5	12.0%
	Total	7.6	8.5	9.5	12.0%
Subtotal, Salaries & Expenses	BA	1,486.8	1,569.2	1,635.7	4.2%
	Fees	381.8	433.5	428.3	-1.2%
	Total	1,868.6	2,002.8	2,064.0	3.1%

 
 Table 5. Food and Drug Administration (FDA) (dollars in millions)

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Buildings & Facilities	BA	7.9	5.0	5.0	0.0%
	Fees		—	—	—
	Total	7.9	5.0	5.0	0.0%
Total, FDA Budget Authority	BA	1,494.7	1,574.2	1,640.7	4.2%
	Fees	381.8	433.5	428.3	-1.2%
Total, FDA Program Level	Total	\$1,876.5	\$2,007.7	\$2,068.9	3.0%

**Sources:** Adapted by CRS from FDA Operating Plan for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007, and FDA, *Fiscal Year 2008 Justification of Estimates for Appropriations Committees*, February 2007, at [http://www.fda.gov/oc/oms/ofm/budget/documentation.htm].

**Notes:** Totals may not add 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. Does not include proposed generic drug user fee (\$15.7 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 44 million Americans who lack health insurance, 50 million Americans who live in rural and poor urban areas where health-care services are scarce, 900,000 people living with HIV/AIDS, and 87,000 Americans who are waiting for an organ transplant.

HRSA provides leadership for and support of 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 care needs for persons living with HIV/AIDS. In addition, HRSA administers the program for community health centers (CHCs), 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 nearly 3,700 health centers and clinics that provide routine access to health care for 14 million people living in inner city and rural areas.
- The Maternal and Child Health Bureau seeks to strengthen the infrastructure for maternal and child health services. The Maternal and Child Health Block 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>28</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 **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.
- The **Bureau of Clinician Recruitment and Service** administers programs authorized under various titles of the PHS Act. The National Health Service Corps (authorized in Title III) and various health professions and nursing programs (authorized in Titles VII and VIII, respectively) 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 **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.

<sup>&</sup>lt;sup>28</sup> P.L. 109-415 was signed on December 19, 2006.

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>29</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 *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, 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 are authorized in Title III of the PHS Act. Also, all Ryan White HIV/AIDS programs are consolidated in Title XXVI of the PHS Act. Maternal and Child Health Block Grants and the Rural Health Policy Development Programs are authorized in various sections of the Social Security Act. Finally, the Black Lung Program, which supports clinics that provide services to retired coal miners and others, is authorized in Section 427(e) of the Federal Mine Safety and Health Amendments Act (P.L. 95-164), which amended the Federal Coal Mine Safety Act of 1969.

**Table 6** presents funding levels for HRSA programs for FY2006 through FY2008.

<sup>&</sup>lt;sup>29</sup> See more information at HRSA's website, at [http://www.hrsa.gov/about/default.htm].

Table 6. Health Resources and Services Administration (HRSA)
(dollars in millions)

		FY2007	FY2008	% change
Bureaus, Offices, and Programs	FY2006	final enacted	Pres. request	FY08 vs. FY07
Health Centers <sup>a</sup>	\$1,785.1	\$1,988.0	\$1,988.5	0.0%
Other BPHC Programs	18.1	18.2	18.3	0.0%
Subtotal, Bureau of Primary Health Care (BPHC)	1,803.2	2,006.3	2,006.8	0.0%
National Health Service Corps	125.4	125.7	116.0	-7.7%
Other — clinician loan programs	37.1	37.1	48.5	30.7%
Subtotal, Bureau of Clinician Recruitment and Service	162.5	162.8	164.5	1.0%
Title VII Health Professions	143.8	183.5	9.7	-94.7%
Title VIII Nursing Workforce Development	113.8	113.9	56.8	-50.1%
Children's Hospitals Graduate Medical Education	296.8	297.0	110.0	-63.0%
Subtotal, Bureau of Health Professions	554.4	594.3	176.5	-70.3%
Maternal and Child Health Block Grant	692.5	693.0	693.0	0.0%
Healthy Start	101.4	101.5	100.5	-1.0%
Other MCHB Programs	40.7	40.7	2.2	-85.8%
Subtotal, Maternal and Child Health Bureau (MCHB)	834.6	835.2	795.7	-4.7%
Subtotal, HIV/AIDS Bureau	2,036.3	2,118.9	2,132.9	0.7%
Subtotal, Healthcare Systems Bureau	75.2	69.1	60.7	-12.2%
Subtotal, Rural Health Programs	167.8	167.9	24.7	-85.3%
Other HRSA Programs				
Family Planning	282.9	283.1	283.1	0.0%
Bioterrorism Hospital Grants to States <sup>b</sup>	494.7	NA	NA	NA
Telehealth + Program Management	151.2	153.1	151.0	-1.4%
Subtotal, Other HRSA Programs	928.8	436.3	434.1	-0.5%
Total, Health Resources and Services account	\$6,562.9	\$6,390.7	\$5,795.8	-9.3%
Health Education Assistance Loans (HEAL)	2.9	2.9	2.9	0.0%
Vaccine Injury Compensation Program	64.5	65.0	61.1	-6.0%
Total, HRSA discretionary budget authority	\$6,630.3	\$6,458.6	\$5,859.8	-9.3%
National Practitioner Data Bank (User Fees) <sup>c</sup>	15.7	16.2	18.9	16.7%
Health Care Integrity and Protection Data Bank (User Fees) <sup>c</sup>	4.0	3.8	0.0	-100%
Family-to-Family Health Information Centers (mandatory) <sup>d</sup>	0.0	3.0	4.0	33.3%
PHS Program Evaluation Set-Aside <sup>e</sup>	25.0	25.0	25.0	0.0%
HEAL Liquidating Account	4.0	4.0	1.0	-75.0%
Total, HRSA program level	\$6,679.0	\$6,510.6	\$5,908.7	-9.2%

**Sources:** Adapted by CRS from HRSA Operating Plan for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007, and House Appropriations Committee table (April 17, 2007).

**Notes:** Numbers may not add due to rounding. "NA" means not applicable (program transferred to the Office of the HHS Secretary.) 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 (72 FR 19540, April 18, 2007). This table reflects the change by posting those programs under a header for the new Bureau.

- a. FY2006 includes \$4 million in one-time supplemental funding for communications equipment for health centers affected by Hurricane Katrina and other hurricanes of the 2005 season, in P.L. 109-234.
- b. Appropriations for bioterrorism hospital grants to states were transferred to the HHS Office of the Secretary in FY2007, pursuant to P.L. 100-5, Revised Continuing Appropriations Resolution, 2007.
- c. User fees available for Bureau of Health Professions.
- d. Mandatory funds for Maternal and Child Health Bureau appropriated in the Deficit Reduction Act of 2005 (P.L. 109-171).
- e. Additional funds for Ryan White AIDS programs from PHS program 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 561 federally recognized Indian<sup>30</sup> tribes (totaling about 1.8 million Indians in 35 states) who are in IHS service delivery areas.<sup>31</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 treaties, statutes, 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

<sup>&</sup>lt;sup>30</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>&</sup>lt;sup>31</sup> IHS also funds limited health services to Indians in certain urban areas.

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 167 service units (each assigned to an area office).<sup>32</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;
- 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 48 inpatient hospitals and 603 ambulatory facilities (which include 272 health clinics, 154 health stations, 166 Alaska village clinics, and 11 school health centers). Fifteen of the hospitals and 511 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>33</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>34</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

<sup>&</sup>lt;sup>32</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.

<sup>&</sup>lt;sup>33</sup> P.L. 93-638, act of January 4, 1975, 88 Stat. 2203, as amended; 25 U.S.C. § 450 et seq.

<sup>&</sup>lt;sup>34</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 2008*, pp. CJ-121 and CJ-251, at [http://www.hhs.gov/budget/docbudget.htm].

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 the new department. 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>35</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>36</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>37</sup> authorizing the PHS to construct sanitation facilities for Indian communities and homes; the Indian Health Care Improvement Act (IHCIA) of 1976,<sup>38</sup> which established many specific IHS programs, such as urban health, professions recruitment, and mental health, and also authorized IHS (through amendments to the Social Security Act) to make direct collections from Medicare/Medicaid and third-party insurers; and the Indian Self-Determination and Education Assistance Act of 1975,<sup>39</sup> which 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 IHCIA'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 IHCIA reauthorization bills since the 106<sup>th</sup> Congress. The IHCIA reauthorization bills in the 110<sup>th</sup> Congress, S. 1200 and H.R. 1328, have been ordered reported from a committee, although the House bill must be considered by other committees of jurisdiction.

**Table 7** presents funding levels for IHS programs for FY2006 through FY2008.

<sup>&</sup>lt;sup>35</sup> Act of November 2, 1921, 42 Stat. 208, as amended; 25 U.S.C. § 13.

<sup>&</sup>lt;sup>36</sup> P.L. 83-568, act of August 5, 1954, 68 Stat. 674, as amended; 42 U.S.C. § 2001 et seq.

<sup>&</sup>lt;sup>37</sup> P.L. 86-121, act of July 31, 1959, 73 Stat. 267; 42 U.S.C. § 2004a.

<sup>&</sup>lt;sup>38</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>&</sup>lt;sup>39</sup> P.L. 93-638, act of January 4, 1975, 88 Stat. 2203, as amended; 25 U.S.C. § 450 et seq.

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

(dollars in millions)

_		FY2007 final	FY2008 Pres.	% change FY08 vs.			
Programs	FY2006	enacted	request	FY07			
Health Services Clinical Services							
	¢1 220 5	¢1 440 5	¢1 402 5	2.50/			
Hospitals and Health Clinics Dental Health	\$1,339.5	\$1,442.5	\$1,493.5	3.5%			
Mental Health	117.7	126.9	135.8	7.0%			
	58.5	61.7	64.5	4.7%			
Alcohol and Substance Abuse	143.2	150.6	162.0	7.6%			
Contract Health Care	499.6	499.6	551.5	10.4%			
Catastrophic Health Emergency Fund	17.7	17.7	18.0	1.5%			
Subtotal, Clinical Services	2,176.2	2,298.9	2,425.3	5.5%			
Preventive Health	40.0	52.0	560	7.00			
Public Health Nursing Health Education	49.0	53.0	56.8	7.2%			
	13.6	14.5	15.2	5.2%			
Community Health Reps.	52.9	55.7	55.8	0.1%			
Immunization (Alaska)	1.6	1.7	1.8	3.2%			
Subtotal, Preventive Health	117.1	124.9	129.6	3.7%			
Other Health Services							
Urban Health Projects	32.7	34.0	0.0	-100%			
Indian Health Professions	31.0	31.7	31.9	0.6%			
Tribal Management	2.4	2.5	2.5	1.8%			
Direct Operations	62.2	63.8	64.6	1.3%			
Self-Governance	5.7	5.8	5.9	1.5%			
Contract Support Costs	264.7	264.7	271.6	2.6%			
Collections (non-add)	(648.2)	(648.2)	(700.3)	(8.0%)			
Subtotal, Other Health Services	398.7	402.5	376.5	-6.5%			
Subtotal, All Health Services	2,692.1	2,826.3	2,931.5	3.7%			
Health	Facilities						
Maintenance and Improvement	51.6	52.7	51.9	-1.4%			
Sanitation Facilities Construction	92.1	94.0	88.5	-5.9%			
Health Care Facilities Construction	37.8	24.3	12.7	-47.9%			
Facilities/Environmental Health Support	150.7	161.3	164.8	2.2%			
Equipment	20.9	21.6	21.3	-1.6%			
Subtotal, Health Facilities	353.2	353.9	339.2	-4.2%			
		<b>#3</b> 400 5	<b>43 65</b> 0 -	• • • •			
Total, IHS discretionary budget authority	\$3,045.3	\$3,180.2	\$3,270.7	2.8%			
Collections	\$648.2	\$648.2	\$700.3	8.0%			
Special Diabetes Program for Indians <sup>a</sup>	\$150.0	\$150.0	\$150.0	0%			
Total, IHS program level	\$3,843.5	\$3,978.4	\$4,121.0	3.6%			

Sources: FY2008 IHS budget justification, IHS FY2007 operating plan.

Note: Numbers may not add due to rounding.

a. Funds available to IHS for Special Diabetes Program for Indians (P.L. 105-33, P.L. 106-554, and P.L. 107-360).

#### 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>40</sup>

NIH is the largest of the PHS agencies, with a budget of \$29.1 billion in FY2007 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 who work in universities, 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 8**, 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>41</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

<sup>&</sup>lt;sup>40</sup> See [http://www.nih.gov/about/].

<sup>&</sup>lt;sup>41</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].

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.
- 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 new NIH Reform Act authorized total funding levels for NIH appropriations for FY2007 to FY2009 and eliminated all of the other specific authorizations in Title IV.

Table 8 presents funding levels for NIH accounts for FY2006 through FY2008.

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

(dollars in millions)

Institutes and Centers (ICs)	FY2006 <sup>a,b</sup>	FY2007 final enacted <sup>a</sup>	FY2008 Pres. request	% change FY08 vs. FY2007
Cancer (NCI)	\$4,790.1	\$4,797.6	\$4,782.1	-0.3%
Heart/Lung/Blood (NHLBI)	2,919.8	2,922.9	2,925.4	0.1%
Dental/Craniofacial Research (NIDCR)	389.1	389.7	389.7	0.0%
Diabetes/Digestive/Kidney (NIDDK)	1,703.8	1,705.9	1,708.0	0.1%
Neurological Disorders/Stroke (NINDS)	1,533.7	1,535.5	1,537.0	0.1%
Allergy/Infectious Diseases (NIAID) <sup>c,d</sup>	4,429.8	4,417.2	4,592.5	4.0%
General Medical Sciences (NIGMS)	1,934.3	1,935.8	1,941.5	0.3%
Child Health/Human Development (NICHD)	1,263.9	1,254.7	1,264.9	0.8%
Eye (NEI)	666.3	667.1	667.8	0.1%
Environmental Health Sciences (NIEHS)	636.2	642.0	637.4	-0.7%
Aging (NIA)	1,045.9	1,047.3	1,047.1	0.0%
Arthritis/Musculoskeletal/Skin (NIAMS)	507.6	508.2	508.1	0.0%
Deafness/Communication Disorders (NIDCD)	393.2	393.7	393.7	0.0%
Nursing Research (NINR)	137.2	137.4	137.8	0.3%
Alcohol Abuse/Alcoholism (NIAAA)	435.6	436.3	436.5	0.1%
Drug Abuse (NIDA)	999.3	1,000.6	1,000.4	0.0%
Mental Health (NIMH)	1,402.6	1,404.5	1,405.4	0.1%
Human Genome Research (NHGRI)	485.7	486.5	484.4	-0.4%
Biomedical Imaging/Bioengineering (NIBIB)	296.6	296.9	300.5	1.2%
Research Resources (NCRR)	1,098.3	1,133.2	1,112.5	-1.8%
Complementary/Alternative Med (NCCAM)	121.4	121.6	121.7	0.1%
Minority Health/Health Disparities (NCMHD)	195.3	199.4	194.5	-2.5%
Fogarty International Center (FIC)	66.3	66.4	66.6	0.2%
Library of Medicine (NLM)	314.7	320.9	312.6	-2.6%
Office of Director (OD) <sup>d,e</sup>	477.7	1,096.4	517.1	-52.8%
Buildings & Facilities (B&F)	85.5	81.1	136.0	67.7%
Subtotal, Labor/HHS Appropriation	\$28,329.8	\$28,998.9	\$28,621.2	-1.3%
Superfund (Interior approp to NIEHS) <sup>f</sup>	79.1	79.1	78.4	-0.9%
Total, NIH discretionary budget authority	\$28,409.0	\$29,078.0	\$28,699.7	-1.3%
Pre-appropriated Type 1 diabetes funds <sup>g</sup>	150.0	150.0	150.0	0.0%
NLM program evaluation <sup>h</sup>	8.2	8.2	8.2	0.0%
Total, NIH program level	\$28,567.2	\$29,236.2	\$28,857.9	-1.3%
Global Fund transfer (AIDS/TB/Malaria) <sup>c</sup>	-99.0	-99.0	-300.0	203.0%
Total, NIH program level after transfer	\$28,468.2	\$29,137.2	\$28,557.9	-2.0%

**Sources:** Adapted by CRS from NIH Operating Plan for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007, and House Appropriations Committee table (April 17, 2007).

- a. The FY2007 program level is an increase of \$669.049m (2.4%) over FY2006. FY2006 and FY2007 do not reflect comparative transfers to HHS (\$0.542m) or among NIH ICs that are shown in the FY2008 budget justification. FY2007 does not reflect the transfer of \$99.0m from NIH to the Office of the Secretary, as mandated by the supplemental appropriations act, P.L. 110-28 (see note d).
- b. FY2006 reflects across-the-board rescission (1%), Interior reduction, and HHS transfer of \$19.462m to Centers for Medicare and Medicaid Services. Also reflects Director's transfer of \$4.480m from NIEHS to B&F. Does not include \$6.896m in NCI breast cancer stamp funds.

- c. NIAID totals include funds for transfer to the Global Fund to Fight HIV/AIDS, TB, and Malaria. FY2006 includes \$18.0m supplemental funding (P.L. 109-148) transferred from the Public Health and Social Services Emergency Fund (PHSSEF) for pandemic flu.
- d. FY2006 and FY2007 include \$49.5m in NIAID for Advanced Development of Medical Countermeasures. The FY2008 request funds the Advanced Development program in the HHS Assistant Secretary for Preparedness and Response. Not reflected in the table: For FY2007, the war/emergency supplemental appropriations act (P.L. 110-28, May 25, 2007) transferred Advanced Development funding to the PHSSEF (\$49.5m from NIAID and \$49.5m from OD).
- e. OD has Roadmap funds for distribution to ICs (FY2006, \$82.170m; FY2007, \$483.000m; FY2008, \$121.540m). In FY2007, all Roadmap/Common Fund money is in OD; in other years, IC budgets are tapped for Roadmap contributions.
- f. Separate account in the Interior/Environment/Related Agencies appropriation for NIEHS research activities related to Superfund.
- g. Funds available to NIDDK for diabetes research under PHS Act § 330B (P.L. 106-554 and P.L. 107-360).
- h. Additional funds from program 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 crosscutting principles.<sup>42</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.

<sup>&</sup>lt;sup>42</sup> SAMHSA, *Matrix of Priorities*, April 2006, at [http://www.samhsa.gov/Matrix/Matrix\_Brochure\_2006.pdf].

#### **Organization and Key Programs**

For FY2007, SAMHSA has a budget of \$3.3 billion and a staff of approximately 540.<sup>43</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>44</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>45</sup> CSAP aims to improve the quality of substance abuse prevention practices nationwide. Through its discretionary grant programs, CSAP provides states, communities, organizations, 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>46</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

<sup>&</sup>lt;sup>43</sup> SAMHSA, *Justification of Estimates for Appropriations Committees, Fiscal Year 2008*, p. Overview-9, available from [http://www.samhsa.gov/Budget/FY2008/index.aspx].

p. overview y, available from [http://www.sailinbu.gov/Duage/112000

<sup>&</sup>lt;sup>44</sup> See [http://mentalhealth.samhsa.gov/cmhs/].

<sup>&</sup>lt;sup>45</sup> See [http://prevention.samhsa.gov/].

<sup>&</sup>lt;sup>46</sup> See [http://csat.samhsa.gov/].

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. SAMHSA's block grants are authorized under PHS Act Title XIX, Part B. SAMHSA was last authorized in 2000, as part of the Children's Health Act.<sup>47</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.

Two SAMHSA programs have authorizations that will expire at the end of FY2007: Suicide Technical Assistance Center (PHS Act § 520C) and Youth Suicide Early Intervention and Prevention Strategies (PHS Act § 520E).

<sup>&</sup>lt;sup>47</sup> P.L. 106-310, Titles XXXI-XXXIV.

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

(dollars in millions)

Centers	FY2006 <sup>a</sup>	FY2007 final enacted	FY2008 Pres. request	% change FY08 vs. FY07
CMHS	F 12000	enacteu	request	1107
Programs of Regional and National Significance	\$263.1	\$263.3	\$186.6	-29.1%
Mental Health Block Grant	406.6	406.8	406.8	0.0%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	21.8	21.4	21.4	0.0%
Children's Mental Health	104.0	104.1	104.1	0.0%
Projects for Assistance in Transition from Homelessness (PATH formula grant)	54.2	54.3	54.3	0.0%
Protection and Advocacy for Individuals with				
Mental Illness (PAIMI formula grant)	34.0	34.0	34.0	0.0%
Subtotal, CMHS budget authority	861.9	\$862.4	\$785.8	-8.9%
CSAT				
Programs of Regional and National Significance	394.4	394.6	347.8	-11.9%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	4.3	4.3	4.3	0.0%
Substance Abuse Prevention and Treatment Block	1 (70.0	1 (70.4	1 (70 4	0.00/
Grant	1,678.2	1,679.4	1,679.4	0.0%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	79.2	79.2	79.2	0.0%
Subtotal, CSAT budget authority	2,072.6	2,074.0	2,027.2	-2.3%
CSAP				
Programs of Regional and National Significance	192.8	192.9	156.5	-18.9%
Subtotal, CSAP budget authority	192.8	192.9	156.5	-18.9%
Program Management				
Program Management	76.0	76.7	77.0	0.4%
PHS Program Evaluation Set-Aside (non-add) <sup>b</sup>	16.0	16.0	16.3	1.9%
Total, Program Management budget authority	76.0	76.7	77.0	0.4%
Total, SAMHSA budget authority	\$3,203.2	\$3,206.1	\$3,046.4	-5.0%
Total, PHS Program Evaluation Set-Aside <sup>b</sup>	121.3	120.9	121.2	0.2%
TOTAL, SAMHSA program level	\$3,324.5	\$3,327.0	\$3,167.6	-4.8%

**Sources:** Adapted by CRS from SAMHSA Operating Plan for FY2007 (March 2007), reflecting final funding levels under P.L. 110-5, Revised Continuing Appropriations Resolution, 2007, and House Appropriations Committee table (April 17, 2007).

Note: Numbers may not add due to rounding.

a. FY2006 reflects 1% rescission and HHS internal transfer.

b. Additional funds from PHS program evaluation set-aside (§ 241 of PHS Act).

# Additional Congressional Research Service (CRS) Reports

#### **Agency Overview Reports**

RL33022, Indian Health Service: Health Care Delivery, Status, Funding, and Legislative Issues, by Donna U. Vogt and Roger Walke.

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

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

## **Appropriations Reports**

RL33412, Agriculture and Related Agencies: FY2007 Appropriations, by Jim Monke, Coordinator. (FDA)

RL34011, *Interior, Environment, and Related Agencies: FY2008 Appropriations*, by Carol Hardy Vincent, Coordinator. (ATSDR, IHS)

RL34076, Labor, Health and Human Services, and Education: FY2008 Appropriations, by Pamela W. Smith, Coordinator. (AHRQ, CDC, HRSA, NIH, SAMHSA)

#### Links to Selected Reports on Current Legislative Issues

*Biomedical Research Policy: Stem Cells, Genetics, and Other Research Areas:* [http://apps.crs.gov/cli/cli.aspx?PRDS\_CLI\_ITEM\_ID=2257&from=3&fromId=13].

*Drugs and Medical Devices: Safety, Effectiveness, and Availability:* [http://apps.crs.gov/cli/cli.aspx?PRDS\_CLI\_ITEM\_ID=2678&from=3&fromId=13].

*Food Supply: Safety, Affordability, and Nutrition:* [http://apps.crs.gov/cli/cli.aspx?PRDS\_CLI\_ITEM\_ID=2621&from=3&fromId=13].

*Public Health and Medical Preparedness and Response:* [http://apps.crs.gov/cli/cli.aspx?PRDS\_CLI\_ITEM\_ID=2628&from=3&fromId=13].