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Subject: **Statutory Authorizations for Department of Health and Human Services (HHS) Operating Divisions**

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This memorandum provides an overview of the statutory provisions (authorization and appropriations) that govern the organizational structure of operating divisions within the U.S. Department of Health and Human Services (HHS, or the Department). Prior to the March 27, 2025 HHS announcement regarding the reorganization of the agency, HHS was organized into 13 main agencies called *operating divisions*, a term the Department generally uses to refer to agencies that directly administer HHS programs.

The March 2025 reorganization plan would, among other things, create certain new operating divisions and other units, consolidate or eliminate certain existing operating divisions and other units, and transfer the functions of certain existing operating divisions and other units.[1] In May 2025, HHS published

[1] U.S. Department of Health and Human Services, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html (accessed on June 5, 2025). The official status of the operating divisions post-March 27, 2025, is unclear. References to the operating divisions prior to March 27, 2025, are not intended to reflect any observations regarding their status after that date.

As of the date of this writing, unions, agency employees, local governments, and at least 19 states and the District of Columbia have challenged different aspects of the agency's reorganization in federal courts across the country. As a result, some aspects of the reorganization have been preliminarily enjoined by a federal court, and litigation remains ongoing. See Order Granting Preliminary Injunction, New York v. Kennedy, No. 25-196 (D.R.I. July 1, 2025) ECF No. 73 (granting preliminary injunction (continued...)

additional information and revised details on its planned reorganization in its FY2026 budget documents, some of which contained information differing from the original announcement.[2] The HHS operating divisions and units that could be affected by the proposed reorganization include those that administer programs or laws related to public health, human services, and health care financing.[3] Certain operating divisions that may be eliminated or consolidated under the reorganization plans are statutorily established.[4]

To facilitate a review of how the reorganization plans may interact with existing laws that govern HHS operating divisions, this memorandum begins with background on HHS organization, including context for how administrative and legislative actions have shaped the Department and its agencies.[5] The memorandum then summarizes, for each of the 13 HHS operating divisions listed in **Table 1**, statutory provisions that govern the agency's establishment, leadership, structure, and key programs and functions, as well as related appropriations provisions. Finally, the memorandum provides a summary table of the key governing provisions discussed for each operating division.

preventing HHS from taking any action to implement or enforce the planned reductions in force (RIFs) or other sub-agency restructuring). Additionally, on July 8, 2025, the Supreme Court stayed an injunction issued by a California federal district court that would have paused further RIFs at HHS and other executive agencies pursuant to a recent executive order (see EO 14210, 90 *Federal Register* 9669, February 11, 2025). Trump v. Am. Fed'n of Gov't Emps., No. 24A1174, 2025 WL 1873440 (U.S. July 8, 2025) (mem.), *staying* Order Granting Preliminary Injunction, No. 25-3698 (N.D. Cal. May 22, 2025), ECF No. 124.

[2] See budget documents available at HHS, "HHS FY 2026 Budget in Brief," https://www.hhs.gov/about/budget/fy2026/index.html, especially HHS, *Fiscal Year 2026: Budget in Brief*, https://www.hhs.gov/sites/default/files/fy-2026-budget-in-brief.pdf, discussion of department-wide reorganization beginning page 1.

[3] U.S. Department of Health and Human Services, "HHS Announces Transformation to Make America Healthy Again," press release, March 27, 2025, https://www.hhs.gov/press-room/hhs-restructuring-doge.html (describing several consolidations, including one involving primarily Public Health Service agencies, one involving human services and health care financing agencies, and one involving agencies administering civil rights law, Medicare appeals, and departmental dispute resolution programs). HHS budget documents released in May 2025 show some changes to the reorganization plan from the original announcement; see HHS, *Fiscal Year 2026: Budget in Brief*, https://www.hhs.gov/sites/default/files/fy-2026-budget-in-brief.pdf, especially the discussion of department-wide reorganization beginning page 1.

[4] For more information about legal questions related to the proposed reorganization of HHS, *see* CRS LSB11311, "The Reorganization of the Department of Health and Human Services: Selected Legal Issues," by Hannah-Alise Rogers and Wen Shen (2025). Note that this CRS product does not yet reflect the revised reorganization plan in the FY2026 HHS budget documents. For more information on legal issues related to agency reorganization generally, see CRS R48523, *Organizing Executive Branch Agencies: Structure and Delegations of Authority*, by Dan Shedd and Jared Cole (2025).

[5] See, for instance, Nat. Federation of Independ. Business v. OSHA, 595 U.S. 109, 117 (2022) ("Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.").

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Background on HHS Organization

As of March 26, 2025, HHS operating divisions largely fell into two main categories: Public Health Service (PHS) agencies and other agencies (administering human services and health care financing programs), as shown in **Table 1** below.

Table 1. HHS Operating Divisions, by Category

As of March 26, 2025

Public Health Service	Other Human Services and Health Care Financing
• Administration for Strategic Preparedness and Response (ASPR) • Agency for Healthcare Research and Quality (AHRQ) • Agency for Toxic Substances and Disease Registry (ATSDR) • Centers for Disease Control and Prevention (CDC) • Food and Drug Administration (FDA) • Health Resources and Services Administration (HRSA) • Indian Health Service (IHS) • National Institutes of Health (NIH), which houses the Advanced Research Projects Agency for Health (ARPA-H)[a] • Substance Abuse and Mental Health Services Administration (SAMHSA)	• Administration for Children and Families (ACF) • Administration for Community Living (ACL) • Centers for Medicare & Medicaid Services (CMS)

Source: HHS Organizational Chart, last updated November 2024; see https://www.hhs.gov/about/agencies/orgchart/index.html.

Notes: The Public Health Service (PHS) structure traces to the Public Health Service Act of 1944 (P.L. 78-410); however, through administrative actions and legislation, the PHS agencies are no longer solely authorized in the Public Health Service Act. The PHS still remains relevant as an organizational unit because several laws and regulations refer to the "Public Health Service" as a whole.

a. Source cited does not list ARPA-H as part of the PHS; however, ARPA-H is housed within NIH, a PHS agency.

The structure of HHS has been shaped both through legislation by Congress and through administrative decisions by the HHS Secretary. Over the years, the HHS Secretary has administratively established some operating divisions and delegated to them the authority to carry out particular functions.[6] At the same time, Congress has statutorily established other operating divisions, sometimes specifying in statute how an operating division should be organized, its leadership structure, and what particular functions it should carry out.[7] Appropriations laws that provide annual funding to HHS also may influence how the Department is organized, as current appropriations are organized around the Department's operating and staff division structure, with some accounts designed to fund the activities of specific subcomponent offices within an agency.

[6] See, for instance, HHS, Public Health Service, *Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority*, 47 *Federal Register* 38409 (August 31, 1982) (establishing the Health Resources and Services Administration); HHS, *Statement of Organization, Functions, and Delegations of Authority; Administration for Community Living*, 77 *Federal Register* 23250 (April 18, 2012) (establishing the Administration for Community Living).

[7] See, for instance, 42 U.S.C. §290aa (establishing SAMHSA and the Assistant Secretary for Mental Health and Substance Abuse, and creating centers within SAMHSA).

A Brief History of HHS and Its Authorizing Statutes

HHS, as it exists today, is built from the roots of predecessor organizations that, in some cases, serve purposes that stretch back over centuries.[8] In its recent history, HHS traces back to 1953, when President Eisenhower established HHS's predecessor department, the Department of Health, Education, and Welfare (HEW) through the Reorganization Plan No. 1 of 1953, which elevated the preexisting Federal Security Agency (FSA) to a new cabinet-level department.[9] At the time, FSA included several components that remain part of HHS today, such as FDA and the PHS. The PHS was headed by the Surgeon General and included predecessors for certain current public health agencies such as NIH and CDC.[10] Section 1 of the Reorganization Plan No.1 of 1953 stated that HEW would be administered by the Secretary.[11] Section 6 of the plan permitted the Secretary to "authoriz[e] the performance of any of the functions of the Secretary" by any other officer, or any employee or agency, of the Department.[12] Despite this reorganization, the Surgeon General, who reported to the HEW Secretary, retained authority over the PHS, which at the time consisted of (1) the Office of the Surgeon General, (2) the Bureau of Medical Services, (3) the Bureau of State Services, and (4) the National Institute of Health.[13]

Then in 1966, President Lyndon B. Johnson implemented Reorganization Plan No. 3 of 1966, which transferred over all the agencies and functions of the PHS from the Surgeon General to the HEW Secretary.[14] The plan further permitted the HEW Secretary to make appropriate provisions to "authoriz[e] the performance of any [transferred] functions ... by any officer, employee, or agency of the Public Health Service or of [HEW]."[15] According to the President's accompanying statement, the plan was intended to provide the HEW Secretary with "the authority to coordinate health functions throughout the department."[16] Those health functions had expanded the year prior with many new health laws, including the establishment of Medicare and Medicaid under the Social Security Amendments of 1965 (P.L. 89-97) and the Older Americans Act (OAA, P.L. 89-73).[17]

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[8] *"A Common Thread of Service" An Historical Guide to HEW*, U.S. Department of Health, Education, and Welfare, Office of Public Information (1970), https://aspe.hhs.gov/reports/common-thread-service.

[9] 42 U.S.C. §3501, note; 67 Stat. 631. This reorganization plan, as well as the Reorganization Plan No. 3 of 1966 discussed below, was submitted to Congress and, in accordance with the Reorganization Act of 1949 (P.L. 81-109), in the absence of congressional disapproval, it went into effect. From 1932 to 1984, Congress intermittently granted the President the authority to develop reorganization plans of portions of the federal government and to present those plans to Congress for consideration under special expedited procedures commonly known as the "legislative veto" process. See P.L. 81-109, §6; see also CRS Report R44909, *Executive Branch Reorganization*, by Henry B. Hogue (2017). In 1984, Congress, through P.L. 98-532, "ratifi[ed] and affirm[ed] as law" each reorganization plan that had been implemented up until then, in response to a Supreme Court decision that invalidated the legislative veto process as unconstitutional. See CRS LSB11311, "The Reorganization of the Department of Health and Human Services: Selected Legal Issues," by Hannah-Alise Rogers and Wen Shen (2025); see also INS v. Chadha, 462 U.S. 919 (1983).

[10] "A Brief History of the Federal Security Agency," in *"A Common Thread of Service" An Historical Guide to HEW*, U.S. Department of Health, Education, and Welfare, Office of Public Information (1970), pp. 1-5.

[11] 42 U.S.C. §3501, note.

[12] 42 U.S.C. §3501, note; 67 Stat. 631, Section 6.

[13] 58 Stat. 683. In addition, the Message of the President accompanying Reorganization Plan No. 1 stated, "The plan at the same time assures that the Office of Education and the Public Health Service retain the professional and substantive responsibilities vested by law in those agencies or in their heads. The Surgeon General, the Commissioner of Education, and the Commissioner of Social Security will all have direct access to the Secretary." See 42 U.S.C. §3501, note.

[14] Reorganization Plan No. 3 of 1966, §1, 80 Stat. 1610.

[15] Reorganization Plan No. 3 of 1966, §6, 80 Stat. 1610.

[16] See "Message from the President" at 42 U.S.C. §202, note.

[17] For a full list of laws enacted in 1965 that affected HEW health functions, see "Secretary Gardner" in *"A Common Thread of Service" An Historical Guide to HEW*, U.S. Department of Health, Education, and Welfare, Office of Public Information (1970), https://aspe.hhs.gov/reports/common-thread-service.

In the years after the 1966 plan, HEW Secretaries—relying on a combination of their authorities under the 1953 and 1966 Reorganization Plans and other authorities—implemented several reorganizations that each addressed different aspects of the HEW's functions, including the PHS, human services, and health care financing.[18] In 1979, HEW was renamed HHS through the Department of Education Organization Act (P.L. 96-88), which transferred HEW's education programs to a newly established Department of Education and changed all HEW references in law to HHS.

In 1984, Congress enacted P.L. 98-532 to "ratif[y] and affirm[] as law" each reorganization plan that had been implemented up until then, preserving the provisions of the 1953 and 1966 Reorganization Plans after a Supreme Court decision cast doubt over the plans' validity.[19] After HEW became HHS, HHS Secretaries continued to invoke their reorganization authority from time to time, including by administratively establishing certain agencies such as HRSA[20] (in 1982), ACL[21] (in 2012), and others, as discussed throughout this memorandum.[22]

In addition to HHS actions that have shaped the Department's structure, Congress has played a significant role in HHS organization through the enactment of authorizing statutes that have addressed programs and functions within HHS. To varying degrees, and often on a case-by-case basis, authorizing statutes have addressed the structure of certain HHS agencies.[23] For some agencies, their governing statutes expressly established the agencies, their leadership, and subcomponents.[24] For other agencies, the relevant statutes address some, but not all, of those structural elements.[25] Additionally, Congress has, through enacted laws, assigned specific functions to certain agencies or officials, at times to entities or individuals with positions that were administratively created.[26] This panoply of statutes defines the parameters for executive actions related to these agencies, where some provisions—depending on their level of specificity—may impose a higher degree of constraint on the HHS Secretary than others.[27]

[18] For histories of past HHS reorganizations, see HHS Office of Administrative Management, *History, Mission and Organization of the Public Health Service*, 1976, https://www.google.com/books/edition/History_Mission_and_Organization_of_the/M-n4arYE5ScC?hl=en&gbpv=1; and *"A Common Thread of Service" An Historical Guide to HEW*, U.S. Department of Health, Education, and Welfare, Office of Public Information (1970), https://aspe.hhs.gov/reports/common-thread-service. In addition to the reorganization plan authorities, the HHS Secretary has also cited 5 U.S.C. §301 as a basis for reorganization, which is sometimes referred to as the "housekeeping statute," and generally authorizes "[t]he head of an Executive department" to "prescribe regulations for the government of his department ... [and] the distribution and performance of its business."

[19] See INS v. Chadha, 462 U.S. 919 (1983); see also CRS LSB11311, "The Reorganization of the Department of Health and Human Services: Selected Legal Issues," by Hannah-Alise Rogers and Wen Shen (2025).

[20] HHS, HRSA Statement of Organization, Functions, and Delegations of Authority, 47 Federal Register 38409, August 31, 1982 (establishing HRSA).

[21] HHS, Administration for Community Living Statement of Organization, Functions and Delegations of Authority, 77 Federal Register 23250, April 18, 2012 (establishing ACL).

[22] HHS's reorganizations prior to March 27, 2025, do not appear to have been the subject of litigation, and no court appears to have interpreted the scope of the HHS Secretary's reorganization authorities, including under the 1953 and 1966 Reorganization Plans. For more information about the legal framework and authorities related to HHS reorganization, and the legal questions raised by the March 27, 2025, announcement, see CRS LSB11311, "The Reorganization of the Department of Health and Human Services: Selected Legal Issues," by Hannah-Alise Rogers and Wen Shen (2025).

[23] See "HHS Operating Divisions."

[24] See "HHS Operating Divisions."

[25] See "HHS Operating Divisions."

[26] See "HHS Operating Divisions."

[27] See CRS LSB11311, "The Reorganization of the Department of Health and Human Services: Selected Legal Issues," by Hannah-Alise Rogers and Wen Shen (2025).

Appropriations

In addition to authorizing statutes, all HHS operating divisions are provided with authority and direction through annual appropriations acts. These appropriations acts' account structure have remained fairly consistent over the years, though the laws' structure have sometimes changed when agencies or their programs were reorganized.[28] Typically, these acts provide funding to carry out specified authorizing statutes or other purposes.[29] Appropriations acts also can effectively authorize entities or activities that were not previously authorized by other statutes.[30] In a smaller number of cases, the appropriations acts also specify that the funds are "for necessary expenses" of a particular named operating division or unit rather than to carry out any particular law.[31]

All HHS operating divisions are appropriated funding under headings providing for accounts that are specific to those operating divisions. Agency-specific accounts are often programmatically focused, meaning they fund specific programs or entities across the operating division. However, the agency-specific accounts in appropriations acts are sometimes aligned with that agency's internal structure, even when that structure is not specifically established in authorizing statutes. For example, HRSA receives funds in appropriations acts under headings or subheadings that correspond with its main bureaus and offices (Primary Health Care, Health Workforce, Maternal and Child Health, Health Systems, Rural Health), even though most of those entities are not named in HRSA's authorizing statutes.[32] By specifying HRSA funding for specific program areas and placing restrictions on transfers and reprogramming of those funds, the appropriations acts may limit HRSA's ability to allocate certain funds to different program areas.[33]

Congressional reports accompanying appropriations acts (e.g., committee reports, explanatory statements) also have historically provided agencies with further instructions on how to spend appropriated funds. These reports have often further directed agencies to spend certain funds on specific programs. However, their directives are not generally legally binding on the agency, unless so specified in the statute itself.[34] For example, the distribution of funds from the Prevention and Public Health Fund across programs in

[28] For annual appropriations laws dating back to FY1999, see the CRS Appropriations Status Table at https://crs.gov/AppropriationsStatusTable/Index.

[29] In addition, almost all HHS agencies also receive certain mandatory appropriations in their authorizing laws.

[30] From Government Accountability Office, *Principles of Federal Appropriations Law: Chapter 2 The Legal Framework*, 4th Edition, 2016, pp. 79-80, https://www.gao.gov/assets/2019-11/675709.pdf: "There is no general statutory requirement that appropriations be preceded by specific authorizations, although they may be required in some instances. Where authorizations are not required by law, Congress may, subject to a possible point of order, appropriate funds for a program or object that has not been previously authorized or which exceeds the scope of a prior authorization. If so, the enacted appropriation, in effect, carries its own authorization and is available to the agency for obligation and expenditure."

[31] For example, as covered in this memorandum, the purposes of the funds in appropriations acts are specifically for ATSDR, FDA, and certain National Institute of Environmental Health Sciences activities, as opposed to funds for carrying out certain statutes administered by those institute or operating divisions.

[32] For example, see P.L. 118-47, 138 STAT. 649 - 651.

[33] Reprogramming is the movement of funds within an appropriations account and is generally allowable absent statutory restrictions. Transfers, which are the movement of funds between appropriations accounts, require statutory authority. Transfer authorities can apply to specific accounts, agencies, or HHS as a whole. For example, Section 205 of the FY2024 LHHS Appropriations Act (P.L. 118-47, Division D) limited, with limited exceptions, HHS from transferring more than 1% out of any discretionary appropriation in the act. The provision also restricted HHS from using such a transfer to increase another discretionary appropriation in the act by more than 3%. Finally, the provision prohibited HHS from using this transfer authority "to create any new program or to fund any project or activity for which no funds are provided" in the act.

[34] For a legal discussion, see CRS Report R46899, *Regular Appropriations Acts: Selected Statutory Interpretation Issues*, by Sean Stiff (2021); For further information, see CRS Report R44124, *Appropriations Report Language: Overview of Development and Components*, by Drew C. Aherne (2023).

different HHS operating divisions programs is typically specified in appropriations report language that is incorporated by reference into the relevant appropriations act.[35]

HHS receives funding in three different annual appropriations acts. Most of the Department's appropriations are provided through the Departments of Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations Act. However, funding for certain HHS agencies and activities is provided in two other acts: the Department of the Interior, Environment, and Related Agencies (INT) Appropriations Act and the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (AG) Appropriations Act. **Table 2** lists HHS agencies by the appropriations act that funds those agencies. In general, the discretionary funding provided by these three appropriations acts tends to be the focus of congressional debate during the annual appropriations process.[36] For some accounts and programs, however, the HHS budget authority provided in these appropriations acts is mandatory. Such programs are typically styled as appropriated mandatories (also known as appropriated entitlements). The amount of obligations under such a program is controlled by an authorizing statute, but Congress provides in an appropriations act the appropriations necessary to pay those obligations.[37] In addition to appropriated mandatories, there are cases in which authorizing laws both establish a program and provide the appropriations necessary to carry out the program.[38] In such cases, the appropriation is provided in the authorizing law, not via an appropriations act.

Table 2. HHS Agencies, by Appropriations Law

Appropriations Bill	HHS Agencies Funded in the Bill
Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (AG)	• Food and Drug Administration (FDA)
Department of the Interior, Environment, and Related Agencies (INT)[a]	• Indian Health Service (IHS) • Agency for Toxic Substances and Disease Registry (ATSDR)

[35] The Prevention and Public Health Fund is a mandatory budget authority appropriated by Affordable Care Act, Section 4002, which provides an appropriation for public health and prevention activities. Through annual appropriations acts, since 2014, Congress has specified how these appropriations are to be allocated among programs at HHS agencies through report tables incorporated by reference in the LHHS Act. For more information, see CRS Report R47895, *Prevention and Public Health Fund: In Brief*, by John H. Gorman and Kavya Sekar (2024).

[36] Discretionary spending programs are generally authorized in acts other than appropriations acts. However, these acts do not control spending under the programs. Instead, annual appropriations acts determine the extent to which those programs will actually be funded, if at all. For more information, see CRS Report R46240, *Introduction to the Federal Budget Process*, by James V. Saturno (2023).

[37] For more information, see CRS Report R44582, *Overview of Funding Mechanisms in the Federal Budget Process, and Selected Examples*, by Jessica Tollestrup (2021).

[38] See, for example, PHSA Section 340H(g) (42 U.S.C. §256h(g)), which authorizes the Teaching Health Center Graduate Medical Education program and appropriates funding for it.

Appropriations Bill	HHS Agencies Funded in the Bill
Departments of Labor, Health and Human Services, and Education, and Related Agencies (LHHS)	• Health Resources and Services Administration (HRSA) • Centers for Disease Control and Prevention (CDC) • National Institutes of Health (NIH)[a] • Advanced Research Projects Agency for Health (ARPA-H) • Substance Abuse and Mental Health Services Administration (SAMHSA) • Agency for Healthcare Research and Quality (AHRQ) • Centers for Medicare & Medicaid Services (CMS) • Administration for Children and Families (ACF) • Administration for Community Living (ACL) • Administration for Strategic Preparedness and Response (ASPR)

Source: CRS. For more information, see CRS Report R40858, *Locate an Agency or Program Within Appropriations Bills*, by Justin Murray (2023).

Note:

a. Funding for NIH comes primarily from the LHHS appropriations bill, with an additional amount for Superfund-related activities at the National Institute of Environmental Health Sciences (NIEHS) provided as part of the INT appropriations bill.

Scope and Approach

The remainder of this memorandum summarizes the current statutes and appropriations governing HHS operating divisions and the programs and functions they administer. HHS operating divisions derive their statutory authority from many different laws, which vary in their level of specificity, particularly the extent to which they establish each operating division and its leadership, structure, programs, and functions. Annual appropriations laws and mandatory budget authorities also sometimes inform each operating division's programs and structures. This memorandum therefore summarizes the overall statutory and appropriations framework for each operating division, focusing on the following categories:

- **Establishment.** Whether the agency is explicitly established as an entity in statute, and any other statutory direction about the agency's placement; for example, if the agency is placed in the PHS or another part of HHS.
- **Leadership.** Whether the agency's leader or other major leadership positions are established in statute, and if so, how the leadership position is defined in terms of appointment method, reporting structure, responsibilities, scope of authority, and other characteristics.
- **Structure.** Whether any specific statutes govern the agency's overall structure, and if not, whether specific centers, institutes, offices, or other components are established as part of the agency by statute. This section focuses on some of the larger entities or components within each agency and generally does not detail smaller offices or organizational units within each operating division.
- **Key Programs and Functions.** Whether and how the agency's main administered regulations and programs are authorized in statute, including whether those program-specific statutes name the agency or its leader to administer the regulations or programs.

- **Appropriations.** How the agency receives its appropriations and how the appropriations laws (including both mandatory and discretionary funding) inform the agency's structure or programs. Unless otherwise noted, all sections on appropriations refer to the FY2024-enacted annual appropriations laws (P.L. 118-47 and P.L. 118-42) and accompanying reports and explanatory statements.[39]

This memorandum is intended to provide a general summary of the above-listed topics for each agency; it does not cover all statutory provisions that pertain to each agency. Moreover, this memorandum does not include all general and federal government-wide authorities under which HHS agencies carry out certain functions.[40]

This memorandum refers to authorizing statutes in different ways. Many HHS programs are authorized in several statutes that have been amended frequently over decades, including the Social Security Act (SSA); the Public Health Service Act (PHSA); the Federal Food, Drug, and Cosmetic Act (FFDCA); the Older Americans Act (OAA); and others. When referring to these major statutes, this memorandum does not use public law numbers. However, when discussing a specific law that established or authorized a certain program or function at a certain time, that law's title is followed by a public law number.

HHS Operating Divisions

Administration for Children and Families (ACF)[41]

The ACF mission is focused on promoting the "economic and social well-being of families, children, individuals and communities."[42] ACF administers a wide array of human services programs across 10 offices or administrations focused on particular programs or policy areas, plus a handful of additional offices focused on internal or regional operations. Programs and activities administered by ACF include Temporary Assistance for Needy Families (TANF); Head Start; child care; the Social Services Block Grant (SSBG); refugee and entrant assistance; child support enforcement (CSE); Federal Payments for Foster Care, Prevention, and Permanency; and various programs serving Native Americans, vulnerable youth, victims of trafficking, and others.[43]

The HHS Secretary created ACF in 1991 by combining the Office of Human Development Services, the Family Support Administration, and the Maternal and Child Health Block Grant Program.[44] Since ACF

[39] See, for example, for the explanatory statement accompanying the FY2024 LHHS Act, *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1886-H2070. This memorandum does not reference FY2025 annual appropriations because those appropriations for HHS were enacted through the Full-Year Continuing Appropriations Act, 2025 (Division A of P.L. 119-4). Those appropriations were provided on a formulaic basis with reference to the FY2024 appropriations acts (P.L. 118-47 and P.L. 118-42). As is typically the case for full-year continuing appropriations, FY2025 appropriations were not accompanied by explanatory materials. For further information, see CRS Report R48517, *Section-by-Section Summary of the Full-Year Continuing Appropriations Act, 2025 (Division A of P.L. 119-4)*, by Drew C. Aherne (2025).

[40] For example, HHS agencies may cite general and federal-wide authorities such as 5 U.S.C. §301 as a basis for issuing regulations or other activities. This memorandum does not cover such provisions.

[41] This section was written by Karen E. Lynch, Specialist in Social Policy, CRS Domestic Social Policy Division, and Jessica Tollestrup, Specialist in Social Policy, CRS Domestic Social Policy Division.

[42] ACF, "What We Do," https://www.acf.hhs.gov/about/what-we-do.

[43] HHS, *Administration for Children and Families FY2025 Congressional Justification*, available at https://acf.gov/sites/default/files/documents/olab/fy-2025-congressional-justification.pdf.

[44] For further background, see ACF, "ACF History," https://acf.gov/about/history. The reorganization also included other organizational units, or portions thereof, that provide support to the offices being transferred to ACF. For additional information, see Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991.

was established, the scope of its work has been altered several times as programs have been enacted into law and assigned to the agency, either specifically in the program's authorizing statute or, more typically, through delegation by the HHS Secretary.[45] In addition, the Secretary has transferred programs that were once administered by ACF elsewhere within HHS (e.g., the Maternal and Child Health Block Grant was returned to HRSA).[46]

Establishment. No specific statute establishes ACF as an agency. The operating division was established by the HHS Secretary on April 15, 1991, relying primarily on authority under Reorganization Plan No. 1 of 1953.[47]

Leadership. No statute explicitly establishes the Assistant Secretary for Children and Families, the position that leads ACF.[48] The Assistant Secretary for Children and Families also assumes the title of Assistant Secretary for Family Support, a predecessor position that is established in law and responsible for a subset of ACF's programs.[49]

The Assistant Secretary for Family Support was established as a presidentially appointed and Senate-confirmed position by Section 603 of the Family Support Act of 1988 (P.L. 100-485).[50] Under this law, the Assistant Secretary for Family Support was tasked with administering programs authorized under Parts A, D, and F of the SSA (e.g., Aid to Families with Dependent Children, Job Opportunities and Basic Skills Training program, and CSE programs).[51]

When ACF was administratively established in 1991, the new agency assumed functions that were previously carried out by the Family Support Administration, in addition to functions that had been located elsewhere within HHS. The 1991 *Federal Register* notice announcing the establishment of ACF clarified that the new operating division would be headed by the "Assistant Secretary for Children and Families... [who] shall report to the Secretary and shall also retain the title of Assistant Secretary for Family Support and the title of Director of the Office of Child Support Enforcement."[52] This notice also made clear that the ACF Assistant Secretary would administer additional programs beyond those named in statute as within the purview of the Assistant Secretary for Family Support (e.g., Head Start, SSBG).[53]

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[45] See, for example, the new ACF organizational structure that was implemented after the enactment of PRWORA (HHS, ACF, "Statement of Organization, Functions, and Delegations of Authority," 65 *Federal Register* 8980, February 23, 2000).

[46] HHS, HRSA, "Statement of Organization, Functions, and Delegations of Authority," 56 *Federal Register* 166, August 27, 1991.

[47] Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991 (stating that the described organizational changes are based on the HHS Secretary's authorities under "Section 6 of Reorganization Plan No.1 of 1953 and pursuant to the authorities vested in [the HHS Secretary]."). For Reorganization Plan No. 1 authority, see 42 U.S.C. §3501, note.

[48] See https://acf.gov/about/leadership. See also Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991.

[49] Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991.

[50] Section 603 of the Family Support Act created a new Section 418 in the Social Security Act (42 U.S.C. §618). Subsequent legislation (P.L. 100-647) redesignated Section 418 of the Social Security Act (42 U.S.C. §618) as Section 417 (42 U.S.C. §617).

[51] See Section 603 of the Family Support Act (P.L. 100-485) or 42 U.S.C. §618, as codified prior to the enactment of the Personal Responsibility and Work Opportunity Reconciliation Act (P.L. 104-193).

[52] Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991. Section 452(a) of the Social Security Act (42 U.S.C. §652(a)) provides, with regard to the CSE program, that it shall be "under the direction of a designee of the Secretary, who shall report directly to the Secretary."

[53] Department of Health and Human Services, "Administration for Children and Families; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 56 *Federal Register* 15885, April 18, 1991. See also Department of Health

(continued...)

Five years after ACF was established, the 1988 provision establishing the Assistant Secretary for Family Support was struck from the law by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, P.L. 104-193).[54] PRWORA replaced the 1988 provision with a similar provision, calling for programs under Parts A and D of the SSA (e.g., TANF, the Child Care Entitlement to States, and CSE) to be administered by a presidentially appointed and Senate-confirmed Assistant Secretary for Family Support.[55] The Assistant Secretary for ACF continues to administer additional programs beyond those specified in PRWORA for the Assistant Secretary for Family Support.

Structure. CRS research did not identify any laws that explicitly establish offices and bureaus within ACF.[56] To the extent that these offices and bureaus are explicitly established in law, they are generally established as part of HHS and not ACF. For example, the Children's Bureau within ACF is established in law as part of HHS, with the requirement that the "chief" of the Children's Bureau be presidentially appointed and Senate confirmed.[57] Likewise, both the Administration for Native Americans (ANA)[58] and Administration on Children, Youth, and Families (ACYF)[59] are established in law as part of HHS, with the requirement that the Commissioners of the ANA and ACYF be presidentially appointed and Senate confirmed. Additionally, the Office of Community Services (OCS) is statutorily established within HHS and is to be headed by a director, although the law does not specify how that director is to be appointed.[60]

Key Programs and Functions. ACF administers programs and activities authorized under a number of different laws, including the Child Abuse Prevention and Treatment Act (CAPTA, P.L. 93-247, as amended), the Child Care and Development Block Grant Act (CCDBG, P.L. 97-35, title VI, subtitle A, Ch. 8, Subchapter C, as amended), the Head Start Act (P.L. 97-35, title VI, subtitle A, Ch. 8, Subchapter B, as amended), the Native American Programs Act (NAPA, P.L. 93-644, as amended), the Refugee Education Assistance Act (REAA, P.L. 96-422, as amended), the Family Violence and Prevention Services Act (FVPSA, P.L. 98-457, title III, as amended), and the SSA (including some or all portions of Titles I, IV, V, X, XI, XIV, XVI, and XX), to name a few.

Several ACF programs and activity areas are authorized by specific statutory provisions throughout these laws. Some statutes reference an ACF role with regard to activity areas, but those references tend to be inconsistent. For example, Title IV-D of the SSA, which authorizes the CSE program, specifically designates ACF as being responsible for administering the program's Access and Visitation grants .[61] However, the remainder of the law assigns administrative authorities for the CSE program to the HHS Secretary.[62] Similarly, the CCDBG Act generally calls for the HHS Secretary to make grants, approve

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and Human Services, "Administration for Children and Families; General Reorganization; Statement of Organization, Functions, and Delegations of Authority," 56 *Federal Register* 42332-42354, August 27, 1991, and subsequent ACF statements of organization.

[54] The establishment of the Assistant Secretary for Family Support is currently codified in Section 416 of the Social Security Act. (42 U.S.C. §616).

[55] Neither the law nor the accompanying conference report addresses the decision to retain the title *Assistant Secretary for Family Support* as opposed to the newer title, *Assistant Secretary for Children and Families*.

[56] There are cases in which particular offices or bureaus are named as being within ACF. For instance, the Head Start Act twice refers to the "Head Start Bureau of the Administration for Children and Families" (see 42 U.S.C. §§9839(h) and 9843(g)(2)(B)). However, the law does not explicitly establish the Head Start Bureau, and HHS has since reorganized the Head Start Bureau into the Office of Head Start. See Department of Health and Human Services, Administration for Children and Families, "Statement of Organization, Functions, and Delegations of Authority," 71 *Federal Register* 29649, May 23, 2006.

[57] 42 U.S.C. §§191 and 192.

[58] 42 U.S.C. §2991b–2(a).

[59] 42 U.S.C. §12311.

[60] 42 U.S.C. §9912.

[61] 42 U.S.C §§651 et seq. The Access and Visitation Program is authorized by 42 U.S.C. §669B.

[62] See, for instance, 42 U.S.C. §652.

applications, monitor state compliance with program requirements, and more.[63] The law also calls for the "Secretary (acting through the Assistant Secretary for Children and Families of the Department of Health and Human Services)" to prepare a particular report.[64] The authorizing law for the Personal Responsibility Education Program (PREP) likewise states that the HHS Secretary shall administer the program through the Assistant Secretary for ACF.[65]

Appropriations. The annual LHHS Appropriations Act provides both discretionary and appropriated mandatory funding for eight accounts under an ACF heading. Typically, these accounts are programmatically focused and do not correspond to individual HHS offices or bureaus. For example, the separate SSBG and Low Income Home Energy Assistance Program (LIHEAP) accounts fund those individual programs. [66] SSBG and LIHEAP, however, are two of several programs administered by a single entity within ACF, the Office of Community Services.[67]

Individual accounts also fund programs that are administered by multiple offices or bureaus within ACF. For example, the Children and Families Services Programs account funds more than a dozen programs and activities (e.g., Head Start, Preschool Development Grants, various Child Welfare programs, the Community Services Block Grant program) that are administered by multiple ACF offices and bureaus.[68] LHHS Appropriations Acts typically specify amounts for a handful of the programs, projects, and activities supported by this account.[69] Accompanying committee reports or explanatory statements typically direct HHS to make additional reservations for specified programs, projects, and activities within the Children and Families Services Programs account, as well as number of other ACF accounts.[70]

Furthermore, ACF receives significant funding outside the annual appropriations process through mandatory spending provided in authorizing acts. The largest ACF-administered program funded in this manner is the TANF program, which accounts for roughly one-quarter of total ACF funding each fiscal year.[71] As noted above, the law specifies that TANF is to be administered by the Assistant Secretary for Family Support, but the law does not require that this leadership position be within ACF.[72]

Administration for Community Living (ACL)[73]

The ACL mission is to "maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers."[74] ACL advocates at the federal level for these populations and administers various human and health-related services through a national, state, and local network of aging and disability community-based programs. These programs provide assistance with nutrition and wellness, prevent abuse, support independence, and fund research, among other activities. ACL consists of five main programmatic units: (1) the Administration on Aging; (2) the

[63] 42 U.S.C. §§9857 et seq. For examples referenced above, see 42 U.S.C. §§9858a, 9858c(d), and 9858g.

[64] 42 U.S.C. §9858c(c)(3)(B)(ii).

[65] 42 U.S.C. §713(d)(1).

[66] See the FY2024 LHHS omnibus (P.L. 118-47) provisions for these accounts starting at 138 Stat. 664-669.

[67] See ACF, Office of Community Services, "Programs," at https://acf.gov/ocs/programs.

[68] For further information, see the *FY2025 ACF Congressional Justification*, https://acf.gov/sites/default/files/documents/olab/fy-2025-congressional-justification.pdf.

[69] For instance, see the FY2024 LHHS omnibus (P.L. 118-47) provisions for this account starting at 138 Stat. 665.

[70] For instance, see the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1893, H2033-H2034.

[71] See the All Purpose Table in the *FY2025 ACF Congressional Justification*, pp. 5-9.

[72] 42 U.S.C. §617.

[73] This section was written by Kirsten J. Colello, Specialist in Health and Aging Policy, CRS Domestic Social Policy Division.

[74] ACL, "About ACL, Mission & Vision," https://acl.gov/about-acl.

Administration on Disabilities; (3) the Center for Innovation and Partnership; (4) the Center for Regional Operations; and (5) the National Institute on Disability, Independent Living, and Rehabilitation Research, along with other offices and administrative components.[75]

The HHS Secretary created ACL in 2012 by combining three entities: (1) the Administration on Aging (AOA), which at the time was an HHS operating division; (2) the Administration on Developmental Disabilities, which was under ACF; and (3) the Office on Disability, which was in the Office of the Secretary.[76] Since its establishment, the scope of ACL's work has been altered several times as programs have been assigned to the agency, either specifically in the program's authorizing statute, through appropriations measures, or through delegation by the HHS Secretary.[77]

Establishment. No specific statute establishes ACL as an agency. The operating division was established by the HHS Secretary on April 18, 2012.[78]

Leadership. No statute explicitly establishes the position of the ACL Administrator, which currently leads ACL. The 2012 *Federal Register* notice announcing the establishment of ACL stated that the operating division is headed by an administrator who reports directly to the HHS Secretary, and that the administrator is also the Assistant Secretary for Aging.[79]

The position of the Assistant Secretary for Aging is established as a presidentially appointed and Senate-confirmed position under Section 201 of the OAA.[80] This section establishes the position of the Assistant Secretary for Aging to be head of the AOA.[81] It further requires a direct reporting relationship between the Assistant Secretary and the HHS Secretary and prohibits any delegation of the functions of the Assistant Secretary (including the functions of the Assistant Secretary carried out through regional offices) to any other officer not directly responsible to the Assistant Secretary.[82]

Structure. CRS research identified two examples of laws that establish an office or entity within ACL. Section 202 of the Rehabilitation Act of 1973 establishes the National Institute on Disability, Independent Living, and Rehabilitation Research within ACL.[83] The Institute is to be headed by a director who is directly responsible to the ACL Administrator.[84] In addition, Section 701A of the Rehabilitation Act of 1973 establishes an Independent Living Administration within ACL and requires the administration to be headed by a director who is directly responsible to the ACL Administrator.[85]

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[75] ACL, "Organizational Chart," https://acl.gov/about-acl/organization/organizational-chart.

[76] For further background, see ACL, "ACL History," https://acl.gov/about-acl/history.

[77] For example, Section 2922 of the American Rescue Plan Act (ARPA, P.L. 117-2) appropriated funding for FY2021 through FY2025 to the HHS Secretary, acting through the ACL Administrator, to establish the National Technical Assistance Center on Grandfamilies and Kinship Families. As another example, the Workforce Innovation and Opportunity Act (WIOA) of 2014 (P.L. 113-128) transferred to ACL the National Institute on Disability, Independent Living, and Rehabilitation Research program, as well as the Independent Living and Assistive Technology program from the Department of Education in FY2015.

[78] Department of Health and Human Services, "Administration for Community Living; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 77 *Federal Register* 23250, April 18, 2012. This notice did not cite any specific statutory authority. According to ACL, "The Secretary of the Department of Health and Human Services (Kathleen Sebelius, at the time) established ACL using her authority on April 18, 2012." See ACL, "History and Impact," at https://acl.gov/about-acl/history.

[79] 77 *Federal Register* 23250.

[80] 42 U.S.C. §3011.

[81] 42 U.S.C. §3011.

[82] 42 U.S.C. §3011.

[83] 29 U.S.C. §762.

[84] 29 U.S.C. §762.

[85] 29 U.S.C. §796-1. On May 9, 2019, ACL amended the Statement of Organization, Functions, and Delegations of Authority to (continued...)

The AOA, another ACL component, is a statutorily established entity under OAA Section 201(a) within the Office of the HHS Secretary.[86] Within the AOA, the OAA establishes the Office for American Indian, Alaskan Native, and Native Hawaiian Programs and the Office of Long-Term Care Ombudsman Programs.[87] Each office is to be headed by a director who is appointed by the Assistant Secretary for Aging.[88]

Key Programs and Functions. ACL administers programs authorized in several statutes, primarily the Developmental Disabilities Act (DD Act; P.L. 106-402, as amended) and the OAA, in addition to other laws.[89] Several ACL programs and activity areas are authorized by specific statutory provisions throughout a number of different laws. Some of these statutes reference an ACL role with regard to these activities. For example, Section 8 of the Assistive Technology (AT) Act requires the ACL Administrator to be responsible for administration of the AT Act, notwithstanding any other provision of law.[90] Section 1253 of the PHSA requires the HHS Secretary, acting through the ACL Administrator, to make grants to protection and advocacy systems regarding traumatic brain injury to eligible entities.[91] Other statutory programs and activities, on the other hand, are directed at the HHS Secretary but are carried out by ACL.[92]

Other statutes reference an AOA role; for example, OAA Section 201(a) requires the AOA to carry out the OAA, with the exception of Title V, which is administered by the U.S. Department of Labor.[93] In addition, the OAA establishes certain functions of regional offices. For example, OAA Section 205(a)(2)(B) requires the regional offices to be responsible for disseminating nutrition guidelines and providing technical assistance to states, area agencies on aging, and nutrition service providers.[94] Several

rename the Independent Living Administration as the Office of Independent Living Programs. According to ACL, this office will continue to serve as the Independent Living Administration as specified in Section 701A of the Rehabilitation Act. The Commissioner for the Administration on Disabilities (AoD) will also serve as the Director of the Independent Living Administration. See also Department of Health and Human Services, "Administration for Community Living; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 84 *Federal Register* 20360, May 9, 2019.

[86] Section 201 of the Older Americans Act of 1965 (P.L. 89-73) initially established the Administration on Aging within the then Department of Health, Education, and Welfare. In 1966, AOA was formally established in the Office of the Secretary, and the OAA was subsequently amended under the Older Americans Comprehensive Services Amendments of 1973 (P.L. 93-29) to reflect the current organizational structure within the HHS Office of the Secretary. In 1987, the OAA Amendments of 1987 (P.L. 100-175) were enacted to establish a direct reporting relationship from the Assistant Secretary for Aging to the now HHS Secretary. AOA was established as an independent HHS operating agency in 1991 (56 *Federal Register* 46620, September 13, 1991).

[87] OAA Section 201(c) and (d); 42 U.S.C. §3011(c) and (d). On May 9, 2019, ACL amended the Statement of Organization, Functions, and Delegations of Authority to include the Long-Term Care Ombudsman functions under the Office of Elder Justice and Adult Protective Services and tasked the Deputy Assistant Secretary for Aging to meet the responsibilities for the Director of the Office of Long-Term Care Ombudsman Programs. See also Department of Health and Human Services, "Administration for Community Living; Statement of Organization, Functions, and Delegations of Authority; Reorganization Order," 84 *Federal Register* 20360, May 9, 2019.

[88] See OAA Section 201(c)(1)(2), 42 U.S.C. §3011(c)(1)(2); OAA Section 201(d)(1)(A); 42 U.S.C. §3011(d)(1)(A).

[89] ACL, "Authorizing Statutes," https://acl.gov/about-acl/authorizing-statutes. DD Act (P.L. 106-402; 42 U.S.C. §15001) and OAA (P.L. 89-73, as amended; 42 U.S.C. §§3001 et seq.).

[90] 29 U.S.C. §3007.

[91] 42 U.S.C. §300d- 53. Also, PHSA Section 1252 (42 U.S.C. §300d-52) authorizes the HHS Secretary, acting through the ACL Administrator, to make grants regarding projects to improve rehabilitation services regarding traumatic brain injury.

[92] See, for instance, DD Act Section 104 (42 U.S.C. §15004).

[93] 42 U.S.C. §3011(a).

[94] 42 U.S.C. §3016(a)(2)(B).

statutes also specifically authorize implementing regulations for ACL programs.[95] Some of these provisions, specifically under OAA, authorize the Assistant Secretary for Aging to establish regulations.[96]

Appropriations. The annual LHHS Appropriations Act provides discretionary funding under an ACL heading to one account titled "Aging and Disability Services Programs." LHHS Appropriations Acts typically specify a lump sum amount of funding for all programs, projects, and activities supported by this account.[97] Accompanying committee reports and explanatory statements typically direct HHS to make reservations from this total for specified programs, projects, and activities across ACL.[98] In addition to discretionary appropriations, provisions in the LHHS Act transfer mandatory funding to certain ACL programs. For example, the Falls Prevention Program and Alzheimer's Disease Program, both authorized under OAA Title IV, receive a transfer of mandatory funding from the Prevention and Public Health Fund (PPHF), as directed in LHHS Acts.[99] The Senior Medicare Patrol Program receives mandatory and discretionary funding from the CMS Health Care Fraud and Abuse Control (HCFAC) account.[100]

Furthermore, ACL receives some funding outside the annual appropriations process through mandatory spending provided in authorizing acts. For example, beginning in FY2009, mandatory funding was provided for outreach and assistance to low-income Medicare beneficiaries under Section 119 of the Medicare Improvements for Patients and Providers Act (MIPPA, P.L. 110-275).[101] Typically, annual LHHS Appropriations Acts direct ACL to administer Section 119 of MIPPA.[102]

Explanatory statements accompanying annual LHHS Appropriations Acts have at times included language signaling the transfer of programs and activities from other HHS operating divisions to ACL. For example, the explanatory statement accompanying the Consolidated Appropriations Act, 2014 (P.L. 113-76), transferred the State Health Insurance Assistance Program (SHIP) from CMS and the Paralysis Resource Center from the CDC to ACL.[103]

[95] These include guiding regulations for OAA programs, Adult Protective Services programs authorized under the Elder Justice Act (Title XX-B of the Social Security Act [SSA]), and programs authorized under the Developmental Disabilities Act (DD Act), among other implementing regulations for programs and activities that ACL administers through a variety of statutes. For a list of regulations, as well as other policy and guidance documents, see ACL, "ACL-Wide Policy and Guidance," https://acl.gov/about-acl/policy-and-regulations. As an example, the authority to prescribe regulations is based in statute that directs the HHS Secretary to establish regulations for certain programs and activities under the DD Act; see 42 U.S.C. §15004(b).

[96] See statutes cited in HHS, ACL, "Older Americans Act: Grants to State and Community Programs on Aging; Grants to Indian Tribes and Native Hawaiian Grantees for Supportive, Nutrition, and Caregiver Services; Grants for Supportive and Nutritional Services to Older Hawaiian Natives; and Allotments for Vulnerable Elder Rights Protection Activities, Final Rule," 89 *Federal Register* 11568, February 14, 2024, at https://www.govinfo.gov/content/pkg/FR-2024-02-14/pdf/2024-01913.pdf. For example. OAA Section 201(e)(3) (42 U.S.C. §3011(e)(3)).

[97] For instance, see the FY2024 LHHS omnibus (P.L. 118-47) provisions for this account starting at 138 Stat. 663-668.

[98] For instance, see the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1893, H2036-H2039.

[99] See the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1894.

[100] See the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1892.

[101] 42 U.S.C. §1395b-3 note.

[102] See, for instance, the FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 668-669.

[103] See the explanatory statement accompanying the FY2014 LHHS (P.L. 113-76) available in the *Congressional Record*, vol. 160, no. 9, book II, January 15, 2014, p. H1041.

Agency for Healthcare Research and Quality (AHRQ)[104]

The Agency for Healthcare Research and Quality is the federal agency charged with supporting research designed to improve the quality of health care, increase the efficiency of its delivery, and broaden access to health services. In addition, AHRQ is required to disseminate its research findings to health care providers, payers, and consumers, among others, and to collect data on health care expenditures and utilization through the Medical Expenditure Panel Survey (MEPS) and the Healthcare Cost and Utilization Project (HCUP). AHRQ also provides administrative and research support, as well as funding, for the U.S. Preventive Services Task Force (USPSTF).[105] Currently, the agency is composed of four main offices of: (1) the Director; (2) Extramural Research, Education and Priority Populations; (3) Communications; and (4) Management Services. Additionally, the agency has three main centers: (1) the Center for Financing, Access and Cost Trends; (2) the Center for Evidence and Practice Improvement; and (3) the Center for Quality Improvement and Patient Safety (CQuIPS).[106]

The agency was established and authorized in 1999 by the Healthcare Research and Quality Act of 1999 (P.L. 106-129), which amended Title IX of the PHSA.[107] This title was later substantially amended in 2005 by the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), to add functions in the area of patient safety, and again in 2010, by the Patient Protection and Affordable Care Act of 2010 (ACA, P.L. 111-148, as amended), to add several functions on topics such as the development of quality measurements, medication management, shared decision-making, quality improvement, and dissemination of comparative clinical effectiveness research results.

Establishment. PHSA Section 901(a)[108] establishes AHRQ as an agency within the Public Health Service.

Leadership. PHSA Section 901(a)[109] requires AHRQ to be led by a director, appointed by the HHS Secretary. The section further requires the activities and authorities in Title IX to be carried out by the HHS Secretary through the director. PHSA Section 946[110] authorizes the Director of AHRQ to appoint a Deputy Director for the agency.

Structure. The overall organization of AHRQ is not specified in statute. AHRQ components specified in statute include

- PHSA Section 901(c)(3), which requires the director to establish an "Office of Priority Populations";[111]
- PHSA Section 925(a), which establishes, within the Office of the Director, an "Office of Women's Health and Gender-Based Research";[112]

[104] This section was written by Amanda K. Sarata, Specialist in Health Policy, CRS Domestic Social Policy Division.

[105] Agency for Healthcare Research and Quality (AHRQ), "About AHRQ," last reviewed March 2025, https://www.ahrq.gov/cpi/about/index.html.

[106] AHRQ, "Organization Chart," https://www.ahrq.gov/cpi/about/organization/orgchart/organizational-chart.html.

[107] AHRQ's predecessor agency, the Agency for Health Care Policy and Research (AHCPR), was established in 1989 by the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239).

[108] 42 U.S.C. §299(a).

[109] 42 U.S.C. §299(a).

[110] 42 U.S.C. §299c–5.

[111] 42 U.S.C. §299(c)(3).

[112] 42 U.S.C. §299b–24a(a).

- PHSA Section 1707A(a), which establishes the "Office of Minority Health" in AHRQ (among a list of other HHS agencies);[113] and
- PHSA Section 915(b)(1),[114] which establishes a Center for Primary Care Research in AHRQ.

In addition, two components have specific *roles* defined in statute. CQuIPS "works to improve the safety, quality, and value of healthcare through research, tools and other resources; implementation and practice improvement; and measurement and data analysis."[115] Its functions (both general and research), dissemination duties, and topic prioritization are found in PHSA Section 933(b).[116] PHSA Section 937(a) requires the Office of Communication and Knowledge Transfer to, among other things, "broadly disseminate the research findings" published by the Patient Centered Outcomes Research Institute (PCORI) and other results of comparative clinical effectiveness research.[117]

Key Programs and Functions. As noted above, PHSA Title IX authorizes AHRQ and its functions. The agency is statutorily required to carry out certain functions, including, for example, the MEPS and HCUP surveys[118] and an annual report for Congress on national health quality and health disparities trends.[119] PHSA Section 915(a)[120] requires the director to convene the USPSTF and to "provide ongoing administrative, research, and technical support for the operations of the Task Force."[121]

Appropriations. AHRQ's budget currently comprises both discretionary and mandatory funds.[122] The annual LHHS Appropriations Act provides discretionary funding for one account under an AHRQ heading.[123] The appropriations act typically does not specify funding for specific programs in the text of the act. However, accompanying committee reports and explanatory statements typically direct funding for specific program categories within AHRQ. AHRQ also receives annual transfers from the mandatory Patient Centered Outcomes Research Trust Fund (PCORTF), as required by its authorizing statute (Internal Revenue Code Section 9511).[124] Per statute, 20% of the amounts appropriated or credited to PCORTF each year is transferred to the HHS Secretary to support activities under PHSA Section 937, which, as mentioned above, requires the dissemination of results of clinical effectiveness research.[125] AHRQ receives 80% of these annual transfers.[126]

[113] 42 U.S.C. §300u–6a(a).

[114] 42 U.S.C. §299b–4(b)(1).

[115] PHSA Section 933(b); 42 U.S.C. §299b-33(b).

[116] 42 U.S.C. §299b-33(b).

[117] 42 U.S.C. §299b-37(a).

[118] PHSA Section 913(a); 42 U.S.C. §299b-2.

[119] PHSA Section 913(b)(2); 42 U.S.C. §299b-2(b)(2) and PHSA Section 903(a)(6); 42 U.S.C. §299a-1(a)(6).

[120] 42 U.S.C. §299b-4(a).

[121] PHSA Section 915(a)(3); 42 U.S.C. §299b-4(a)(3).

[122] CRS Report R44136, *The Agency for Healthcare Research and Quality (AHRQ) Budget: Fact Sheet*, by Amanda K. Sarata and Sylvia L. Bryan (2024).

[123] For instance, see the FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 661-662.

[124] 26 U.S.C. §9511.

[125] 42 U.S.C. §299b-37(a).

[126] CRS Insight IN11010, *Funding for ACA-Established Patient-Centered Outcomes Research Trust Fund (PCORTF) Extended Through FY2029*, by Amanda K. Sarata (2020).

Administration for Strategic Preparedness and Response (ASPR)[127]

ASPR leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies.[128] ASPR manages several programs that help the health sector prepare for and respond to emergencies. ASPR also administers several programs that enable the development, availability, and distribution of medical products during emergencies, including for specific health threats (e.g., smallpox, anthrax). ASPR is organized into an Immediate Office for the Assistant Secretary for Preparedness and Response, with seven main centers that report to the Immediate Office.[129]

Aspects of ASPR's functionalities for public health emergencies date back to the 1950s.[130] The current Assistant Secretary for Preparedness and Response position, which leads ASPR, was established in 2006 by the Pandemic and All-Hazards Preparedness Act (PAHPA, P.L. 109-417).[131] PAHPA renamed a preexisting similar Assistant Secretary position and enacted the new position into law.[132] Until 2023, ASPR was a staff division in the HHS Office of the Secretary: the Office of the Assistant Secretary for Preparedness and Response. In July 2022, HHS announced that ASPR would be elevated to an operating division, which was followed by a formal *Federal Register* notice detailing that this change became effective February 2023.[133]

Establishment. No specific statute explicitly establishes ASPR as an agency. ASPR became an HHS operating division, as established by the HHS Secretary, effective on February 11, 2023.[134]

Leadership. PHSA Section 2811 establishes the position of the Assistant Secretary for Preparedness and Response within HHS as a presidentially appointed and Senate-confirmed position.[135] The provision directs the Assistant Secretary to report to the HHS Secretary and to "serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies."[136] By statute, the Assistant Secretary is also to oversee many aspects of federal public health emergency strategy and coordination, including personnel, logistics, countermeasures (i.e., medical products to address specific threats), and medical product and supply capacity planning.[137] This

[127] This section was written by Kavya Sekar, Specialist in Health Policy, CRS Domestic Social Policy Division, and Hassan Z. Sheikh, Analyst in Health Policy, CRS Domestic Social Policy Division.

[128] ASPR, "About Us," https://aspr.hhs.gov/AboutASPR/ProgramOffices/Pages/ProgramOffice.aspx.

[129] ASPR, "Department of Health and Human Services Administration for Strategic Preparedness and Response," https://aspr.hhs.gov/AboutASPR/ProgramOffices/Documents/ASPR-Organizational-Chart.pdf.

[130] Eli Y. Adashi, Daniel P. O'Mahony, and I. Glenn Cohen, "Should the Administration for Strategic Preparedness and Response Lead the National Response to a Public Health Emergency?," *Journal of the American Medical Association*, vol. 4, no. 1 (2023).

[131] See Section 102 of P.L. 109-417.

[132] The preexisting position was called the Assistant Secretary for Public Health Emergency; see U.S. Congress, Senate Health, Education, Labor, and Pensions Committee, *Pandemic and All-Hazards Preparedness Act*, 109th Cong., 2nd sess., August 3, 2006, S. Rept. 109-319, p. 7.

[133] HHS, "HHS Strengthens Country's Preparedness for Health Emergencies, Announces Administration for Strategic Preparedness and Response (ASPR)," press release, July 22, 2022, https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2023-01-01T06:35:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2022%2F07%2F22%2Fhhs-strengthens-countrys-preparedness-health-emergencies-announces-administration-for-strategic-preparedness-response.html&timestamp=2023-01-01T03:43:25Z, and HHS ASPR, "Statement of Organization, Functions and Delegations of Authority," 88 *Federal Register* 10125, February 16, 2023.

[134] HHS Administration for Strategic Preparedness and Response, "Statement of Organization, Functions and Delegations of Authority," 88 *Federal Register* 10125, February 16, 2023. This notice did not cite a specific statutory authority for this change.

[135] 42 U.S.C. §300hh–10.

[136] PHSA Section 2811(b)(1); 42 U.S.C. §300hh–10(b)(1).

[137] PHSA Section 2811(b); 42 U.S.C. §300hh–10(b).

section also provides the Assistant Secretary with authority and responsibility over several programs (see "Key Programs and Functions" below).

Structure. ASPR's overall structure is not laid out in statute, but some components of the agency are established in statute. For example, PHSA Section 319L establishes the Biomedical Advanced Research and Development Authority (BARDA, named the "Center for the Biomedical Advanced Research and Development Authority" in ASPR's organizational chart).[138] While PHSA Section 319L(c) establishes BARDA within HHS generally, PHSA 2811(c) provides that the Assistant Secretary for Preparedness and Response is to have "authority over and responsibility for" BARDA.[139]

Key Programs and Functions. ASPR's programs are authorized primarily in PHSA Titles III, XII, and XXVIII. PHSA Section 2811(c) provides that the Assistant Secretary is to have "authority over and responsibility for" the following programs:[140]

- National Disaster Medical System;[141]
- Hospital Preparedness Cooperative Agreement Program;[142]
- Biomedical Advanced Research and Development Authority;[143]
- Medical Reserve Corps;[144]
- Emergency System for Advance Registration of Volunteer Health Professionals;[145] and
- Trauma care grants and related authorities in PHSA XII, Parts A through C.[146]

PHSA Section 2811[147] also states that ASPR is to "exercise the responsibilities and authorities of the Secretary with respect to the coordination of" (1) the Public Health Emergency Preparedness Cooperative Agreement Program,[148] (2) the Strategic National Stockpile,[149] and (3) the Cities Readiness Initiative.[150]

ASPR also administers Project BioShield, which is not listed in PHSA Section 2811. ASPR cites PHSA Section 319F-2(g)[151] as the program's authorization.[152] That subsection creates a Special Reserve Fund for the HHS Secretary to allocate to BARDA and to make purchases for the Strategic National Stockpile.

[138] 42 U.S.C. §247d–7e.

[139] 42 U.S.C, §300hh-10.

[140] 42 U.S.C. §300hh–10(c).

[141] PHSA Section 2812; 42 U.S.C. §300hh–11.

[142] PHSA Section 319C–2; 42 U.S.C. §247d–3b.

[143] PHSA Section 319L; 42 U.S.C. §247d–7e.

[144] PHSA Section 2813; 42 U.S.C. §300hh–15.

[145] PHSA Section 319I; 42 U.S.C. §247d–7b.

[146] PHSA Section 2811(c); 42 U.S.C. §300hh-10(c). The statute specifically transferred from HRSA to ASPR the authority to carry out activities related to trauma care. See §300hh-10(c)(2)(F).

[147] 42 U.S.C. §300hh–10.

[148] PHSA Section 319C–1; 42 U.S.C. §247d–3a.

[149] PHSA Section 319F–2; 42 U.S.C. §247d–6b.

[150] CDC has administered the Cities Readiness initiative as part of the Public Health Emergency Preparedness Cooperative Agreement Program; see CDC, "Cities Readiness Initiative (CRI), https://www.cdc.gov/readiness/php/cri/index.html.

[151] 42 U.S.C. §247d–6b(g).

[152] The statute does not specifically mention "Project BioShield." See citation at ASPR, *Congressional Justification FY2025*, p. 93, https://aspr.hhs.gov/AboutASPR/BudgetandFunding/Documents/FY2025/ASPR-cj.pdf.

BARDA currently manages Project BioShield.[153] In addition, PHSA Section 2811-1 establishes the Public Health Emergency Medical Countermeasures Enterprise and directs ASPR to serve as a co-chair.[154]

Appropriations. Beginning in FY2024, ASPR has received discretionary LHHS appropriations under an ASPR heading with two subheadings that align with broad program areas: (1) Research, Development, and Procurement and (2) Operations, Preparedness and Emergency Response.[155] The text of the appropriations act specifies funding levels for several programs within ASPR, such as for BARDA and the Strategic National Stockpile.[156] The text of the act also specifies funding levels for certain purposes within ASPR, for example, $300 million to prepare for or respond to an influenza pandemic.[157] Accompanying reports typically provide further direction for how funds should be distributed among certain ASPR programs and activities.[158]

Centers for Disease Control and Prevention (CDC)[159]

Under its most recent official mission statement, CDC "serves as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States."[160] CDC's main programs and activities generally fall into three categories: (1) support to public health infrastructure, including grant funding and technical assistance for public health programs at the international, state, and local level; (2) science and data collection and (3) health education and guidance.[161] CDC comprises 23 main centers, institutes, and offices (CIOs).[162]

CDC was established in 1946 as the Communicable Disease Center within the Bureau of State Services of the PHS.[163] Since it was first established, CDC has been administratively reorganized and renamed several times.[164] CDC was elevated to agency (operating division) status in 1973.[165] Congress changed all CDC references in law to its current name in 1992 (P.L. 102-531). Appropriations laws and accompanying report language have shaped CDC's overall programmatic scope by funding CDC programs related to specific disease and health topics. In addition, Congress has enacted several statutes that authorize specific positions, components, authorities, and programs within CDC, as summarized below.[166] In

[153] ASPR, "Project Bioshield," https://aspr.hhs.gov/AboutASPR/ProgramOffices/BARDA/Pages/Project-Bioshield.aspx.

[154] 42 U.S.C. §300hh–10a.

[155] See the FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 669-670.

[156] See the FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 669-670.

[157] See the FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 670.

[158] See the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1893, H2034-H2041.

[159] This section was written by Kavya Sekar, Specialist in Health Policy, CRS Domestic Social Policy Division.

[160] CDC, "Immediate Office of the Director (IOD): Mission Statement," https://www.cdc.gov/about/pdf/organization/iod-mission-statement.pdf. Established by Public Health Service, "Center for Disease Control; Office of the Assistant Secretary for Health Statement of Organization, Functions and Delegations of Authority," 45 *Federal Register* 67772 (Oct. 14, 1980).

[161] CRS In Focus IF12241, *The Centers for Disease Control and Prevention (CDC)*, by Kavya Sekar (2024).

[162] CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*, by Kavya Sekar (2024).

[163] CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*, by Kavya Sekar (2024).

[164] CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*, by Kavya Sekar (2024).

[165] Public Health Service, "Reorganization Order," 38 *Federal Register* 18261, July 9, 1973.

[166] CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*, by Kavya Sekar (2024).

December 2022, Congress formally enacted the position of the CDC Director into law as part of the PREVENT Pandemics Act included in Consolidated Appropriations, Act 2023 (P.L. 117-328).[167]

Establishment. No specific statute establishes CDC as an agency. The provision that establishes the CDC Director position (cited below) acknowledges that there is a "Centers for Disease Control and Prevention" that is to be headed by a CDC Director. CDC was established administratively in 1946 as the Communicable Disease Center, funded by an appropriation from Congress.[168]

Leadership. PHSA Section 305 establishes the position of the CDC Director as a presidentially appointed and Senate-confirmed position.[169] The provision requires the director to perform several functions, including implementing relevant PHSA authorities and responsibilities related to the prevention or control of diseases or conditions, preserving and improving public health domestically and globally, and addressing injuries and occupational and environmental hazards. PHSA Section 305 also requires the CDC Director to develop a strategic plan every four years to identify the agency's overall priorities and objectives. The provisions that authorize specific CDC CIOs, as explained in the next section, also authorize their leaders.

Structure. Of CDC's 23 main CIOs, three centers and institutes are explicitly established in authorizing statutes. Of these, one is specifically established within CDC: the National Center on Birth Defects and Developmental Disabilities, authorized in PHSA Section 317C.[170] The other two, National Institute for Occupational Safety and Health (NIOSH) and the National Center for Health Statistics, are generally established within HHS.[171]

Some CDC offices within the main 23 CIOs, such as the CDC Office of Women's Health, are also established in law.[172]

Key Programs and Functions. Since its inception, CDC has relied on the HHS Secretary's general public health authorities in PHSA for many of its core public health programs across topic areas.[173] Several CDC programs and activity areas are authorized by specific statutory provisions throughout several titles of the PHSA and other laws.[174] Some of these statutes direct functions to be specifically carried out by CDC. For example, the authorization for the Epidemiology and Laboratory Capacity grant program in PHSA Section 2821 directs the Secretary to establish the program "acting through" the CDC Director.[175] Others are directed to the HHS Secretary but carried out by CDC, for example, an

[167] See Section 2101 of Division FF, Title II, in P.L. 117-328.

[168] Based on accounts from federal officials involved in CDC's establishment from Elizabeth W. Etheridge, "Chapter 1: War and the Mosquito," in *Sentinel for Health: A History of the Centers for Disease Control and Prevention* (University of California Press, 1992), pp. 16-17. According to the book, "the U.S. Public Health Service had all the authority it needed to set up the new center, however, it needed funding from Congress." FY1946 appropriations (P.L. 79-124) for the Public Health Service included a new line item for "communicable diseases" with a funding level of $1.04 million (the FY1945 appropriations law [P.L. 78-373] did not include a similar line item.).

[169] 42 U.S.C. §242c.

[170] 42 U.S.C. §247b-4.

[171] NIOSH is authorized by the Occupational Safety and Health Act of 1970 (29 U.S.C. §671). The National Center for Health Statistics is authorized in PHSA Section 306 (42 U.S.C. §242k).

[172] PHSA Section 310A; 42 U.S.C. §242s.

[173] General authorities include those related to research and investigation (PHSA Section 301; 42 U.S.C. §241), international cooperation (PHSA Section 307; 42 U.S.C. §242l), health conferences and education (PHSA Section 310; 42 U.S.C. §242o), federal-state cooperation in public health (PHSA Section 311; 42 U.S.C. §243); and preventive health grants (PHSA Section 317; 42 U.S.C. §247b).

[174] Includes PHSA Titles III, VII, XI, XV, XVII, XIX, XXI, XXIII, XXV, XXVI, XVII, XXVIII, and XXXIII.

[175] 42 U.S.C. §300hh–31.

authorization for activities related to the prevention and control of sexually transmitted diseases in PHSA Section 318.[176]

Separate from its main public health programs, CDC administers certain regulations, including those related to the medical examination of immigrants and refugees, possession and use of select biological agents and toxins, occupational health, and interstate and foreign regulations for the control of communicable diseases, known as its quarantine regulations. The Secretary delegates authority to CDC to implement most of these regulations, with a few exceptions for occupational health regulations which are specifically directed to be carried out by NIOSH.[177]

Appropriations. The annual LHHS Appropriations Act provides both discretionary and mandatory funding to CDC. For discretionary funding, the appropriations account titles or the subheadings within an account under the CDC heading generally correspond with CDC CIOs.[178] For example, appropriations provided under the CDC's Immunization and Respiratory Diseases subheading fund its National Center for Immunization and Respiratory Diseases. NIOSH—whose authorizing statute, as noted above, establishes the agency generally within HHS—is funded under a CDC subheading for NIOSH.[179] In some cases, appropriations provided under a single CDC subheading fund multiple CIOs, such as the Public Health Scientific Services account. In addition, through LHHS Appropriations Acts, certain mandatory PPHF transfers are allocated to specific CDC programs.[180] With a few exceptions, the annual LHHS Appropriations Act does not direct funding for specific CDC programs in the text of the act. Accompanying reports specify funding for programs and activities within CDC accounts. In FY2024, the accompanying explanatory statement specified funding for more than 160 budget lines within CDC.[181]

CDC also administers a few large programs funded by mandatory spending with authorizations that are not specifically directed at CDC. For example, the Vaccines for Children program is a Medicaid-financed program authorized by Social Security Act Section 1928 (42 U.S.C. §1396s) to provide recommended childhood vaccines at no cost to eligible children. The statute does not specifically name CDC to lead the program but is directed at the HHS Secretary generally. CDC's NIOSH administers the World Trade Center Health Program as directed in statute, which authorizes and funds medical monitoring and treatment for certain conditions related to health exposures from the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, PA, pursuant to PHSA Title XXXIII.[182] Statutes provide that, with certain exceptions, the Director of NIOSH serves as Administrator of the program.[183] (NIOSH is established by statute generally within HHS, not specifically within CDC as summarized above.)

[176] 42 U.S.C. §247c.

[177] See the "Regulations" section in CRS Report R47981, *Centers for Disease Control and Prevention (CDC): History, Overview of Domestic Programs, and Selected Issues*, by Kavya Sekar (2024). Examples of statutes directing NIOSH regulations include 42 U.S.C. §7384q(c)(1) and 30 U.S.C. §843.

[178] In general, the appropriations language below these subheadings does not reference CDC. One exception is that the CDC-Wide Activities and Program Support subheading provides that the purpose of the funds is for specified "cross-cutting activities and program support for activities funded in other appropriations included in this Act for the Centers for Disease Control and Prevention."

[179] FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 654.

[180] CRS Report R47207, *Centers for Disease Control and Prevention (CDC) Funding Overview*, by Kavya Sekar (2024).

[181] CRS In Focus IF12241, *The Centers for Disease Control and Prevention (CDC)*, by Kavya Sekar (2025).

[182] 42 U.S.C. §§300mm et seq.

[183] PHSA Section 3306(16)(A); 42 U.S.C. §300mm-5(16)(A).

Agency for Toxic Substances and Disease Registry (ATSDR)[184]

ATSDR is a public health agency responsible primarily for summarizing toxicity information on chemicals most commonly present at contaminated sites and assessing whether exposures to such chemicals at specific contaminated sites, especially those that warrant federal attention, may pose risks to human health.[185] ATSDR also conducts other health studies involving chemical exposures and may have a response role in emergencies involving chemical releases. Although ATSDR's role is informational and not regulatory, the agency's findings and recommendations may inform response decisions made by federal, state, and local regulatory agencies for incidents involving chemical releases.[186] As of January 2020, ATSDR is headed by an Office of the Administrator, to which several offices report.[187] ATSDR has maintained several joint offices with CDC's National Center for Environmental Health.[188]

ATSDR was first authorized in law by the of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, P.L. 96-510, as amended), enacted in 1980.[189] HHS did not formally establish ATSDR administratively until 1983, when the CDC Director became the first ATSDR Administrator.[190] The CDC Director remains the ATSDR Administrator, as statutorily established in 2022 by the PREVENT Pandemics Act included in Consolidated Appropriations, Act 2023 (P.L. 117-328).[191]

Establishment. CERCLA Section 104(i)(1) explicitly establishes ATSDR as an agency within the Public Health Service.[192]

Leadership. CERCLA Section 104(i)(1) references an ATSDR Administrator and its responsibilities, and provides that ATSDR shall report directly to the Surgeon General.[193] Additionally, PHSA Section 305 directs the CDC Director, a presidentially appointed and Senate-confirmed officer, to serve as the ATSDR Administrator.[194]

Structure. CERCLA Section 104(i) does not provide direction on ATSDR's organizational structure but directs the President to provide adequate personnel for ATSDR, which shall not be fewer than 100 employees, measured in terms of full-time equivalents.[195]

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[184] This section was written by Jerry H. Yen, Analyst in Environmental Policy, CRS Resources, Science and Industry Division.

[185] ATSDR, "About the Agency for Toxic Substances and Disease Registry," November 12, 2024, https://www.atsdr.cdc.gov/about/index.html.

[186] CRS In Focus IF13007, *The U.S. Agency for Toxic Substances and Disease Registry (ATSDR): Statutory Authorities and Responsibilities*, by Jerry H. Yen and Lance N. Larson (2025).

[187] ATSDR, *Organizational Chart*, January 9, 2020, https://www.cdc.gov/about/media/pdfs/atsdr-org-chart.pdf

[188] See ATSDR mission statement, effective January 2020 (now archived), at https://web.archive.org/web/20241130092202/https://www.cdc.gov/about/media/pdfs/atsdr-mission-statement.pdf.

[189] P.L. 96-510.

[190] See HHS, "Statement of Organization, Functions, and Delegations of Authority: Agency for Toxic Substances and Disease Registry," 48 *Federal Register* 17652, April 25, 1983. After that notice was published, on May 12, 1983, HHS announced that the CDC Director would serve as the new ATSDR Administrator. See Richard G. Stoll, "Resolution of EDF/CMA Suit to Promote Government Health Studies," *Natural Resources Law Newsletter*, vol. 15, no. 4 (Summer 1983), pp. 3-4. See also General Accounting Office, *Interim Report on Establishment of the Agency for Toxic Substances and the Adequacy of Superfund Staff Resources*, GAO/HRD-83-81, August 10, 1983, https://www.gao.gov/assets/hrd-83-81.pdf.

[191] PHSA Section 305(a); 42 U.S.C. §242c(a).

[192] 42 U.S.C. §9604(i)(1).

[193] 42 U.S.C. §9604(i)(1).

[194] 42 U.S.C. §242c(a).

[195] 42 U.S.C. §9604(i).

Key Programs and Functions. CERLCA Section 104(i)(3) directs ATSDR to prepare toxicological profiles for hazardous substances, pollutants, and contaminants.[196] Additionally, CERCLA Section 104(i)(6) directs ATSDR to conduct a public health assessment (PHA) at each site—as designated by the Environmental Protection Agency—on the CERCLA National Priorities List (NPL).[197] ATSDR is also authorized to conduct PHAs at non-NPL sites in response to public petitions indicating that a chemical release is the probable source for exposure to a hazardous substance, pollutant, or contaminant.[198] CERCLA Section 104(i)(4) also authorizes ATSDR to conduct more limited health consultations in response to public petitions.[199] Health consultations may focus on a specific hazardous substance, pollutant, or contaminant, or a specific pathway of exposure at a site. In addition, Section 3019 of the Solid Waste Disposal Act (SWDA, P.L. 89-272, as amended) authorizes ATSDR to assess human health risks at landfills and surface impoundments.[200] In addition, CERCLA Section 104(i)(1)(D) authorizes ATSDR to provide medical care and testing to individuals, along with epidemiological studies and other assistance in the event of a public health emergency caused by, or believed to be caused by, exposure to toxic substances.[201]

Aside from CERCLA and SWDA, certain laws have directed specific ATSDR studies. For example, Section 316 of the National Defense Authorization Act for Fiscal Year 2018, as amended, authorizes CDC and ATSDR to conduct a joint study to assess risks from per- and polyfluoroalkyl substances exposure.[202]

Appropriations. The INT Appropriations Act provides ATSDR appropriations in one account to carry out authorized activities. These appropriations are directed specifically toward "necessary expenses for the Agency for Toxic Substances and Disease Registry" (i.e., the appropriations act directs the funds to ATSDR via bill text as well as the ATSDR heading).[203] Accompanying reports specify funding for certain programs and activities within ATSDR's account.

Centers for Medicare & Medicaid Services (CMS)[204]

CMS administers Medicare, Medicaid, the State Children's Health Insurance Program (CHIP), and the Health Insurance Marketplaces.[205] According to its website, the agency provides health coverage to more than 160 million individuals and "works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system."[206] In addition, the agency is tasked with other health functions, including enforcing (along with the U.S. Department of the Treasury and the Department

[196] 42 U.S.C. §9604(i)(3).

[197] 42 U.S.C. §9604(i)(6).

[198] In general, PHAs evaluate the extent to which the presence of hazardous substances, pollutants, or contaminants at a site may result in exposures that are harmful to individuals who may come in contact with such substances. Based on the findings of a PHA, ATSDR may take further action to study health effects among a potentially exposed population at a site.

[199] 42 U.S.C. §9604(i)(4).

[200] 42 U.S.C. §6939a.

[201] 42 U.S.C. §9604(i)(1)(D).

[202] P.L. 115-91, Section 316. This study is ongoing.

[203] For example, see 138 Stat. 277 for FY2024 ATSDR appropriations in the FY2024 INT Appropriations Act (Division E of the Consolidated Appropriations Act, 2024; P.L. 118-42).

[204] This section was written by Kirsten J. Colello, Specialist in Health and Aging Policy, CRS Domestic Social Policy Division; Karen E. Lynch, Specialist in Social Policy, CRS Domestic Social Policy Division; Jessica Tollestrup, Specialist in Social Policy, CRS Domestic Social Policy Division; and Hannah-Alise Rogers, Legislative Attorney, CRS American Law Division.

[205] See, for instance, SSA Title XVIII (42 U.S.C. §§1801, et seq.), SSA Title XIX (42 U.S.C. §§1900, et seq.), SSA Title XXI (42 U.S.C. §§2101, et seq.), Affordable Care Act Section 1321 (41 U.S.C. §18041).

[206] Centers for Medicare & Medicaid Services (CMS), "About Us," https://www.cms.gov/about-cms.

of Labor) federal private health insurance requirements,[207] as well as federal requirements on clinical laboratory testing.[208] The agency is subdivided into more than 20 offices, covering a variety of agency administrative and operational functions, and six centers.[209]

The origin of CMS dates back to March 1977, when the HEW Secretary announced a restructuring of the agency primarily under the authority of the Reorganization Plan No. 1 of 1953, creating a new operating division called the Health Care Financing Administration (HCFA).[210] HCFA combined the Bureau of Health Insurance, which administered Medicare under the Social Security Administration (then part of HEW), and the Medical Services Administration, which administered Medicaid under the Social and Rehabilitation Service, into a new entity tasked with administering both programs.[211] Additionally, the Secretary assigned other tasks to HCFA, including administering several quality assurance programs designed to curb fraud and abuse in Medicare and Medicaid.[212] In 1984, Section 2332 of Medicare and Medicaid Budget Reconciliation Amendments of 1984 (P.L. 98-369, Title III) added SSA Section 1117, which established the HCFA Administrator as a presidentially appointed, Senate-confirmed position. HCFA continued to exist as an operating division of HHS until 2001, when the Secretary renamed it the Centers for Medicare & Medicaid Services.[213] In 2003, Section 900(c) of the Medicare Prescription Drug, Improvement, and Modernization Act (P.L. 108-173) amended relevant statutory references to HCFA to reflect the agency's new name.

Establishment. No specific statute explicitly establishes CMS as an agency. HCFA, the predecessor to CMS, was administratively established by the HHS Secretary on March 9, 1977, as announced in a *Federal Register* notice on March 9, 1977, relying primarily on authority in Reorganization Plan No. 1 of 1953.[214] HCFA was later renamed CMS in 2001.[215]

Leadership. CMS is headed by an administrator. SSA Section 1117(a) requires the CMS Administrator to be a presidentially appointed and Senate-confirmed position.[216] SSA Section 1117(b) establishes the

[207] See CRS Report R46637, *Federal Private Health Insurance Market Reforms: Legal Framework and Enforcement*, by Jennifer A. Staman (2020).

[208] See PHSA Section 353 (42 U.S.C. §263a).

[209] Includes the Center for Medicare, the Center for Medicaid & CHIP Services, the Center for Medicare and Medicaid Innovation (CMMI), the Center for Program Integrity, the Center for Clinical Standards and Quality, and the Center for Consumer Information and Insurance Oversight (CCIIO). See HHS, CMS, "Approved Leadership," https://www.cms.gov/about-cms/agency-information/cmsleadership/downloads/cms_organizational_chart.pdf (Apr. 22, 2025).

[210] Department of Health, Education, and Welfare, Office of the Secretary, Health Care Financing Administration et al., "Reorganization Order," 42 *Federal Register* 13262 March 9, 1977 (establishing HCFA pursuant to "the authority of section 6 of Reorganization Plan No. 1 of 1953 and pursuant to the authorities vested in me as Secretary of Health, Education, and Welfare…").

[211] Department of Health, Education, and Welfare, Office of the Secretary, Health Care Financing Administration et al., "Reorganization Order," 42 *Federal Register* 13262 March 9, 1977. See also Alan P. Balutis, "The Reorganization of DHEW: What Happened, Why, and So What?," 1 *J. Health & Human Resources Admin.*, 504, 515 (May 1979), available at https://www.jstor.org/stable/25779930.

[212] Department of Health, Education, and Welfare, Office of the Secretary, Health Care Financing Administration et al., "Reorganization Order," 42 *Federal Register* 13262 March 9, 1977. See also Alan P. Balutis, "The Reorganization of DHEW: What Happened, Why, and So What?," 1 *J. Health & Human Resources Admin.*, 504, 515 (May 1979), available at https://www.jstor.org/stable/25779930.

[213] HHS, CMS, "Statement of Organization, Functions and Delegations of Authority; Reorganization Order," 66 *Federal Register* 35437, July 5, 2001 (stating that the reorganization order was based on "the authority of Section 6 of Reorganization Plan No. 1 of 1953 and pursuant to the authorities vested in me as Secretary of Health and Human Services…").

[214] Department of Health, Education, and Welfare (HEW), Office of the Secretary, Health Care Financing Administration (HCFA) et al., "Reorganization Order," 42 *Federal Register* 13262, March 9, 1977.

[215] HHS, CMS, Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 *Federal Register* 35437, July 5, 2001.

[216] 42 U.S.C. §1317(a).

position of Chief Actuary in CMS, who is appointed by, and in direct line of authority to, the CMS Administrator.[217]

Structure. A few CMS offices and centers are statutorily established, but not all. For example, Section 3021(a) of the ACA establishes the Center for Medicare and Medicaid Innovation (CMMI) as a CMS center.[218] Similarly, Section 2602 of the ACA establishes the Federal Coordinated Health Care Office within CMS to better coordinate and integrate benefits for dual-eligible beneficiaries receiving Medicare and Medicaid. This office is headed by a director appointed by, and in direct line of authority to, the CMS Administrator.[219] SSA Section 1808 establishes a center within CMS to coordinate administration of the Medicare prescription drug and Medicare Advantage programs; this center is also headed by a director who reports directly to the CMS Administrator.[220] PHSA Section 1707A establishes an Office of Minority Health within CMS to be headed by a director. [221]

Key Programs and Functions. CMS oversees a number of health care coverage and financing programs, including Medicare, Medicaid, and CHIP, and provisions related to private health insurance and health insurance exchanges, among other health and oversight-related activities. CMS programs and activity areas are authorized by specific statutory provisions throughout several titles of the SSA, including Titles XVIII, XIX, XXI, as well as the ACA and other laws. Most provisions provide authority to the HHS Secretary, who in-turn delegates this authority to CMS.[222] Some examples by program type include (1) SSA Title XVIII, which authorizes Medicare and requires the HHS Secretary to administer the program;[223] (2) SSA Titles XIX and XXI, which authorize Medicaid and CHIP, respectively, and direct the HHS Secretary to oversee state agencies' operation of Medicaid and CHIP state plans;[224] and (3) Sections 1311 and 1321 of the ACA, which direct the HHS Secretary to facilitate the establishment of state exchanges or, if a state chooses not to establish its own exchange, to establish and operate a federal exchange within the state.[225]

Some statutory provisions refer explicitly to CMS. One example is SSA Section 1848(k), which requires the HHS Secretary to implement a quality reporting system by eligible health care professionals on certain specified quality measures, acting through the CMS Administrator.[226]

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[217] 42 U.S.C. §1317(b).

[218] 42 U.S.C. §1315A(a)(1) (as added by P.L. 111-148, title III, §3021(a)). The statute further specifies that "the purpose of [CMMI] is to test innovative payment and service delivery models to reduce program expenditures" in the Medicare and Medicaid programs. 42 U.S.C. §1315A(a)(1).

[219] 42 U.S.C. §1315b(a)(1)-(2) (as added by P.L. 111-148, title II, §2602(a)(1)-(2)). The statute also sets forth the structure and goals for the office. 42 U.S.C. §1315b(a)(1)-(2).

[220] 42 U.S.C. §1395b-9(a).

[221] 42 U.S.C. §300u-6a. In addition to CMS, the statute also explicitly establishes an individual Office of Minority Health in other HHS operating Divisions, including CDC, the HRSA, SAMHSA, AHRQ, and FDA.

[222] See, for example, HEW, Office of the Secretary, HCFA et al., "Reorganization Order," 42 *Federal Register* 13262, March 9, 1977.

[223] See SSA Section 1874; 42 U.S.C §1395kk. Medicare Part A is authorized in SSA §1816; 42 U.S.C. §1395h. Medicare Part B is authorized in SSA Section 1842; 42 U.S.C. §1395u. Medicare Part C is authorized in SSA Section 1851; 42 U.S.C. §1395w-21. Medicare Part D is authorized in SSA §1860D-1; 42 U.S.C. §1395w-101. HHS Secretary has, in turn, delegated "responsibilities related to the administration of Medicare, Medicaid and supporting functions and services" to CMS. See HEW, Office of the Secretary, HCFA et al., "Reorganization Order," 42 *Federal Register* 13262, March 9, 1977.

[224] See SSA Section 1904; 42 U.S.C. §1396c. SSA Section 2106; 42 U.S.C. §1397ff. HHS Secretary has, in turn, delegated responsibilities related to the administration of Medicaid and CHIP to CMS. See HEW, Office of the Secretary, HCFA et al., "Reorganization Order," 42 *Federal Register* 13262, March 9, 1977; HHS, HCFA, "Statement of Organization, Functions, and Delegations of Authority," 42 *Federal Register* 65813, December 16, 1997.

[225] 42 U.S.C. §§18031(b)(1), 18041(c)(1).

[226] 42 U.S.C. §1395w–4(k)(8).

Appropriations. The annual LHHS Appropriations Act provides both discretionary and appropriated mandatory funding for four accounts under a CMS heading. More than 95% of this funding is appropriated mandatory spending.[227] The four accounts are generally programmatically focused and do not correspond with CMS centers and offices. The largest account (in terms of budget authority appropriated by the LHHS bill), Grants to States for Medicaid, is the primary source of funding for that program.[228] The next largest account, Payments to the Health Care Trust Funds, provides transfers from the Treasury's General Fund to finance aspects of the Medicare program.[229] The two entities in CMS that administer these respective programs, the Center for Medicaid & CHIP Services and the Center for Medicare, are funded by these accounts but also receive funding from other sources within LHHS and elsewhere.[230] The remaining two CMS accounts in LHHS, Program Management and Health Care Fraud and Abuse Control, fund a number of programmatic and administrative activities spread across (and beyond) CMS.[231] Much of this provision of funds across programs is directed in accompanying committee reports and explanatory statements and not in the text of the LHHS Appropriations Act itself.[232]

Furthermore, CMS receives significant funding outside the annual appropriations process through mandatory spending provided in authorizing acts. This funding includes the account that funds CMMI, which is specifically tied to that center and, as discussed above, was explicitly established in statute within CMS.[233] The two primary funding streams for CHIP (State Children's Health Insurance Fund and Child Enrollment Contingency Fund) are also funded in authorizing acts.[234]

Food and Drug Administration (FDA)[235]

FDA protects public health by regulating consumer and medical products such as drugs, biologics, (including vaccines), medical devices, food, cosmetics, and tobacco. As of March 2025, FDA reported that it comprises 22 main centers and offices, including 9 center-level organizations and 13 headquarter offices.[236]

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[227] See, for instance, the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H2029-2031, and CRS Report R48060, *Department of Health and Human Services: FY2025 Budget Request*, by Karen E. Lynch, Jessica Tollestrup, and Ada S. Cornell (2024).

[228] See, for instance, the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H2029-2030.

[229] See, for instance, the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H2030.

[230] See, for instance, the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H2029-2031. See also HHS, *Centers for Medicare & Medicaid Services: Congressional Justification FY2026*, https://www.cms.gov/files/document/fy2026-cms-congressional-justification-estimates-appropriations-committees.pdf.

[231] For example, the LHHS appropriations language for the Health Care Fraud and Abuse (HCFAC) account typically reserves a portion of the appropriation for CMS, a portion for the HHS Office of the Inspector General, and a portion for the Department of Justice. For example, see text at 138 Stat. 663 in the FY2024 LHHS omnibus (P.L. 118-47).

[232] For instance, see the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1893, H2033-H2034.

[233] SSA Section 1115A(a) & (f); 42 U.S.C. §1315a(a) & (f).

[234] SSA Section 2104; 42 U.S.C. §1397dd.

[235] This section was written by Hassan Z. Sheikh, Analyst in Health Policy, CRS Domestic Social Policy Division; Amanda K. Sarata, Specialist in Health Policy, CRS Domestic Social Policy Division; and Nora Wells, Analyst in Health Policy, CRS Domestic Social Policy Division.

[236] See FDA, "FDA Organization Charts," January 3, 2025, https://www.fda.gov/about-fda/fda-organization/fda-organization-charts; FDA, "FDA Overview Organization Chart," https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart.

FDA was part of the U.S. Department of Agriculture until 1940, when FDA was transferred to the Federal Security Agency (HEW/HHS's predecessor).[237] In 1968, following the Reorganization Plan No. 3 of 1966, FDA became part of PHS within HEW. By the end of 1973, FDA was one of six main PHS agencies (operating divisions).[238] In 1988, FDA was established within HHS in statute by the Food and Drug Administration Act of 1988, included in the Health Omnibus Programs Extension of 1988 (P.L. 100-607).[239] Some of FDA's regulatory functions have a long history, tracing back to the mid-1800s. FDA's authorizing statutes have been amended and reestablished numerous times over its history.[240] Today, FDA derives its authority primarily from the FFDCA, in addition to the PHSA and other laws.

Establishment. FDA is established within HHS by Section 1003 of the FFDCA.[241]

Leadership. FFDCA Section 1003(d)(1) establishes the FDA Commissioner as a presidentially appointed, Senate-confirmed position.[242] The statute further outlines the Commissioner's general authority and responsibilities, including

- providing overall direction to FDA, including the management and operation of its programs and activities;
- coordinating and overseeing the operation of all FDA administrative entities;
- supporting research relating to foods, drugs, cosmetics, devices, and tobacco products;
- conducting educational and public information programs relating to the responsibilities of FDA; and
- performing other functions as the Secretary may prescribe (FFDCA Section 1003(d)(2)(A)-(E)).[243]

Structure. FDA's overall organization is not specified in statute.

Although FDA's overall organization is not statutorily specified, Congress directed the establishment of certain FDA centers, offices, institutes, and entities in authorizing statutes. For example:

- The Center for Tobacco Products (CTP) (FFDCA Section 901(e)).[244]
- CTP's Office of Small Business Assistance (FFDCA Section 901(f)).[245]
- The Office of Combination Products (FFDCA Section 503(g)(8)).[246]
- The Office of the Chief Scientist (FFDCA Section 1010(a)).[247]

[237] FDA was renamed the Food and Drug Administration in 1930 (from the Food, Drug, and Insecticide Administration); see FDA, "Milestones in U.S. Food and Drug Law," January 30, 2023, https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law.

[238] PHS, "Reorganization Order," 38 *Federal Register* 18261, July 9, 1973, and HEW PHS Office of Administrative Management, *History, Mission and Organization of the Public Health Service*, 1976, pp. 3-5, https://www.google.com/books/edition/History_Mission_and_Organization_of_the/M-n4arYE5ScC?hl=en&gbpv=1.

[239] P.L. 100-607, Title V, §503.

[240] See FDA, "Milestones in U.S. Food and Drug Law."

[241] 21 U.S.C. §393(a).

[242] 21 U.S.C. §393(d)(1).

[243] 21 U.S.C. §393(d)(2)(A)-(E).

[244] 21 U.S.C. §387a(e).

[245] 21 U.S.C. §387a(f).

[246] 21 U.S.C. §353(g)(8).

[247] 21 U.S.C. §399a(a).

- The Office of Women's Health (FFDCA Section 1011(a)).[248]
- Intercenter Institutes for major disease areas (FFDCA Section 1014(a)).[249]
- Drug Safety Oversight Board (FFDCA Section 505–1(j)(1)).[250]
- FDA expert panels for drug and biologic products (FFDCA Section 505(n)(1)).[251]

Although most centers within FDA are not explicitly established by law,[252] the FFDCA generally charges FDA with the regulation of certain types of products, which roughly correlate with these centers (FFDCA Section 1003(b)(2)).[253] In addition, some FDA advisory committees are specifically authorized by statute, such as the Technical Electronic Product Radiation Safety Standards Committee (FFDCA Section 534(f)(1)(A)).[254]

Key Programs and Functions. As defined in statute (FFDCA Section 1003(b)(1)), FDA's mission is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[255] With respect to specific product types, FDA is to ensure that

- foods are safe, wholesome, sanitary, and properly labeled;
- human and veterinary drugs are safe and effective;
- there is reasonable assurance of the safety and effectiveness of devices intended for human use;
- cosmetics are safe and properly labeled; and
- public health and safety are protected from electronic product radiation.[256]

Generally, FDA's authorities for the regulation of these products types are delegated through the HHS Secretary[257] and found both within the FFDCA and the PHSA. For example, drugs and devices are approved or cleared under the FFDCA, whereas biologics are licensed under the PHSA.[258] Given the range of products that FDA regulates and the unique risks associated with each product type, the regulation of each of these product types is subsequently subject to a range of further controls as directed in statute.[259]

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[248] 21 U.S.C. §399b(a).

[249] 21 U.S.C. §399g(a).

[250] 21 U.S.C. §355–1(j)(1).

[251] 21 U.S.C. §355(n)(1).

[252] See, for example, the Center for Biologics Evaluation & Research (CBER), the Center for Drug Evaluation & Research (CDER). HHS, "Statement of Organization, Functions, and Delegations of Authority; Food and Drug Administration," 52 *Federal Register* 38275, October 15, 1987, https://archives.federalregister.gov/issue_slice/1987/10/15/38274-38276.pdf#page=2.

[253] 21 U.S.C. §393(b)(2).

[254] 21 U.S.C. §360kk(f)(1)(A).

[255] 21 U.S.C. §393(b)(1).

[256] 21 U.S.C. §393(b)(2)(A)-(E).

[257] See, for example, FFDCA §401 (21 U.S.C. §341); FFDCA §505(b)(1)(A)(21 U.S.C. §355(b)(1)(A)); FFDCA §515(c) (21 U.S.C. §360e(c)). But see PHSA §351(k)(5)(B) (42 U.S.C. §262(k)(5)(B)) (directing a biological product application to be "reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed").

[258] CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Sheikh (2023).

[259] For example, although the controls for certain medical products may include premarket review, labeling, establishment registration and product listing, quality system regulation, and postmarket requirements, other product types, such as cosmetics, may be subject to different regulatory requirements altogether.

Appropriations. The annual AG Appropriations Act provides discretionary funding for FDA.[260] These funds are provided under an FDA heading, with subheadings for FDA accounts or components thereof. Most of the FDA's appropriations are provided under the Salaries and Expenses subheading, with smaller amounts for Buildings and Facilities and the FDA Cures Act Innovation Account.[261] The funds appropriated under the Salaries and Expenses subheading are specifically provided for "necessary expenses of the Food and Drug Administration" (i.e., the appropriations act directs these funds to FDA via bill text as well as the FDA heading).[262] FDA's overall account structure therefore does not directly align with its organizational or program structure. However, the appropriations language under the FDA Salaries and Expenses subheading typically specifies funds for several FDA components, including (1) the Center for Food Safety and Applied Nutrition, (2) the Center for Drug Evaluation and Research, (3) the Center for Biologics Evaluation and Research, (4) the Center for Veterinary Medicine, (5) the Center for Devices and Radiological Health, (6) the National Center for Toxicological Research, and (7) the Center for Tobacco Products. Several appropriations lines also direct funds to the Office of Regulatory Affairs.[263]

The FDA funding in the AG Appropriations Act comes from two different sources: the Treasury's General Fund and user fees collected by the agency. In general, authorizing laws (see above) establish the legal framework that governs the fees, while the AG Appropriations Acts provide FDA the authority to collect and expend them. The largest and oldest FDA medical product user fee program was first authorized by the Prescription Drug User Fee Act (PDUFA, P.L. 102-571) in 1992. After PDUFA, Congress added other user fee authorities, for example, for medical devices, biosimilar drugs, animal drugs, generic drugs, tobacco products, and over-the-counter drugs.[264]

Like other authorizing provisions of the FFDCA, the authorizing provisions governing the user fees often direct the HHS Secretary to implement the provisions.[265] Many of these provisions, however, also specifically reference the FDA and its personnel in a manner that contemplates their role in implementation.[266] The provisions, however, generally do not reference the relevant FDA components.[267]

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[260] See the FDA section of CRS Report R48060, *Department of Health and Human Services: FY2025 Budget Request*, by Karen E. Lynch, Jessica Tollestrup, and Ada S. Cornell (2024).

[261] CRS Report R44576, *The Food and Drug Administration (FDA) Budget: Fact Sheet*, by Amanda K. Sarata (2022). The authorization for the Cures Act Innovation Account expires after FY2025.

[262] For instance, see 138 Stat. 97 of the FY2024 AG omnibus (P.L. 118-42).

[263] See, for instance, FY2024 AG omnibus (P.L. 118-42) at 138 Stat. 97-99.

[264] For a list of FDA user fee programs, see HHS, *Fiscal Year 2024 Food and Drug Administration Justification of Estimates for Appropriations Committees*, p. 17.

[265] See, for instance, FFDCA Section 919; 21 U.S.C. §387s.

[266] See, for instance, FFDCA Section 735(6)-(7) (21 U.S.C. §379g(6)-(7)) (defining "process for the review of human drug applications" to refer to specified activities "of the Secretary," but also defining the "costs of resources allocated for the process for review of human drug applications" to include expenses incurred by "officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees…."); FFDCA Section 737(6)-(7) (21 U.S.C. §379i(6)-(7) (same definitions for device applications); FFDCA Section 743(a), (c) (21 U.S.C. §379j-31(a), (c)) (directing the Secretary to assess and collect fees related to food safety activities but defining the circumstances of fee refund by reference to "food safety activities at the Food and Drug Administration"); FFDCA Sec. 744H, (21 U.S.C. §379j-52) (directing the Secretary to assess and collect fees for biosimilar biological products but setting the fees' inflation adjustment percentage by reference to change in the cost of personnel compensation at FDA).

[267] The FFDCA's user fee provisions also limit how FDA can use collected fees. For example, under PDUFA, collected user fees may only be used for those activities and costs included in the "process for the review of human drug applications," such as the inspection of prescription drug establishments or other facilities undertaken as part of FDA's review of pending drug applications or for leasing of facilities (FFDCA Section 735(6)-(7); 21 U.S.C. §379g(6)-(7)). User fee revenue collected under one user fee program can support certain activities throughout the FDA. See, for example, FFDCA §735(6)-(7); 21 U.S.C. §379g(6)-(7). For example, while most PDUFA revenue supports activities managed by CDER, PDUFA revenue also contributes to other FDA (continued...)

Health Resources and Services Administration (HRSA)[268]

HRSA's mission is "to improve health outcomes through access to quality services, a skilled health workforce, and innovative, high-value programs."[269] HRSA is primarily a grant-making agency that awards grants to states, public and private organizations, and institutions of higher education, among others. Some of HRSA's grant requirements shape how health facilities provide free or reduced-cost care.[270] HRSA includes six bureaus that administer programs related to health workforce, primary health care, health systems, HIV/AIDS, maternal and child health, and provider relief related to COVID-19. The operating division also includes 10 offices. Some offices are devoted to administrative functions (e.g., the Office of Operations and the Office of Planning, Analysis, and Evaluation), while others focus on health services or programs for specific populations (e.g., the Federal Office of Rural Health Policy and the Office of Women's Health).[271] HRSA also includes the Office of Advancement of Telehealth, which supports HHS-wide telehealth efforts.[272]

HRSA was established administratively in 1982, when the Secretary combined the then Health Services Administration and the Health Resources Administration.[273] Since HRSA was established, the scope of its work has been altered several times as programs have been enacted into law and assigned to the agency, either specifically in the program's authorizing statute or, more typically, through delegation by the HHS Secretary.[274]

Establishment. No specific statute establishes HRSA as an agency. Rather, the HHS Secretary established the agency administratively, as announced in a *Federal Register* notice in 1982.[275]

Leadership. No law explicitly establishes a leader for HRSA. The agency is headed by an administrator,[276] but this position and its duties are not established in statute. Traditionally, this position is

organizational components that support the PDUFA program, including CBER, CDRH, ORA, and FDA headquarters. See CRS Report R44750, *FDA Human Medical Product User Fee Programs*, by Amanda K. Sarata (2024).

[268] This section was written by Elayne J. Heisler, Specialist in Health Services, CRS Domestic Social Policy Division, and Alexandria K. Mickler, Analyst in Health Policy, CRS Domestic Social Policy Division.

[269] Health Resources and Services Administration (HRSA), "About HRSA," https://www.hrsa.gov/about.

[270] As part of HRSA's activities to monitor compliance with the terms and conditions of the funds it awards, HRSA accepts and investigates reports of entities that do not comply with the terms of receipt of Hill-Burton funds, a program not currently active that had provided grants to health facilities for construction and renovation projects. The program last provided funding in 1997; however, about 127 entities that received funding continue to have responsibility to provide free and reduced-cost care to individuals who qualify based on their income. HRSA receives and investigates complaints for individuals who believe they were denied Hill-Burton free or reduced care. See HRSA, "Hill-Burton Free and Reduced-Cost Health Care," https://www.hrsa.gov/get-health-care/affordable/hill-burton. Entities that receive funds under the Ryan White HIV/AIDS Program and the health center program must also provide care to all, regardless of their ability to pay.

[271] HRSA, "Bureaus & Offices," https://www.hrsa.gov/about/organization/bureaus.

[272] HRSA, "Office for the Advancement of Telehealth," https://www.hrsa.gov/about/organization/bureaus/oat.

[273] Public Health Service, "Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority," 47 *Federal Register* 38409-38424, August 31, 1982. This notice did not cite a specific statutory authority for HRSA's establishment. Notably, some components of HRSA today existed prior to the agency's creation in 1982 (e.g., the Bureau of Health Professions was part of the prior entity, which is the predecessor to the current Bureau of Health Workforce).

[274] See, for example, HHS, HRSA, "Statement of Organization, Functions, and Delegations of Authority," 56 *Federal Register* 166, August 27, 1991.

[275] Public Health Service, "Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority," 47 *Federal Register* 38409-38424, August 31, 1982.

[276] Public Health Service, "Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority," 47 *Federal Register* 38410, August 31, 1982.

appointed by the President but is not Senate confirmed.[277] However, some statutory provisions do reference the HRSA Administrator, including as an individual with whom to consult or collaborate. For example, PHSA Section 319-C directs the Assistant Secretary for Preparedness and Response to consult with a number of HHS officials, including "the Administrator of the Health Resources and Services Administration," when developing emergency preparedness guidelines.[278] Some statutes also direct certain programs to be carried out by the HRSA Administrator, as discussed in the "Key Programs and Functions" section below.

Structure. Of HRSA's six bureaus and 10 offices, only the Office for the Advancement of Telehealth is established in statute as part of HRSA.[279] Another major HRSA office, the Federal Office of Rural Health Policy, is established by statute within HHS generally.[280] The statute does not specifically place the office in HRSA. Since HRSA was established, the Secretary has at times created new HRSA bureaus and delegated authority to them to carry out specific activities (e.g., the Provider Relief Bureau).[281]

Key Programs and Functions. HRSA's programs are authorized in various titles of the PHSA, the SSA, and in other laws. For example, programs administered by the Bureau of Health Workforce are authorized in PHSA Titles III, VII, and VIII. As another example, programs administered by the Maternal and Child Health Bureau are authorized in SSA Title V, as well as in PHSA Titles III, XI, XII, XIX. Generally, most programs that HRSA administers are directed to be administered by the Secretary, and the Secretary delegates their operations to HRSA.[282] Some program statutes refer to HRSA explicitly as the administering entity. For example, PHSA Section 379 authorizes the C.W. Bill Young Cell Translation Program, which has been administered by the HRSA Health Systems Bureau.[283] The statute directs the HHS Secretary to carry out the program "acting through the Administrator of the Health Resources and Services Administration."[284]

Appropriations. The annual LHHS Appropriations Act provides discretionary funding for several accounts under a HRSA heading. Appropriations for the largest of these accounts are provided under several subheadings that correspond to bureaus and offices within the agency.[285] Under the HRSA heading is funding for the Family Planning Program authorized in Title X of the PHSA and administered by the Office of Population Affairs in the HHS Office of the Secretary.[286] HRSA also receives appropriations to

[277] Neither HRSA nor HHS appears to have issued a press release announcing the current HRSA administrator (Thomas J. Engels). However, the biography of the current administrator includes the statement, "Mr. Engels is the first person to be twice appointed HRSA Administrator by a U.S. President serving nonconsecutive terms." See HRSA, "Thomas J. Engels" https://www.hrsa.gov/about/organization/engels-bio.

[278] 42 U.S.C. §319C-3.

[279] PHSA Section 330I(c); 42 U.S.C. §254c-14(c).

[280] SSA Section 711; 42 U.S.C. §912. Statute refers to this office as the "Office of Rural Health Policy."

[281] For example, P.L. 116-136 appropriated $1,000,000,000 "to prevent, prepare for, and respond to coronavirus domestically or internationally," and for "necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus" (134 Stat. 563). This money became known as the "Provider Relief Fund." The Secretary delegated authority to HRSA to carry out this activity and created the Provider Relief Bureau. See HHS, HRSA, Statement of Organization, Functions, and Delegations of Authority, 87 *Federal Register* 59105-59106, September 29, 2022.

[282] For example, HRSA administers most programs authorized in PHSA Title VII (42 U.S.C. 292 et seq.).

[283] 42 U.S.C. §274k.

[284] 42 U.S.C. §274k.

[285] In general, the appropriations language below these subheadings does not reference HRSA, except that language under the HRSA-Wide Activities and Program Support subheading provides that funding is for "cross-cutting activities and program support for activities funded in other appropriations included in this Act for the Health Resources and Services Administration."

[286] For further information, see the HRSA FY2025 CJ; the description of the Title X Family Planning Program is on pages 373-377. For additional information on this program, see CRS In Focus IF10051, *Title X Family Planning Program*, by Alexa C. DeBoth and Angela Napili (2025).

make payments from the Vaccine Injury Compensation Program trust fund, which is established within HHS under PHSA Section 2101.[287] LHHS Appropriations Acts typically specify amounts for a handful of the programs, projects, and activities supported by this account.[288] Accompanying committee reports or explanatory statements typically direct HHS to make additional reservations for specified programs, projects, and activities across HRSA.[289]

Certain programs that HRSA administers also receive mandatory appropriations in authorizing laws, all of which are directed by the HHS Secretary and not HRSA specifically. These programs include the Health Center Program in the Bureau of Primary Care, the National Health Service Corps and Teaching Health Centers administered by the Bureau of Health Workforce,[290] and two programs administered by the Maternal and Child Health Bureau: Maternal, Infant, and Early Childhood Home Visiting program and the Family-to-Family Health Information Centers Program.[291]

Indian Health Service (IHS)[292]

IHS's mission is "to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level."[293] IHS is responsible for providing health services to American Indians and Alaska Natives who are members of federally recognized tribes.[294] IHS provides health care directly or provides funds for Indian tribes or tribal organizations to operate health care facilities.[295] The agency provides limited services free of charge to approximately 2.8 million eligible American Indians and Alaska Natives in 37 states.[296] IHS is organized by geographic area, with 12 Area Offices covering one or more states. Area Offices are subdivided into service units that may consist of multiple facilities. Service units sometimes cover a number of small reservations, or a larger reservation sometimes is covered by multiple service units. In addition to Area Offices, IHS's headquarters in Rockville, MD, also includes 10 component offices, such as the Office of the Director and the Office of Clinical and Preventive Services, among other administrative functions.[297]

Federal health care services for tribes were first formally authorized in law as part of the Snyder Act of 1921 (P.L. 67-85), which provided basic authority for the federal government to provide health services to American Indians and Alaska Natives. In 1955, the Transfer Act (P.L. 83-568) transferred IHS from the

[287] 42 U.S.C. §300aa-1.

[288] For instance, see the FY2024 LHHS omnibus (P.L. 118-47) provisions for this account starting at 138 Stat. 649.

[289] For instance, see the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1893, H2033-H2034.

[290] These programs most recently received appropriations in Division B, Title I, Section 2101, of P.L. 119-4.

[291] The authorization and funding for the Maternal, Infant, and Early Childhood Home Visiting program have been extended multiple times, most recently in Division FF, Title IV, Section 6101 (P.L. 117-328). Appropriations for the Family-to-Family Health Information Center program were most recently provided in Division B, Title II, Section 2302, of P.L. 119-4.

[292] This section was written by Elayne J. Heisler, Specialist in Health Services, CRS Domestic Social Policy Division.

[293] Indian Health Service, "About IHS," https://www.ihs.gov/aboutihs/.

[294] For information on federally recognized tribes, see CRS Report R47414, *The 574 Federally Recognized Indian Tribes in the United States*, by Mainon A. Schwartz (2024).

[295] The Indian Health Service (IHS) also provides grants to Urban Indian Organizations (UIOs) that operate smaller health facilities in urban areas. These facilities vary in terms of the services available; some provide comprehensive services, while others provide information and referral services. UIOs do not provide inpatient services. Outside of the grants they receive, UIOs are generally not eligible to receive funds from the overall IHS budget. For more information on the IHS system and UIOs, see CRS Report R43330, *The Indian Health Service (IHS): An Overview*, by Elayne J. Heisler (2016).

[296] HHS, IHS, *Fiscal Year 2025 Indian Health Service Justification of Estimates*, Justification of Estimates for Appropriations Committees (ihs.gov), https://www.ihs.gov/sites/ofa/themes/responsive2017/display_objects/documents/FY-2025-IHS-CJ030824.pdf; see CJ.2.

[297] IHS, "Organizational Structure," https://www.ihs.gov/aboutihs/organizationalstructure/.

Department of the Interior to the PHS within HEW. Then, in the 1970s, the Indian Self-Determination and Education Assistance Act of 1975 (ISDEAA, P.L. 93-638)[298] provided for the tribal administration of their own programs, including health care programs, and the Indian Health Care Improvement Act (IHCIA) of 1976 (P.L. 94-437) then authorized many of IHS's specific programs. The Indian Health Care Amendments of 1988 (P.L. 100-713) formally established IHS as a separate agency within the PHS in law; previously the agency was part of HRSA.[299]

Establishment. IHCIA Section 601 establishes the IHS as an agency withing the PHS.[300] The statute specifies that IHS is not to be an office or a component of another agency within HHS.[301]

Leadership. IHCIA Section 601 establishes the position of the IHS Director as presidentially appointed and Senate confirmed.[302] The provision directs the director to perform several functions relating to the maintenance and operation of IHS hospitals and health facilities, including a responsibility to ensure that all agency personnel have the skills, knowledge, ability, and education to fulfill the mission of the service. Under IHCIA Section 601(c)(3), the IHS Director is responsible for administering all health programs under the authority of IHCIA, the Snyder Act of 1921, the Transfer Act of 1954, the Indian Sanitation Facilities Act of 1959 (P.L. 86-121), and ISDEAA. The statute also specifies that the director is responsible for administering IHS's student loan programs, developing IHS's budget, and advising HHS (including the Assistant Secretary for Health and the heads of other operating divisions) on matters that affect Indian health. Most IHS positions below the director were established administratively; however, the Director of HIV/AIDS Prevention and Treatment was established in the 2010 IHICA reauthorization in IHCIA Section 832.[303]

Structure. The central IHS organizational component, the Area Office, is defined in Section 4 of IHCIA,[304] but the number of areas is not delineated. Areas are subdivided into service units, which are defined in IHCIA Section 4.[305]

Some IHS offices are explicitly authorized in IHCIA. For example, IHCIA Section 223[306] authorizes the Secretary to establish the Offices of Men's Health and the Office of Women's Health, and IHCIA Section 603[307] establishes the Office of Direct Service Tribes and specifies that the office shall be in the Office of the Director.[308]

Key Programs and Functions. IHCIA authorizes many of the specific programs that IHS administers and provides general authority for IHS to operate programs or provide services that seek to "ensure the

[298] CRS Report R48256, *Tribal Self-Determination Authorities: Overview and Issues for Congress*, by Mariel J. Murray, Cassandria Dortch, and Elayne J. Heisler (2025).

[299] P.L. 100-713; see also Public Health Service, "Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority," 47 *Federal Register* 38409-38424 (August 31, 1982).

[300] 25 U.S.C. §1661.

[301] 25 U.S.C. §1661.

[302] 25 U.S.C. §1661.

[303] 25 U.S.C. §1680v.

[304] 25 U.S.C. §1603.

[305] IHS's organization reflects where Indian tribes are located; as such, some states with large numbers of tribes (e.g., Alaska, California, and Oklahoma) are covered by one area office, while the East Coast, which has relatively fewer federally recognized tribes, is covered by a single area office located in Nashville, TN. A map of IHS areas is available in Figure 1 of CRS Report R43330, *The Indian Health Service (IHS): An Overview*, by Elayne J. Heisler (2016).

[306] 25 U.S.C. §1621v.

[307] 25 U.S.C. §1663.

[308] Direct Service Tribes are tribes that receive health services from federally operated programs, in contrast to self-determination tribes, which operate their own programs under the authority of the Indian Self-Determination and Education Assistance Act (25 U.S.C. §§5301 et seq.).

highest possible health status for Indians and urban Indians."[309] IHCIA includes eight titles, most of which authorize health programs. In most cases, IHCIA authorizes the Secretary "acting through the Service" to undertake specific health service activities, workforce support, or sanitation facilities among other things.[310]

Appropriations. The annual INT Appropriations Act provides discretionary appropriations under an IHS heading for four accounts.[311] The Indian Health Services account is the largest of IHS's appropriations accounts and funds most IHS health service programs.

The account includes specified funding levels for certain activities (e.g., the Indian Health Care Improvement Fund authorized in IHCIA Section 201),[312] but it does not closely align with IHS's agency or program structure.[313] Accompanying committee reports or explanatory statements typically direct HHS to make additional reservations for specified programs, projects, and activities across IHS.[314]

IHS also receives direct appropriations for the Special Diabetes Program for Indians in PHSA Section 330B.[315] This program is placed by law in HHS and is not specific to IHS.

National Institutes of Health (NIH)[316]

The National Institutes of Health is the nation's leading health and medical research agency. NIH comprises 27 semi-autonomous Institutes and Centers (IC) and the Office of the Director (OD). Of these, 24 ICs and the OD oversee research programs. The individual research ICs are focused on particular diseases (e.g., the National Cancer Institute), body systems (e.g., National Heart, Lung, and Blood Institute), life stages (e.g., the National Institute on Aging), and scientific fields (e.g., the National Institute of Biomedical Imaging and Bioengineering). Each research IC plans and manages its own research programs in coordination with the OD. Three centers provide support to and infrastructure for other NIH components: the Clinical Center, the Center for Information Technology, and the Center for Scientific Review.[317]

NIH traces its roots to the late 1880s, when it was a single research laboratory.[318] In 1930, Congress designated the research laboratory the National Institute of Health (P.L. 71-251). By 1948, several new institutes and divisions had been created, and the agency was renamed as the National Institutes of Health in the National Heart Act (P.L. 80-655), which amended the PHSA enacted in 1944. Congress and the executive branch created new ICs intermittently over the following decades, resulting in the 27 ICs that exist today. In 1985, NIH's authorizing statutes were substantially revised by the Health Research

[309] 25 U.S.C. §1602(1).

[310] 25 U.S.C. §1611. "The Service" in the Indian Health Care Improvement Act refers to the Indian Health Service.

[311] HHS, IHS, *Fiscal Year 2026 Indian Health Service Justification of Estimates*, https://www.ihs.gov/sites/ofa/themes/responsive2017/display_objects/documents/FY_2026_IHS_Congressional_Justification_Plan.pdf, p. CJ-8.

[312] 25 U.S.C. §1621.

[313] For instance, see the FY2024 Consolidated Omnibus Appropriations Act (P.L. 118-42) provisions for this account starting at 138 Stat. 272.

[314] For instance, see the explanatory statement accompanying the FY2024 Consolidated Omnibus Appropriations Act (P.L. 118-42) available in the *Congressional Record*, vol. 170, no. 39, March 5, 2024, pp. S1173-S1174.

[315] 42 U.S.C. §254c-2.

[316] This section was written by Kavya Sekar, Specialist in Health Policy, CRS Domestic Social Policy Division.

[317] CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Kavya Sekar (2025).

[318] CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Kavya Sekar (2025).

Extension Act of 1985 (P.L. 99-158), which created the current structure of PHSA Title IV, NIH's main authorizing statute. Many of the key governing provisions that inform NIH's current structure were also revised by the NIH Reform Act of 2006 (P.L. 109-482), in addition to other laws.[319]

Establishment. PHSA Section 401(a) establishes NIH as an agency within the Public Health Service.[320]

Leadership. PHSA Section 402 establishes the position of the NIH Director as a presidentially appointed and Senate-confirmed position and outlines its responsibilities.[321] PHSA Section 405 establishes the positions of IC Directors. Under the provision, the National Cancer Institute Director is appointed by the President.[322] The other IC Directors are appointed by the HHS Secretary acting through the NIH Director.

Structure. PHSA Section 401(b) names the 24 research ICs as agencies of NIH. Under the statute, NIH also includes "any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006."[323] The 24 research ICs are also authorized by specific statutory provisions within PHSA Title IV, as follows:

- Part C authorizes the 20 national research institutes,[324]
- Part D authorizes the National Library of Medicine,[325] and
- Part E authorizes the three research centers in addition to a few offices within OD.[326]

In addition, CRS identified one NIH office established outside of PHSA Title IV: the NIH Office of AIDS Research, established by PHSA Section 2351.[327]

PHSA Sections 401(d)(2)(A) and (B) also authorize the HHS Secretary to reorganize NIH, including pursuant to the recommendations of the Scientific Management Review Board (established by PHSA Section 401(e)).[328] The Secretary may establish, abolish, or reorganize any research institute, and such organizational changes may take effect 180 days after providing notice to the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor, and Pensions. The number of NIH research ICs is capped at 27 by PHSA Section 401(d)(1).[329] The NIH Director may reorganize the Office of the Director after a series of public hearings and with the approval of the HHS Secretary.[330] NIH

[319] CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*, by Kavya Sekar (2025).

[320] 42 U.S.C. §281(a).

[321] 42 U.S.C. §282.

[322] 42 U.S.C. §284.

[323] 42 U.S.C. §281(b). The report (H. Rept. 109-687) accompanying the House bill version of the NIH Reform Act of 2006 (H.R. 6164) stated, regarding this section, "In addition, the section recognizes any other national center that, as an agency separate from any national research institutes, was established within the NIH as of the day before the date of enactment of the Act. The Committee recognizes these centers to include the Center for Scientific Review, the Center for Information Technology, and the NIH Clinical Center, thereby totaling 27 national research institutes and centers." See U.S. Congress, House Energy and Commerce Committee, *National Institutes of Health Reform Act of 2006*, report to accompany H.R. 6164, 109th Cong., 2nd sess., 2006, 109-687.

[324] 42 U.S.C. Chapter 6A, Subchapter III, Part C.

[325] 42 U.S.C. Chapter 6A, Subchapter III, Part D.

[326] 42 U.S.C. Chapter 6A, Subchapter III, Part E.

[327] 42 U.S.C. §300cc–40.

[328] 42 U.S.C. § 281(e). Subject to certain exceptions, PHSA Section 401(f) generally directs NIH officials with organizational authorities under PHSA Section 401(d) to implement the Board's recommendations.

[329] 42 U.S.C. §281(d)(1).

[330] PHSA Section 401(d)(3); 42 U.S.C. §281(d)(3).

IC Directors may reorganize within their respective ICs after a series of public hearings and with the approval of the NIH Director.[331]

Key Programs and Functions. PHSA Title IV is the main authorizing title for NIH, which outlines the overall policies and requirements for NIH research. The title also specifies each NIH research IC's scope and some specific programs within each (PHSA Title IV, Part C-Part E).[332] All of the research ICs are covered by specific provisions in these sections, but the provisions vary considerably in the amount of detail included in the statutory language.

Some NIH programs are authorized elsewhere in the PHSA or in other laws. For example, PHSA Title XXIII authorizes certain NIH HIV/AIDS research programs and authorities. As another example, the 21st Century Cures Act (P.L. 114-255) authorizes NIH Innovation projects. NIH also cites PHSA Section 301, a general research authority of the HHS Secretary, as a basis for many of its programs.[333]

Appropriations. LHHS Appropriations Acts provide NIH with discretionary funding for several accounts under an NIH heading. Appropriations for the largest of these accounts are provided under a series of subheadings that correspond to NIH research ICs. [334] For the most part, the appropriations act and accompanying reports do not specify funding for programs within NIH or its ICs, with limited exceptions.

In addition, the NIH National Institute of Environmental Health Sciences receives an appropriation in the INT Appropriations Act that provides funding for the Superfund Research Program and related activities. These funds are specifically appropriated for "necessary expenses for the National Institute of Environmental Health Sciences" (i.e., the appropriations act directs these funds to this NIH institute via bill text as well as the heading).[335] NIH also receives mandatory funding for the Special Diabetes Programs for Type 1 Diabetes.[336] This program is placed by law in HHS and is not specific to NIH.[337]

Advanced Research Projects Agency for Health (ARPA-H)[338]

The Advanced Research Projects Agency for Health "advances high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity."[339] ARPA-H is modeled after other advanced research projects agencies, especially the Defense Advanced Research Projects Agency (DARPA) within the Department of Defense.[340] ARPA-H is housed within NIH, but its director reports to the HHS Secretary.

President Biden first proposed ARPA-H as part of the President's FY2022 budget request for the NIH.[341] ARPA-H was first established through an appropriation provided by Consolidated Appropriations

[331] PHSA Section 401(d)(4); 42 U.S.C. §281(d)(4).

[332] 42 U.S.C. Chapter 6A, Subchapter III, Part C-Part E.

[333] 42 U.S.C. §241.

[334] In general, the appropriations language below these subheadings does not reference NIH programs and entities. Some exceptions are that the National Cancer Institute (NCI) subheading includes funding for facilities repairs and improvements at a specific NCI Center, funding under the Office of the Director (OD) subheading is specifically for the NIH OD, and funding under the Buildings and Facilities subheading is for several related purposes at the NIH.

[335] For instance, see 138 Stat. 277 of the FY2024 INT omnibus (P.L. 118-42).

[336] PHSA Section 330B.

[337] CRS Report R43341, *National Institutes of Health (NIH) Funding: FY1996-FY2025*, by Kavya Sekar (2024).

[338] This section was written by Kavya Sekar, Specialist in Health Policy, CRS Domestic Social Policy Division.

[339] ARPA-H, "About Us," https://arpa-h.gov/about.

[340] ARPA-H, "Our Story," https://arpa-h.gov/about/timeline.

[341] NIH, *Congressional Justification: FY2022*, May 28, 2021, https://officeofbudget.od.nih.gov/pdfs/FY22/br/2022%20CJ%20Overview%20Volume%20May%2028.pdf, pp. 1-11

Act, 2022 (P.L. 117-103), and then enacted in authorizing statute as a part of the PREVENT Pandemics Act, which was included in the Consolidated Appropriations Act, 2023 (P.L. 117-328).[342]

Establishment. PHSA Section 499A(a) establishes ARPA-H within NIH.[343]

Leadership. PHSA Section 499A(c) establishes the ARPA-H Director position as a presidentially appointed position that is not subject to Senate confirmation.[344] The provision further requires the ARPA-H Director to report to the HHS Secretary and outlines the Director's duties and authorities. The authorities encompass an authority to appoint a Deputy Director who serves as the principal assistant to the Director (PHSA Section 499A(c)(7)).[345]

Structure. PHSA Section 499A(a)(2) specifies that ARPA-H is to consist of (1) an Office of the Director, (2) not more than eight program offices, and (3) special project offices as the Director chooses to establish.[346] The provision further requires that no fewer than two-thirds of the ARPA-H program offices are to be exclusively dedicated to supporting research and development activities.

Key Programs and Functions. PHSA Section 499A is ARPA-H's main authorization. Within this section, subsection (b) delineates ARPA-H's overall goals and functions.[347] Subsection (j) provides the ARPA-H Director with authority to appoint program managers who oversee specific ARPA-H programs, including by setting overall goals, making awards, and tracking outcomes for each program.

Appropriations. LHHS Appropriations Acts provide ARPA-H with discretionary funding in one account under an NIH heading.[348] Appropriations reports do not specify funding for specific programs within ARPA-H.[349]

Substance Abuse and Mental Health Services Administration (SAMHSA)[350]

The Substance Abuse and Mental Health Services Administration is the federal agency primarily responsible for supporting community-based mental health and substance abuse treatment and prevention services.[351] SAMHSA provides federal funding to states, local communities, and private entities that support education and training, prevention programs, early intervention activities, treatment services, and technical assistance. SAMHSA does not provide mental health or substance abuse treatment. Rather, the agency supports states' efforts in providing community-based behavioral health services. SAMHSA also conducts surveillance and data collection of national behavioral health issues, provides statistical and

[342] CRS Report R47568, *Advanced Research Projects Agency for Health (ARPA-H): Overview and Selected Issues*, by Kavya Sekar and Marcy E. Gallo (2023).

[343] 42 U.S.C. §290c(a).

[344] 42 U.S.C. §290c(c).

[345] 42 U.S.C. §290c(c)(7).

[346] 42 U.S.C. §290c(a)(2).

[347] 42 U.S.C. §290c.

[348] See FY2024 LHHS omnibus (P.L. 118-47) at 138 Stat. 660.

[349] See the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1890, H2025.

[350] This section was written by Johnathan Duff, Specialist in Health Policy, CRS Domestic Social Policy Division.

[351] Substance Abuse and Mental Health Services Administration, *Justification of Estimates for Appropriations Committees, FY2024*, Rockville, MD, https://www.samhsa.gov/about/budget. For more information on SAMHSA, see CRS Report R46426, *Substance Abuse and Mental Health Services Administration (SAMHSA): Overview of the Agency and Major Programs*, by Johnathan H. Duff (2020).

analytic support to grantees, and administers other agency-wide initiatives. SAMHSA is organized into four main centers, several offices, and a national policy laboratory.[352]

SAMHSA was formed in 1992 by Congress following the reorganization of the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA). ADAMHA, which was initially administratively established in 1973[353] but legislatively enacted in 1974 (P.L. 93-282),[354] supported treatment service delivery and scientific research related to mental health and addiction. In 1992, Congress enacted the ADAMHA Reorganization Act of 1992 (P.L. 102-321), which moved three research institutes (that still existed as of March 2025) from ADAMHA to the NIH.[355] The law further renamed and restructured SAMHSA to reflect its primary focus on funding community-based treatment services.[356]

Establishment. PHSA Section 501(a) establishes SAMHSA as an agency within the PHS.[357]

Leadership. PHSA Section 501(c)(1) establishes the position of the Assistant Secretary for Mental Health and Substance Use (Assistant Secretary) as a presidentially appointed and Senate-confirmed position.[358] PHSA Section 501[359] provides the authority for the Assistant Secretary to appoint a Deputy Assistant Secretary,[360] and requires the Assistant Secretary to appoint a Chief Medical Officer.[361] PHSA Section 501(d) directs the Assistant Secretary to perform several functions, related primarily to the prevention and treatment of mental health and substance use disorders.[362]

Structure. All four main SAMHSA centers and most of its offices are established in statute. PHSA Section 501(b) (42 U.S.C. §290aa(b)) establishes three of SAMHSA's four centers:

- the Center for Substance Abuse Treatment,
- the Center for Substance Abuse Prevention, and
- the Center for Mental Health Services.[363]

PHSA Section 505[364] establishes SAMHSA's fourth center, the Center for Behavioral Health Statistics and Quality. Other provisions within Title V of the PHSA establish some SAMHSA offices and entities, such

[352] SAMHSA, "SAMHSA Headquarters Offices and Centers," last updated April 2024, https://www.samhsa.gov/about/offices-centers. For more information about SAMHSA's organization, see CRS Report R46426, *Substance Abuse and Mental Health Services Administration (SAMHSA): Overview of the Agency and Major Programs*, by Johnathan H. Duff (2020).

[353] See 38 *Federal Register* 27316, October 2, 1973.

[354] Section 201 of P.L. 93-282.

[355] The National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), and the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

[356] See CRS Report R46426, *Substance Abuse and Mental Health Services Administration (SAMHSA): Overview of the Agency and Major Programs*, by Johnathan H. Duff (2020).

[357] 42 U.S.C. §290aa(a).

[358] 42 U.S.C. §290aa(c)(1).

[359] 42 U.S.C. §290aa.

[360] 42 U.S.C. §290aa(c)(2).

[361] 42 U.S.C. §290aa(g). PHSA Section 501 also requires the Assistant Secretary to appoint an Associate Administrator for Women's Services (42 U.S.C. §290aa(f)) and authorizes permission for an Associate Administrator for Alcohol Prevention and Treatment Policy (42 U.S.C. §290aa(e)).

[362] 42 U.S.C. §290aa(d).

[363] These centers are also established at PHSA Section 507 (42 U.S.C. §290bb), Section 515 (42 U.S.C. §290bb-21), and Section 520 (42 U.S.C. §290bb-31), respectively, which specify, among other things, that the centers shall each be headed by a Director appointed by the Secretary. PHSA Section 502 (42 U.S.C. §290aa-1) requires the Assistant Secretary to appoint advisory councils for each of these three centers, in addition to an advisory council for the Substance Abuse and Mental Health Services Administration (SAMHSA) generally.

[364] 42 U.S.C. §290aa-4.

as the Behavioral Health Crisis Coordinating Office[365] and the National Mental Health and Substance Use Policy Laboratory.[366] The Secretary has administratively established other offices and entities, such as SAMHSA's Office of Recovery.[367] Other provisions within Title V of the PHSA further authorize the Assistant Secretary to establish peer review groups and advisory committees, as needed.[368]

Key Programs and Functions. PHSA Title V is SAMHSA's main authorizing statute. Many SAMHSA programs and activities have explicit authorizations within Title V, while others are carried out under general authorities included in Title V, including many discretionary grant programs known as Programs of Regional and National Significance. Some statutory programs and functions are directed to be carried out by the HHS Secretary acting through the Assistant Secretary for Mental Health and Substance Use. For instance, PHSA Section 520E-3 requires the Secretary, acting through the Assistant Secretary, to maintain the National Suicide Prevention Lifeline.[369]

PHSA Title XIX authorizes SAMHSA's two largest grant programs: the Substance Use Prevention, Treatment, and Recovery Block Grant (SUBG) and the Community Mental Health Services Block Grant (MHBG). PHSA Section 1911(a) requires the Secretary, "acting through the Director of the Center for Mental Health Services," to make an allotment each fiscal year for each state for the MHBG.[370] Similarly, PHSA Section 1921(a) requires the Secretary, "acting through the Center for Substance Abuse Treatment," to make an allotment each fiscal year for each state for the SUBG.[371]

Appropriations. The annual LHHS Appropriations Act provides discretionary funding for SAMHSA in one account with four subheadings that generally correspond with SAMHSA's four statutorily established centers.[372] In any given year, funding levels for some programs, projects, or activities are specified in the text of the LHHS Appropriations Act. Accompanying committee reports or explanatory statements further specify funding amounts for particular programs, projects, and activities under each subheading.[373] The LHHS Act also directs that SAMHSA receive certain transfers in LHHS Acts, including transfers of mandatory funding from the PPHF.[374]

[365] PHSA Section 501B; 42 U.S.C. §290aa-0a.

[366] PHSA Section 501A; 42 U.S.C. §290aa-0.

[367] Substance Abuse and Mental Health Services Administration, "Statement of Organization, Functions, and Delegation of Authority," 87 *Federal Register* 26213, May 3, 2022.

[368] See, for instance, PHSA Section 501(i) (42 U.S.C. §290aa(i)).

[369] 42 U.S.C. §290bb-36b.

[370] 42 U.S.C. §300x(a).

[371] 42 U.S.C. §300x-21(a).

[372] Center for Behavioral Health Statistics and Quality (CBHSQ) activities are integrated throughout the other centers and cross over multiple funding lines. CBHSQ receives much of its funding from the health surveillance and program support appropriations account, in addition to a set-aside in the SUBG.

[373] For instance, see the explanatory statement accompanying the FY2024 LHHS omnibus (P.L. 118-47) available in the *Congressional Record*, vol. 170, no. 51, book II, March 22, 2024, pp. H1891-1892, H2025-H2028.

[374] For more information, see CRS Report R44796, *The ACA Prevention and Public Health Fund: In Brief*, and CRS Report R47895, *Prevention and Public Health Fund: In Brief*, by Kavya Sekar and John H. Gorman (2024).

Summary Table

Table 3. HHS Operating Divisions: Governing Statutes

Key Provisions, by Category

HHS Operating Division	Specific Establishment	Leadership	Structure	Key Functions and Programs	Appropriations[a]
ACF	No specific provision. Established by the HHS Secretary in 1991 (56 *Federal Register* 15885).	No provision for ACF specifically. ACF Assistant Secretary currently carries out statutory functions of Assistant Secretary for Family Support (SSA Section 416; 42 U.S.C. §616) in addition to other functions.	**No overarching provision.** ACF component offices that are established in law generally are placed within HHS.	ACF programs are authorized in several titles of the SSA and many other laws. Some statutory authorizations of ACF programs and activity areas reference an ACF role, but these references tend to be inconsistent.	The LHHS Act provides appropriations under an ACF heading that are programmatically focused and organized and generally do not correspond to individual ACF offices or bureaus. Programs administered by ACF also receive significant funding through mandatory spending provided in authorizing acts.
ACL	No specific provision. Established by the HHS Secretary in 2012 (77 *Federal Register* 23250).	No provision for ACL specifically. ACL Administrator currently carries out statutory functions of Assistant Secretary for Aging (OAA Section 201; 42 U.S.C. §3011) in addition to other functions.	**No overarching provision.** A few laws establish specific offices within ACL (e.g., 29 U.S.C. §§762 and 796-1). Other laws reference AOA, for example, for regional offices (OAA Section 205(a)(2)(B); 42 U.S.C. §3016(a)(2)(B)).	ACL programs are primarily authorized in the DD Act, the OAA and a few other laws. Some of these statutes reference an ACL or AOA role with regard to these activities.	The LHHS Act provides appropriations under an ACL heading to an account titled "Aging and Disability Services Programs." ACL also directly receives smaller amounts of mandatory funding. ACL programs receive annual transfers of the Prevention and Public Health Fund (PPHF) as directed in LHHS Acts.
AHRQ	PHSA Section 901(a); 42 U.S.C. §299(a).	**AHRQ Director:** PHSA Section 901(a); 42 U.S.C. §299(a).	**No overarching provision.** Several AHRQ components established by	AHRQ's main programs and functions are	The LHHS Act provides appropriations under an AHRQ heading to

HHS Operating Division	Specific Establishment	Leadership	Structure	Key Functions and Programs	Appropriations[a]
		Deputy Director: PHSA Section 946 (42 U.S.C. §299c–5).	specific statutes (e.g., Office of Priority Populations at PHSA Section 901(c)(3); 42 U.S.C. §299(c)(3)). Some components have roles defined in statute (e.g., the Center for Quality Improvement and Patient Safety (PHSA Section 933(b); 42 U.S.C. §299b-33(b)).	authorized in PHSA Title IX.	an account titled "Healthcare Research and Quality." AHRQ also receives annual transfers from the mandatory Patient-Centered Outcomes Research Trust Fund, as directed in statute (Internal Revenue Code Section 9511; 26 U.S.C. §9511).
ASPR	No specific provision. The HHS Secretary elevated ASPR from an office to an operating division in 2023 (88 *Federal Register* 10125).	**Assistant Secretary for Preparedness and Response:** PHSA Section 2811 (42 U.S.C. §300hh–10).	**No overarching provision.** At least one ASPR component, BARDA is established in law (PHSA Section 319L; 42 U.S.C. §247d–7e). Assistant Secretary is to have authority over BARDA per PHSA Section 2811(c).	ASPR's programs are primarily authorized in PHSA Titles III, XII, and XXVIII. PHSA Section 2811(c) also provides a list of functions for which the Assistant Secretary has "authority and responsibility."	The LHHS Act provides appropriations under an ASPR heading that align with broad program areas. The appropriations law text directs funding for several specific programs and purposes that are administered by ASPR.
CDC	No specific provision. CDC became an operating division of the PHS in 1973 (38 *Federal Register* 18261).	**CDC Director:** PHSA Section 305 (42 U.S.C. §242c).	**No overarching provision.** Three institutes and centers established in law. One in CDC (PHSA Section 317C; 42 U.S.C. §247b-4) and two within HHS (PHSA Section 306; 42 U.S.C. §242k and 29 U.S.C. §671).	CDC's programs and regulations are based in many general and specific authorities, mostly in the PHSA, some of which are directed at CDC specifically.	The LHHS Act provides appropriations under a CDC heading with subheadings that align generally with CDC centers and institutes. The LHHS Act also allocates mandatory PPHF funding to specific CDC programs.
ATSDR	CERCLA Section 104(i)(1) (42 U.S.C. §9604(i)(1)).	CERCLA Section 104(i)(1) (42 U.S.C. §9604(i)(1)) assigns responsibilities to the ATSDR Administrator and provides that ATSDR is to report to the Surgeon General.	**No overarching provision.** CERCLA Section 104(i)(16) (42 U.S.C. §9604(i)(16)) directs the President to provide for adequate personnel, which is to include	ATSDR's responsibilities and programs are primarily authorized in CERLCA Section 104(i) (42 U.S.C. §9604(i)), Solid Waste Disposal Act Section 3019 (42 U.S.C.	The INT Act appropriates funds specifically to ASTDR under an ASTDR heading to an account titled "Toxic Substances and Environmental Public Health."

HHS Operating Division	Specific Establishment	Leadership	Structure	Key Functions and Programs	Appropriations[a]
		Per PHSA Section 305 (42 U.S.C. §242c(a)), the CDC Director is to serve as the ATSDR Administrator.	not fewer than 100 employees.	§6939a), and a few other laws.	
CMS	No specific provision. The HHS Secretary established CMS's predecessor, the Health Care Financing Administration, in 1977 (42 *Federal Register* 13262). HCFA was renamed CMS in 2001 (66 *Federal Register* 35437).	**CMS Administrator:** SSA Section 1117(a) (42 U.S.C. §1317(a)).	**No overarching provision.** Three centers are established in law within CMS (ACA Section 2602, 42 U.S.C. §1315b(a)(1)-(2); ACA Section 3021(a), 42 U.S.C. §1315A(a)(1)); and SSA Section 1808, 42 U.S.C. §1395b-9(a)).	CMS's programs and regulations are based in specific authority, mostly in the SSA and directed by the HHS Secretary.	The LHHS Act provides appropriations (mostly appropriated mandatory and some discretionary) under a CMS heading that mostly align with CMS program areas (e.g., Medicaid). Programs administered by CMS also receive considerable mandatory spending provided in authorizing acts.
FDA	FFDCA Section 1003 (21 U.S.C. §393).	**FDA Commissioner:** FFDCA Section 1003(d)(1) (21 U.S.C. §393(d)(1)).	**No overarching provision.** Several specific centers and offices are established in law, such as The Center for Tobacco Products (CTP) (FFDCA Section 901(e); 21 U.S.C. §387a(e)). While not all centers are explicitly authorized, FDA is generally charged with regulation of certain product types, which roughly correlate with centers (FFDCA Section 1003(b)(2); 21 U.S.C. §393(b)(2)).	FDA's functions and programs are based in many general and specific authorities in FFDCA and PHSA (e.g., FFDCA Section 1003(c); 21 U.S.C. §393(c)).	The AG Act appropriates funds specifically to the FDA under an FDA heading for the FDA's main account, the Salaries and Expenses account. This account includes line items for several FDA centers and components.
HRSA	No specific provision.	No specific provision.	**No overarching provision.** One	HRSA's programs are	The LHHS Act provides

HHS Operating Division	Specific Establishment	Leadership	Structure	Key Functions and Programs	Appropriations[a]
	The HHS Secretary established HRSA in 1982 (47 *Federal Register* 38409).	The HHS Secretary established the position of the HRSA Administrator when establishing HRSA (47 *Federal Register* 38410).	office established in HRSA by law (PHSA Section 330I; 42 U.S.C. §254c-14). Another HRSA office is established within HHS generally (SSA Section 711; 42 U.S.C. §912).	authorized in several titles of the PHSA, SSA, and other laws. Some statutes direct programs to be carried out by HRSA specifically.	appropriations under a HRSA heading that align generally with HRSA's main bureaus and offices. Several programs are funded by mandatory spending provided in authorizing acts.
IHS	IHCIA Section 601(25 U.S.C. §1661).	**IHS Director:** IHCIA Section 601(25 U.S.C. §1661).	Area Offices defined in IHCIA Section 4 (25 U.S.C. §1603). Some IHS program offices authorized in statute (e.g., IHCIA Section 223 [25 U.S.C. §1621v]) authorizes the Offices of Men's Health and the Office of Women's Health.	IHS is authorized in IHCIA that consists of eight titles, most of which authorize health programs.	The INT Act provides appropriations under an IHS heading. One account, the Indian Health Services account, funds most IHS health service programs, with specified funding levels for certain IHS activities.
NIH	PHSA Section 401(a) (42 U.S.C. §281(a)).	**NIH Director:** PHSA Section 402 (42 U.S.C. §282). **IC Directors:** PHSA Section 405 (42 U.S.C. §284).	**Overall structure:** PHSA Section 401(b) (42 U.S.C. §281(b)). **Reorganization authority:** PHSA Section 401(d) (42 U.S.C. §281(d)).	NIH's programs are authorized primarily in PHSA Title IV, especially Part C-Part E (42 U.S.C. Chapter 6A, Subchapter III, Part C-Part E), which authorizes all NIH research ICs.	The LHHS Act provides appropriations under an NIH heading in paragraphs that correspond with NIH research ICs. Additional funds are appropriated to one specific institute, the National Institute of Environmental Health Sciences, under an NIH heading, in the INT Act.
ARPA-H	PHSA Section 499A(a) (42 U.S.C. §290c(a)).	**ARPA-H Director:** PHSA Section 499A(c) (42 U.S.C. §290c(c)). **Deputy Director:** PHSA Section 499A(c)(7)) (42 U.S.C. §290c(c)(7)).	**Overall structure:** PHSA Section 499A(a)(2) (42 U.S.C. §290c(a)(2)).	PHSA Section 499A (42 U.S.C. §290c).	The LHHS Act provides appropriations under an NIH heading to an account titled "Advanced Research Projects Agency for Health."

HHS Operating Division	Specific Establishment	Leadership	Structure	Key Functions and Programs	Appropriations[a]
SAMHSA	PHSA Section 501(a) (42 U.S.C. §290aa(a)).	**Assistant Secretary for Mental Health and Substance Use:** PHSA Section 501(c) (42 U.S.C. §290aa(c)).	All four main centers and several offices are established in statute. PHSA Section 501(b) (42 U.S.C. §290aa(b)) establishes three of SAMHSA's centers. PHSA Section 505 (42 U.S.C. §290aa-4) establishes a fourth center. Other PHSA Title V provisions establish some SAMHSA offices and entities.	SAMHSA is authorized primarily in PHSA Title V, including many activities explicitly, while other programs and activities are carried out under general authorities included in Title V. Several block grant programs are authorized in PHSA Title XIX.	The LHHS Act provides appropriations under a SAMHSA heading with subheadings that generally corresponds with SAMHSA's four statutorily established centers. SAMHSA also receives a transfer from the mandatory PPHF, as directed in the LHHS Act.

Source: CRS research and analysis of agencies' statutes, regulations, history, programs and funding, as reflected in the rest of this memorandum.

Notes: See the **Appendix** table below for abbreviations.

a. Unless otherwise specified, examples of mandatory funding provided outside of appropriations acts in this column are directed to specific programs and activities, not to HHS operating divisions.

Appendix. Table of Abbreviations

Abbreviation	Full Name
ACA	Patient Protection and Affordable Care Act of 2010 (P.L. 111-148, as amended)
ACF	Administration for Children and Families
ACL	Administration for Community Living
ACYF	Administration for Children, Youth, and Families
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
AG	Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
AHRQ	Agency for Healthcare Research and Quality
ANA	Administration for Native Americans
AOA	Administration on Aging
ARPA-H	Advanced Research Projects Agency for Health
ASPR	Administration for Strategic Preparedness and Response
AT	Assistive Technology
ATSDR	Agency for Toxic Substances and Disease Registry
BARDA	Biomedical Advanced Research and Development Authority
CAPTA	Child Abuse Prevention and Treatment Act (P.L. 93-247)
CCDBG	Child Care Development Block Grant (P.L. 97-35)
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (P.L. 96-510, as amended)
CHIP	State's Children's Health Insurance Program
CIOs	Centers, Institutes, and Offices
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare and Medicaid Services
CQuIPS	Center for Quality Improvement and Patient Safety
CSE	Child Support Enforcement
CTP	Center for Tobacco Products
DARPA	Defense Advanced Research Projects Agency
DD Act	Development Disabilities Act
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSA	Federal Security Agency
FVPSA	Family Violence and Prevention Services Act (P.L. 98-457)
HCFA	Health Care Financing Administration
HCFAC	Health Care Fraud and Abuse Control
HCUP	Healthcare Cost and Utilization Project
HEW	Department of Health, Education, and Welfare

Abbreviation	Full Name
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
ICs	Institutes and Centers
IHCIA	Indian Health Care Improvement Act
IHS	Indian Health Service
INT	Department of the Interior, Environment, and Related Agencies
ISDEAA	Indian Self-Determination and Education Assistance Act of 1975 (P.L. 93-638)
LHHS	Departments of Labor, Health and Human Services, Education, and Related Agencies
LIHEAP	Low Income Home Energy Assistance Program
MEPS	Medical Expenditure Panel Survey
MHBG	Community Mental Health Services Block Grant
MIPPA	Medicare Improvements for Patients and Providers Act (P.L. 110-275)
NAPA	Native American Programs Act (P.L. 93-644)
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NPL	National Priorities List
OAA	Older Americans Act (P.L. 89-73)
OCS	Office of Community Services
OD	Office of the Director
PAHPA	Pandemic and All-Hazards Preparedness Act (P.L. 109-417)
PCORI	Patient Centered Outcomes Research Institute
PCORTF	Patient Centered Outcomes Research Trust Fund
PDUFA	Prescription Drug User Fee Act (P.L. 102-571)
PHA	Public Health Assessment
PHS	Public Health Service
PHSA	Public Health Service Act
PPHF	Prevention and Public Health Fund
PREP	Personal Responsibility Education Program
PRWORA	Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (P.L. 104-193)
REAA	Refugee Education Assistance Act (P.L. 96-422)
SAMHSA	Substance Abuse and Mental Health Services Administration
SHIP	State Health Insurance Assistance Program
SSA	Social Security Act
SSBG	Social Services Block Grant
SUBG	Substance Use Prevention, Treatment, and Recovery Block Grant
SWDA	Solid Waste Disposal Act (P.L. 89-272, as amended)
TANF	Temporary Assistance for Needy Families

Abbreviation	Full Name
TVPRA	Trafficking Victims Protection Reauthorization Act of 2005 (P.L. 106-386)
USPSTF	U.S. Preventive Services Task Force