# **CRS Reports & Analysis**

Health Policy: Resources for Congressional Staff

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#### Purpose and Scope

This report is intended to serve as a starting point for congressional staff assigned to cover issues related to health care policy. It outlines major government stakeholders as well as relevant laws, regulations, federal programs, sources of data, and Congressional Research Service (CRS) products. It also provides <u>links to lists of CRS products on a particular health policy topic</u>.

The report focuses on major government health care programs, private health insurance, public health, and the health care delivery system. It does not include information related to global (foreign) health programs or health care services provided by the military, Veterans Health Administration, Indian Health Service, or Federal Bureau of Prisons.

Introduction to Health Policy

The Federal Government's Role in Health Policy

In 2016, national health care spending in the United States was approximately \$3.3 trillion, or about 17.9% of the gross domestic product (GDP). Although the United States spends substantially more on health care per person than other industrialized countries, it scores average or lower on many health-status, quality-of-care, and access-to-care indicators.

The federal government's share of national health care spending was 28% in 2016. In FY2016, 31.6% of all federal spending was for health programs.<sup>3</sup>

The federal government has a role in numerous aspects of the health care system. For example, it provides health benefits through programs such as Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP). Government payment and coverage policies affect health care spending in various ways, such as by setting payment rates; covering or not covering certain services; or restricting payments for fraudulent, unnecessary, or unsafe care. Government eligibility policies can affect individuals' access to health care, for example by providing coverage to low-income persons, the elderly, and persons with disabilities.

The federal government also influences the private health insurance market. The federal government has established consumer protections and minimum standards for private health plans by restricting exclusions for preexisting conditions and requiring that many plans cover certain preventive services and essential health benefits. These requirements are enforced and may be expanded by states. Through tax policy, the federal government encourages the purchase of private health insurance by excluding the value of employer-sponsored coverage from federal income and employment taxes, offering a health care tax credit for small businesses, and penalizing most persons who do not have health coverage under the individual mandate in the Patient Protection and Affordable Care Act<sup>4</sup> (ACA; P.L. 111-148,

as amended). Under the ACA, the federal government also created, or supported states in creating, health insurance exchanges through which individuals and small businesses can buy private health plans. The federal government subsidizes premiums for many consumers in those exchanges. These federal policies can affect access to health care for millions of Americans through private health insurance.

Through its public health efforts, the federal government can influence the health of the population. For example, the federal government's disease control efforts include the financing of pediatric vaccinations and the surveillance of infectious diseases. Federal public health efforts also include safety promotion, such as seat-belt use and the "Safe to Sleep" campaign to prevent Sudden Infant Death Syndrome.

In addition, through regulation and oversight, the federal government can affect the safety and efficacy of medical drugs and devices. For example, the federal government requires that most drugs and some devices be reviewed by the Food and Drug Administration (FDA) before they are approved for the U.S. market. For drugs and devices already on the market, the federal government monitors adverse event reports and alerts health professionals and the public to safety problems. The federal government also inspects drug and device manufacturing facilities for quality and safety violations.

Furthermore, the federal government performs and finances health-related research, including clinical research, comparative effectiveness research, health services research, and basic biomedical research. Federally supported research can evaluate the effectiveness of certain treatments, support the discovery of new treatments, and inform clinical practice.

Various federal programs also support the development of the health system's basic infrastructure. For example, the federal government impacts the health care workforce through programs such as student loans, scholarships, grants to higher education institutions, and graduate medical education (GME) payments to teaching hospitals. These federal efforts can affect workforce composition, supply, and training.

The above are just a few examples of the current federal role in health care. 5 Congress provides oversight and is responsible for considering legislation (including authorizing and appropriating funds) for federal health care activities.

#### Committees of Jurisdiction

Committee jurisdiction is determined by a variety of factors, including rules, agreements, and precedent. Many committees play a role in legislation or oversight of health programs, services, and products. Table 1 provides simplified guidance on jurisdiction using language from each committee's website. The focus is on committees and subcommittees that were most active in health legislation and oversight during the 112<sup>th</sup> through 115<sup>th</sup> Congresses.

Table 1. Committees and Jurisdictions

(Jurisdiction as described on the committee website as of May 2018)

Committee	Full Committee	Health-Related	Subcommittee
	Jurisdiction <sup>a</sup>	Subcommittees	Jurisdiction <sup>b</sup>
House Appropriations	Appropriations measures.	Labor, Health and Human Services, Education, and Related Agencies	Subcommittee jurisdiction over appropriations for the Department of Health and Human Services (except as noted below).

Agriculture, Rural
Development, Food
and Drug
Administration, and
Related Agencies

Subcommittee jurisdiction over appropriations for the Food and Drug Administration.

Interior, Environment, and Related Agencies Subcommittee jurisdiction over appropriations for the Agency for Toxic Substances and Disease Registry, Indian Health Service, and the superfund-related activities of the National Institute of Environmental Health Sciences.

House Education and the Workforce

Education and workforce matters generally.

Health, Employment, Labor, and Pensions Subcommittee jurisdiction over employment-related health and retirement security, including health benefits.

Higher Education and Workforce Development

Subcommittee jurisdiction over matters dealing with programs and services for the elderly, including nutrition programs and the Older Americans Act.

House Energy and Commerce

Includes consumer protection, food and drug safety, public health research, and environmental quality. Oversees multiple Cabinet-level departments and independent agencies, including the

**Health** 

Subcommittee
jurisdiction over the
health sector broadly,
including private and
public health
insurance (Patient
Protection and
Affordable Care Act,
Medicare, Medicaid,
CHIP); biomedical
research and
development; hospital

Department of Health and Human Services.

construction; mental health: health information technology, privacy, and cybersecurity; medical malpractice and medical malpractice insurance; the 340B drug discount program; the regulation of food, drugs, and cosmetics; drug abuse; the Department of Health and Human Services: the National Institutes of Health: the Centers for Disease Control and Prevention: Indian Health Service; and all aspects of the abovereferenced jurisdiction related to the Department of Homeland Security.

# Oversight and Investigations

Subcommittee jurisdiction over responsibility for conducting oversight and investigations of any matter related to the jurisdiction of the full committee

# House Oversight and Government Reform

Legislative jurisdiction over bills that would impact the operations of the federal government and oversight jurisdiction over all levels of government.

# Government Operations

Subcommittee legislative and oversight jurisdiction over government management and accounting measures; the economy, efficiency, and management of government operations and activities; procurement; federal property; public information; federal

records. The subcommittee also has legislative jurisdiction over drug policy and the Office of Information and Regulatory Affairs.

Health Care, Benefits, and Administrative Rules

Subcommittee oversight jurisdiction over health care policy, administration, and programs; regulatory affairs; governmentwide rules and regulations; financial services: and the administration and solvency of benefit and entitlement programs; and legislative jurisdiction over regulatory affairs and federal paperwork reduction.

Interior, Energy, and Environment

Subcommittee oversight jurisdiction over food and drug safety.

House Small Business

Jurisdiction over matters related to small business financial aid, regulatory flexibility, and paperwork reduction. Health and Technology

Subcommittee addresses how health care policies may inhibit or promote economic growth and job creation by small businesses, including oversight of implementation of the Affordable Care Act and availability and affordability of health care coverage for small businesses.

House Ways and Means

Jurisdiction over revenue measures

Health

Bills and matters that relate to programs

generally, the bonded debt of the United States, trade and tariff legislation, and national Social Security programs, including Medicare. providing payments (from any source) for health care, health delivery systems, or health research.

# Senate Appropriations

Appropriations measures.

Labor, Health and Human Services, Education, and Related Agencies Subcommittee jurisdiction over appropriations for the Department of Health and Human Services (except as noted below).

Agriculture, Rural
Development, Food
and Drug
Administration, and
Related Agencies

Subcommittee jurisdiction over appropriations for the Food and Drug Administration.

Interior, Environment, and Related Agencies

Subcommittee jurisdiction over appropriations for the Agency for Toxic Substances and Disease Registry, Indian Health Service, and a portion of National Institute of Environmental Health Sciences.

# Senate Commerce, Science, and Transportation

Jurisdiction over interstate commerce and consumer affairs, and regulation of consumer products and services.

Consumer Protection, Product Safety, Insurance, and Data Security Subcommittee authorizes and oversees efforts of various federal consumer protection agencies.

# Senate Finance

Jurisdiction over taxation and other revenue measures generally, including health Health Care

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programs under the Social Security Act, such as Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Other health and human services programs financed by a specific tax or trust fund

Senate Health, Education, Labor and Pensions Jurisdiction over aging, biomedical research and development, and public health.

Primary Health and Retirement Security

Subcommittee jurisdiction over a wide range of issues, including Health Resources and Services Act. substance abuse and mental health, oral health, health care disparities, the Pension Benefit **Guaranty Corporation** through the **Employee Retirement** Income Security Act of 1974 (ERISA), and the domestic activities of the Red Cross.

**Source:** Compiled by the Congressional Research Service (CRS). Language describing jurisdiction is based on information from committee websites.

- a. More information on committee jurisdiction is given on the committee websites.
- b. The "Subcommittee Jurisdiction" column provides selected health-related jurisdiction information for each subcommittee; see subcommittee websites for full subcommittee jurisdiction information.
- c. Subcommittee jurisdiction not described on the committee website as of May 2018.

For more information on committees and jurisdiction, see

- CRS Report 98-242, *Committee Jurisdiction and Referral in the Senate*.
- CRS Report 98-175, *House Committee Jurisdiction and Referral: Rules and Practice*.

# Federal Agencies

The Department of Health and Human Services (HHS) is the "U.S. government's principal agency for protecting the

health of all Americans and providing essential human services." HHS represents "almost a quarter of all federal outlays, and it administers more grant dollars than all other federal agencies combined."

HHS provides health care coverage to more than 100 million people through Medicare (the nation's largest health insurer), Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace. HHS works closely with state and local governments, and many HHS-funded services are provided at the local level by state or county agencies or through private-sector grantees. HHS programs are administered by 11 operating divisions, including 8 agencies in the U.S. Public Health Service and 3 human services agencies. HHS administers more than 100 programs, covering a wide spectrum of activities. In addition to providing services, HHS programs provide for equitable treatment of beneficiaries nationwide and enable the collection of national health and other data.

Table 2. Selected Department of Health and Human Services (HHS) Agencies Involved in Health Policy

Agency	Purpose	
Administration for Community Living (ACL)	Provides grants to support home- and community-based services for older adults and persons with disabilities.	
Agency for Healthcare Research and Quality (AHRQ)	Conducts and supports health services research to improve the quality of health care.	
Center for Consumer Information and Insurance Oversight (CCIIO)	A largely regulatory agency created under CMS by the Affordable Care Act (P.L. 111-148, as amended) to implement private health insurance provisions.	
Centers for Disease Control and Prevention (CDC)	Coordinates and supports population-based programs to prevent and control disease, injury, and disability. Supports data collection and disease surveillance. The CDC director also oversees the Agency for Toxic Substances and Disease Registry (ATSDR).	
Centers for Medicare & Medicaid Services (CMS)	Administers Medicare, Medicaid, and State Children's Health Insurance Programs (CHIP).	
Food and Drug Administration (FDA)	Assures the safety of most foods for humans and animals, dietary supplements, cosmetics, and radiation-emitting products, and the safety and effectiveness of human and veterinary drugs, human vaccines, and medical devices. Also regulates tobacco	

products.

Health Resources and Services Administration (HRSA) Supports health care by funding programs and systems to improve access to health care among the uninsured and medically underserved

**Indian Health Service (IHS)** 

Supports a health care delivery system for American Indians and Alaska Natives.

National Institutes of Health (NIH)

Conducts and supports basic, clinical, and translational biomedical and behavioral research.

HHS Office of the Inspector General (HHS-OIG) Investigates waste, fraud, and abuse in Medicare, Medicaid, and more than 100 other HHS programs.

Office of Minority Health (OMH)

Supports health policies and programs that improve the health of racial and ethnic minority populations.

Substance Abuse and Mental Health Services Administration (SAMHSA) Supports health care by funding mental health and substance abuse prevention and treatment services

U.S. Public Health Service Commissioned Corps (USPHS) One of the 7 uniformed services of the United States, the 6,700 health professionals in the USPHS protect and promote public health and advance public health science.

U.S. Surgeon General

Administers the U.S. Public Health Service Commissioned Corps and advocates for public health.

**Source:** Prepared by CRS based on information on HHS.gov.

#### **Budget and Appropriations**

Federal law requires the President to submit an annual budget to Congress no later than the first Monday in February. The budget informs Congress of the President's overall federal fiscal policy based on proposed spending levels, revenues, and deficit (or surplus) levels. The budget request lays out the President's relative priorities for federal programs. The President's budget also may include legislative proposals for spending and tax policy changes. Although the President is not required to propose legislative changes for those parts of the budget that are governed by permanent law, such changes are generally included in the budget.

For more information on budget and appropriations, see

- Office of Management and Budget (OMB), "The President's Budget for Fiscal Year 2019."
- OMB, Department of Health and Human Services, FY2019 (excerpted from The Budget for Fiscal Year FY2019).
- CRS Report 98-721, Introduction to the Federal Budget Process, Introduction to the Federal Budget Process.

In addition to OMB budget materials, individual agencies issue annual congressional budget justifications. These justifications provide budget information by program as well as narratives that explain the programs and their activities.

Although the President recommends spending levels, it is Congress, through appropriations and authorizations, that provides funding for the operations of federal agencies. The House and Senate Appropriations Committees issue reports to accompany each of the annual appropriations bills that are reported from committee. The report language typically includes additional direction to the agencies on congressional priorities and concerns. The following are selected CRS resources on the appropriations process and status:

- CRS Report R42388, *The Congressional Appropriations Process: An Introduction*.
- CRS Report R45083, *Labor, Health and Human Services, and Education: FY2018 Appropriations*.
- CRS Report R45138, Department of Health and Human Services: FY2019 Budget Request.
- CRS, "Issue Area: Appropriations."
- CRS, reports on Labor, HHS, and Education Appropriations.
- CRS, reports on Budget and Appropriations Procedure.
- CRS, "Appropriations Status Table" (includes links to reports, votes, and bills).

Table 3. Selected Health-Related Budget Documents

Agency	Appropriations Bill	Budget Websites and Documents
Department of Health and Human Services	multiple appropriations bills	HHS Budget Home HHS FY2019 Budget in Brief
Agency for Healthcare Research and Quality	Labor-HHS-ED	AHRQ Budget Home  AHRQ FY2019 Congressional Budget Justification
Centers for Disease Control and Prevention <sup>a</sup>	Labor-HHS-ED	CDC Budget Home  CDC FY2019 Budget Request Overview  CDC FY2019 Congressional Budget Justification
Centers for Medicare & Medicaid Services	Labor-HHS-ED	CMS Budget Home  CMS FY2019 Congressional Budget Justification
Food and Drug Administration	Agriculture	FDA Budget Home

FDA FY2019 Congressional

**Budget Justification** 

**HRSA Budget Home** 

Health Resources and Labor-HHS-ED

**Services** 

Administration HRSA FY2019 Congressional

**Budget Justification** 

National Institutes of Labor-HHS-ED

Health<sup>b</sup>

NIH Budget Home

NIH Overview of FY2019

President's Budget

NIH Congressional Budget
Justifications, by Institute and

<u>Center</u>

Substance Abuse and Labor-HHS-ED SAMHSA Budget Home

Mental Health

Services SAMHSA FY2019 Congressional

Administration Budget Justification

**Source:** Compiled by CRS from information on agency websites.

**Notes:** Labor-HHS-ED refers to the Labor, Health and Human Services, Education, and Related Agencies appropriations bill. Agriculture refers to the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies bill. Additional HHS Agency Budget Justifications are at <a href="https://www.hhs.gov/about/budget/index.html">https://www.hhs.gov/about/budget/index.html</a>.

- a. The Agency for Toxic Substances and Disease Registry, headed by the CDC director, is funded through the Interior, Environment, and Related Agencies appropriations bill.
- b. The National Institute of Environmental Health Sciences at NIH is shared between the Labor-HHS-ED and Interior, Environment, and Related Agencies appropriations bills.

#### Spending and Costs

U.S. health care spending (government, private, and out-of-pocket) consumed 17.9% of the U.S. GDP in 2016. In the ten years from 2007 through 2016, health care spending grew from \$2.3 trillion to \$3.3 trillion. Per capita health care spending grew from \$7,627 per person in 2007 to \$10,348 per person in 2016. The federal government accounted for 28% of total health spending in 2016, and state and local governments financed an additional 17%. 10

The rate of growth of health care spending has outpaced that of the national economy. With federal health care programs consuming a large portion of the federal budget, the federal role in health care has been central in the debate on federal spending and government reform. At the same time, the high cost of health care and health insurance has consumed workers' wage growth and threatened the economic well-being of America's families.

For more information on health care spending and costs, see

- Centers for Medicare & Medicaid Services (CMS), "National Health Expenditure Data."
- CMS, "National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage

## Expansions."

- OMB, "Table 15.1 Outlays for Health Programs: 1962-2023" in *Fiscal Year 2019 Historical Tables: Budget of the U.S. Government.*
- Agency for Healthcare Research and Quality, "Medical Expenditure Panel Survey."
- Bureau of Labor Statistics, "Consumer Price Index" (medical care is one of eight major groups in the Consumer Price Index).
- OECD, "Chapter 7 Health Expenditure," in Health at a Glance 2017: OECD Indicators.

#### Federal Support of Health Insurance

Medicare

Overview

Medicare is a federal program that pays for covered health care services of qualified beneficiaries. It was established in 1965 under Title XVIII of the Social Security Act to provide health insurance to individuals aged 65 and older, and it has been expanded over the years to include permanently disabled individuals under the age of 65. The program is administered by the Centers for Medicare & Medicaid Services (CMS) within HHS.

# Medicare consists of four distinct parts:

- Part A (Hospital Insurance, or HI) covers inpatient hospital services, skilled nursing care, hospice care, and some home health services. The HI trust fund is mainly funded by a dedicated payroll tax of 2.9% of earnings, shared equally between employers and workers.
- Part B (Supplementary Medical Insurance, or SMI) covers physician services, outpatient services, and some home health and preventive services. The SMI trust fund is funded through beneficiary premiums (set at 25% of estimated program costs for the aged) and general revenues (the remaining amount, approximately 75%).
- Part C (Medicare Advantage, or MA) is still Medicare but is a private plan option for beneficiaries that covers all Parts A and B services, except hospice. Individuals choosing to enroll in Part C must also enroll in Part B. Part C is funded through the HI and SMI trust funds.
- Part D covers outpatient prescription drug benefits. Funding is included in the SMI trust fund and financed through beneficiary premiums, general revenues, and state transfer payments.

#### For background resources on Medicare, see

- CRS Report R40425, *Medicare Primer*.
- CRS In Focus IF10885, *Medicare Overview*.
- CMS, Medicare and You: The Official U.S. Government Medicare Handbook.
- CMS, Brief Summaries of Medicare & Medicaid.
- CMS, Trustees Reports.

#### Laws

Most Medicare law is in <u>Title XVIII of the Social Security Act</u> (SSA, as amended; <u>42 U.S.C. §1395-1395III</u>).

The entire SSA, as amended, is also available in a <u>compilation</u> from the Office of Legislative Counsel.

#### Regulations

Most federal Medicare regulations are in Title 42 of the *Code of Federal Regulations* (42 C.F.R. §§405-426).

In addition to federal laws and regulations, CMS issues program guidance through informational bulletins, <u>manuals</u>, <u>transmittals</u> to Medicare contractors, and CMS <u>rulings</u>.

#### More Information

- CRS, reports on Medicare.
- CRS Report R44735, *Finding Medicare Enrollment Statistics*.
- CMS, CMS Fast Facts.
- CMS, <u>CMS Statistics Reference Booklet</u> (national statistics on enrollment, expenditures, and services).
- CMS, Medicare Enrollment Dashboard.
- CMS, Medicare & Medicaid Statistical Supplement.
- <u>Medicare Payment Advisory Commission</u> (MedPAC), an independent congressional agency established to advise Congress on issues affecting the Medicare program, publishes data, policy analysis, and recommendations to Congress.
- Congressional Budget Office (CBO), "Medicare."
- Government Accountability Office (GAO), "Medicare."

Medicaid and the State Children's Health Insurance Program

#### Overview

Medicaid is a means-tested entitlement program that finances the delivery of primary and acute medical services as well as long-term services and supports. Medicaid is jointly funded by the federal government and the states. Participation in Medicaid is voluntary for states; all states, the District of Columbia, and U.S. territories choose to participate. States must follow federal rules to receive federal matching funds, but they have the flexibility to design their own versions of Medicaid within the federal statute's framework. This flexibility results in variability across state Medicaid programs in factors such as Medicaid eligibility, covered benefits, and provider payment rates. In addition, there are several waiver and demonstration authorities that allow states to operate their Medicaid programs outside of federal program rules. Federal Medicaid spending is open-ended, with total outlays partly dependent on states' policy decisions and enrollees' use of services

The State Children's Health Insurance Program (CHIP) provides health insurance coverage to low-income, uninsured children in families with incomes above applicable Medicaid income standards. States also have the option to cover certain specified pregnant women. Like Medicaid, CHIP is jointly funded by federal and state governments and states administer their programs within federal rules to receive enhanced federal matching funds for program expenditures. However, CHIP differs from Medicaid in that federal CHIP funding is capped and there is no individual entitlement to covered services. Under CHIP, states may enroll targeted low-income children in a CHIP-financed expansion of Medicaid; create one or more separate CHIP programs; or devise a combination of both approaches. Current federal law provides federal funding for CHIP through FY2027.

For background resources on Medicaid and CHIP, see

- CRS In Focus IF10322, <u>Medicaid Primer</u>.
- CRS In Focus IF10399, Overview of the ACA Medicaid Expansion.
- CRS Report R43949, Federal Financing for the State Children's Health Insurance Program (CHIP).
- Centers for Medicare & Medicaid Services (CMS) Office of the Actuary, "Medicaid: A Brief Summary," in Brief Summaries of Medicare & Medicaid.
- HHS/HealthCare.gov, "The Children's Health Insurance Program (CHIP)."
- Medicaid and CHIP Payment and Access Commission (MACPAC), *Medicaid 101*.
- MACPAC, *CHIP*.
- CMS, "Medicaid."
- CMS, "Children's Health Insurance Program (CHIP)."

#### Laws

Most federal Medicaid law is in <u>Title XIX of the Social Security Act</u> (SSA, as amended; <u>42 U.S.C. §1396-1396w-5</u>).

Most federal CHIP law is in <u>Title XXI of the SSA (42 U.S.C. §1397aa-1397mm</u>).

Title XI of the SSA has several general provisions relevant to Medicaid and CHIP, including, for example, provisions

on demonstration projects, the Center for Medicare & Medicaid Innovation, quality measures, and program integrity. Title XI is codified in the *U.S. Code* (42 U.S.C. §§1301-1320e-3).

The entire SSA, as amended, is also available in a <u>compilation</u> from the Office of Legislative Counsel.

## Regulations

Most federal Medicaid regulations are in Title 42 of the Code of Federal Regulations (42 C.F.R. §§430.0-456.725).

Most federal CHIP regulations are in Title 42 of the *Code of Federal Regulations* (42 C.F.R. §457.1-457.1285).

In addition to federal laws and regulations, CMS issues sub-regulatory program guidance through publications such as the <u>State Medicaid Manual</u>, <u>frequently asked questions</u>, <u>informational bulletins and letters to State Medicaid Directors</u> and State Health Officials.

#### More Information

- CRS, reports on Medicaid & CHIP.
- Medicaid and CHIP are administered at the federal level by the <u>Centers for Medicare & Medicaid Services (CMS)</u> in HHS.
- The federal <u>Medicaid and CHIP Payment and Access Commission (MACPAC)</u> publishes data and policy analysis and makes recommendations to Congress, the HHS Secretary, and states.
- MACPAC's "MACStats" compiles key national and state statistics from a variety of sources.
- <u>CMS Fast Facts</u> has national statistics on beneficiaries, expenditures, and services.

Each state operates its own Medicaid and CHIP programs within federal guidelines.

- Links to information on each state's Medicaid program.
- <u>Links to each state's Medicaid website and contact information</u>; scroll to "2. Through your state Medicaid agency."
- Links to each state's CHIP website.

#### Private Health Insurance

#### Overview

Health insurance provides protection against the possibility of financial loss due to high health care expenses. Paying for health insurance on a regular basis through monthly premiums reduces financial uncertainty, helps regulate an individual's out-of-pocket spending, and provides greater access to health care.

The regulation of insurance traditionally has been a state responsibility. Individual states have established standards and regulations overseeing the "business of insurance," including requirements related to the finances, management, and business practices of an insurer.

Despite the states' role as the primary regulators of health insurance, overlapping federal requirements complicate regulation of the health insurance industry. Four federal laws in particular significantly impact how private health insurance is provided: 11

- The Employee Retirement Income Security Act of 1974 (ERISA; <u>P.L. 93-406</u>, as amended) outlines minimum federal standards for private-sector employer-sponsored benefits.
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104-191, as amended) addresses the concern that insured persons have about losing their coverage if they switch jobs or change health plans by ensuring the availability and renewability of coverage for certain employees and other persons under specified circumstances.
- The Internal Revenue Code of 1986, as amended, provides significant tax benefits for health insurance and

- expenses. By far the largest is the exclusion for employer-paid coverage, which employees may omit from their individual income taxes, but there are many others.
- The Patient Protection and Affordable Care Act (ACA; <u>P.L. 111-148</u>, as amended) includes private insurance provisions that impose new requirements on individuals, employers, and health plans; restructures the private health insurance market; sets minimum standards for health coverage; and provides financial assistance to certain individuals and, in some cases, small employers.

#### Laws

In general, many of the provisions in ERISA, IRC, and HIPAA are codified in the *U.S. Code* (29 U.S.C. §§1001-1461; Title 26 of the U.S.C.; and 42 U.S.C. §1320d et seq.). Much of the ACA is codified in the *U.S. Code* (42 U.S.C. §§18001-18122), where it is part of the Public Health Service Act.

The following are compilations of public laws:

- The Patient Protection and Affordable Care Act, as amended (Office of Legislative Counsel).
- The Employee Retirement Income Security Act of 1974, as amended (Office of Legislative Counsel).
- The Internal Revenue Code of 1986, as amended (Internal Revenue Service, IRS).

#### Regulations

Selected federal regulations about private health insurance are in Titles 29 and 45 of the *Code of Federal Regulations* (29 C.F.R. §2590 and 45 C.F.R. §§144-159).

The IRS also provides <u>regulations</u> and other official <u>guidance</u>.

The Center for Consumer Information & Insurance Oversight (CCIIO) maintains a library of Affordable Care Act regulations and guidance, by theme, along with additional explanatory materials.

#### More Information

- CRS, reports on Private Health Insurance.
- CRS, reports on Health Care Reform.
- CRS Report R45146, Federal Requirements on Private Health Insurance Plans.
- CRS Report R43981, *The Affordable Care Act's (ACA) Employer Shared Responsibility Determination and the Potential Employer Penalty.*
- CRS Report R44438, *The Individual Mandate for Health Insurance Coverage: In Brief.*
- CRS Report R43215, <u>Patient Protection and Affordable Care Act (ACA): Resources for Frequently Asked Ouestions</u>.

#### Public Health

Protection and Promotion of Public Health

#### Overview

The National Academies of Sciences, Engineering, and Medicine<sup>12</sup> defines the mission of public health as "fulfilling society's interest in assuring conditions in which people can be healthy." The World Health Organization says public health is "the science and art of promoting health, preventing disease, and prolonging life through the organized efforts of society." 14

The federal government's role in the protection and promotion of public health is led by the Centers for Disease Control and Prevention (CDC), which collects health data, supports disease surveillance, and coordinates and supports population-based programs to prevent and control disease, injury, and disability. Other agencies under HHS also support public health through health research, regulation of medical products, food safety, and health care safety net programs.

Assistance to states is provided for many of these activities. For a description of operating divisions (agencies) and their roles within HHS, see <u>Table 2</u>.

Public health is also supported by, among other agencies, the Environmental Protection Agency, which enforces clean air and water laws and regulates pesticides and hazardous materials; the U.S. Department of Agriculture, which inspects meat and poultry and tracks animal illnesses that can affect humans; and the Department of Homeland Security, which helps with border screening and coordination of biodefense detection activities.

Although the federal government has a key role funding and regulating public health activities, most public health authority rests in state law 15 and most public health work is carried out at the local level. Each state has a state health agency (SHA) and a state health official (SHO), the lead official for public health. SHAs vary considerably in the scope of public health activities performed. SHOs may be appointed by elected officials and may have short tenures. In addition, there are approximately 2,800 local health departments (LHDs). Some LHDs are under state control, whereas others are under local control.

More information on public health service agencies is provided in CRS Report R44916, <u>Public Health Service Agencies: Overview and Funding (FY2016-FY2018)</u>.

#### Laws

The principal federal law related to promotion and protection of public health is the Public Health Service Act (PHSA, as amended; 42 U.S.C. §§201-300mm-61).

The PHSA, as amended, is also available in a compilation from the Office of Legislative Counsel.

#### Regulations

Most federal regulations related to public health appear in Title 42, Chapter I of the Code of Federal Regulations.

#### More Information

- CRS, reports on <u>Public Health Services & Special Populations</u>.
- CRS, reports on Public Health Emergency Preparedness & Response.
- CRS, reports on Health Care Reform.
- CRS, reports on Health Care Delivery.
- CRS, reports on Food Safety.

#### Regulating Drugs and Devices

#### Overview

The Food and Drug Administration regulates the safety of human foods, dietary supplements, cosmetics, radiation-emitting products, and animal foods; the safety and effectiveness of human drugs, biological products (e.g., vaccines), medical devices, and animal drugs; and the manufacture, marketing, and distribution of tobacco products. In addition to congressional appropriations, the FDA has the authority to collect user fees from industry to support the review processes for drugs (human and veterinary), biological products, devices, tobacco products, and some food activities.

FDA oversees the approval and regulation of the safety and effectiveness of drugs and biologics sold in the United States. The divides this responsibility into two phases. In the preapproval (premarket) phase, FDA reviews manufacturers' applications to market drugs in the United States; a drug may not be sold unless it has FDA approval. The review covers evidence of safety and effectiveness, manufacturing facility and procedures, and labeling. Once a drug is on the market, FDA continues its oversight of drug safety and effectiveness. This postapproval (postmarket) phase lasts as long as the drug is on the market.

Medical device regulation is complex, in part because of the wide variety of items that are categorized as medical

devices. Devices range from simple tools used during medical examinations, such as tongue depressors and thermometers, to high-tech, life-saving implants such as heart valves and coronary stents. A manufacturer must obtain the FDA's prior approval or clearance before marketing many medical devices in the United States. The FDA classifies devices according to the risk they pose to consumers. Premarket review is required for moderate- and high-risk devices. Many low-risk devices, such as plastic bandages and ice bags, are exempt from premarket review. Once a device is allowed on the market, its manufacturer must comply with regulations on manufacturing, labeling, surveillance, device tracking, and adverse-event reporting.

## For background resources, see

- CRS Report R41983, How FDA Approves Drugs and Regulates Their Safety and Effectiveness.
- CRS Report R42130, FDA Regulation of Medical Devices.
- CRS Report R44620, Biologics and Biosimilars: Background and Key Issues.
- CRS Report R43062, Regulation of Dietary Supplements.
- CRS In Focus IF10463, Regulation of Over-the-Counter (OTC) Drugs.
- CRS Report R44961, FDA Reauthorization Act of 2017 (FDARA, P.L. 115-52).
- CRS Report R44576, *The Food and Drug Administration (FDA) Budget: Fact Sheet*.

#### Laws

The principal law related to drugs and devices is the Federal Food, Drug, and Cosmetic Act (FFDCA, as amended; 21 U.S.C. §§301-399f). The FFDCA, as amended, is also available in a compilation from the Office of Legislative Counsel.

FDA maintains a list of other relevant laws on the site "Laws Enforced by FDA."

# Regulations

Most FDA regulations are in <u>Title 21</u>, <u>Chapter I of the *Code of Federal Regulations*</u>.

FDA also maintains a database of federal regulations and list of guidance documents.

#### More Information

- CRS, reports on FDA Product Regulation & Medical Research.
- FDA website.
- <u>Drugs@FDA</u>, a database with information about <u>prescription</u> and <u>over-the-counter</u> human drugs and <u>therapeutic</u> <u>biological products</u> currently approved for sale in the United States.
- <u>Devices@FDA</u>, a database of cleared and approved medical device information from FDA, including links to the device summary information, manufacturer, approval date, user instructions, and other consumer information.
- FDA Warning Letters, a database with historical and recent warning letters.

### Federal Support of Biomedical Research

#### Overview

The U.S. government supports a broad range of scientific and engineering research and development (R&D). The R&D funded by the federal government is performed in support of the unique missions of the funding agencies. About 27.3% of the federal funding available for R&D goes to HHS, primarily for biomedical research carried out under the National Institutes of Health (NIH). 19

NIH is the primary agency of the federal government charged with the conduct and support of biomedical and behavioral research. It is made up of 27 institutes and centers, each with a specific research agenda often focusing on particular diseases or areas of human health and development. More than 80% of the NIH's budget goes to more than 300,000 research positions at more than 2,500 universities and research institutions. In addition, the NIH intramural

research program employs about 5,300 scientists and technical support staff who are government employees and another 5,000 nonemployee trainees, most of whom are located on the NIH main campus in Bethesda, Maryland.<sup>20</sup>

For background resources, see

- CRS Report R45150, Federal Research and Development (R&D) Funding: FY2019.
- CRS Report R43341, NIH Funding: FY1994-FY2019.
- CRS Report R44916, *Public Health Service Agencies: Overview and Funding (FY2016-FY2018)*.
- CRS Report R41705, *The National Institutes of Health (NIH): Background and Congressional Issues*.

#### Laws

NIH derives its statutory authority from the Public Health Service Act, as amended (42 U.S.C. §§281-290a). The PHSA, as amended, is also available in a compilation from the Office of Legislative Counsel.

## Regulations

Most regulations pertaining to NIH grants are in Titles 2 and 42 of the *Code of Federal Regulations* (42 C.F.R. §§50-60 and 2 C.F.R. §§300-399).

#### More Information

- CRS, reports on FDA Product Regulation & Medical Research.
- CRS, reports on <u>Health Care Delivery</u>.
- NIH website.
- NIH, Estimates of Funding for Various Research, Condition, and Disease Categories.
- NIH, Awards by Location & Organization.

Education and Training of the Health Workforce

#### Overview

The federal government has a long-standing role in the education and training of the health workforce. PHSA authorizes a variety of workforce development programs supporting the education and training of physicians, dentists, physician assistants, public health workers, nurses, and allied health professionals through grants, scholarships, and loan repayment. Among other objectives, programs are designed to encourage physicians and other providers to enter primary care, serve in rural or otherwise underserved areas, and promote racial and ethnic diversity in the health care workforce. These programs are administered primarily within HHS's Health Resources and Services Administration (HRSA).<sup>21</sup> They provide assistance directly to individuals and health professions schools and training programs, which use the funds to develop and expand their efforts to train the health workforce.

The federal government also plays a role in graduate medical education (GME). GME is clinical training in an approved residency program following graduation from schools of medicine, osteopathy, dentistry, and podiatry. All states require residency training to be licensed. The residents, who are serving a form of apprenticeship, provide patient care under the supervision of a teaching physician, primarily in teaching hospitals. Medicare and, in some states, Medicaid make explicit payments to teaching hospitals for their GME costs. Federal appropriations under the PHSA also support primary care residency programs and other health professional education, as well as children's teaching hospitals. Other sources of funding include research grants, endowments, and foundation grants. The Department of Veterans Affairs and the Department of Defense also support residency positions. The flow of funds among those involved in GME is complex and frequently involves cross-subsidies between medical schools, teaching hospitals, and other training sites.

#### For background resources, see

- CRS Report R44376, Federal Support for Graduate Medical Education: An Overview.
- CRS Report R41278, Public Health, Workforce, Quality, and Related Provisions in ACA: Summary and Timeline.

- CRS Report R43587, The Veterans Health Administration and Medical Education: In Brief.
- CRS Report R43571, Federal Student Loan Forgiveness and Loan Repayment Programs.
- CRS Report R43255, *The Mental Health Workforce: A Primer*.
- CRS Report R45067, *Children's Hospital Graduate Medical Education (CHGME)*.
- Health Affairs, "Health Policy Brief: Graduate Medical Education."
- GAO, Health Care Workforce: Federally Funded Training Programs in Fiscal Year 2012.
- GAO, <u>Physician Workforce</u>: <u>Locations and Types of Graduate Training Were Largely Unchanged, and Federal Efforts May Not Be Sufficient to Meet Needs</u>.
- GAO, <u>Physician Workforce: HHS Needs Better Information to Comprehensively Evaluate Graduate Medical Education Funding</u>
- CMS, "Direct Graduate Medical Education."
- IOM, "Graduate Medical Education That Meets the Nation's Health Needs."

#### Laws

Many federal programs that support health workforce development are authorized in Titles III, VII, and VIII of the PHSA (42 U.S.C. §§254b-256h) on primary health care; 42 U.S.C. §§292-295p on health professions education; and 42 U.S.C. §§296-297x on nursing workforce development. The PHSA, as amended is also available in a compilation from the Office of Legislative Counsel.

Medicare and Medicaid GME payments are authorized in <u>Title XVIII of the Social Security Act</u> (42 U.S.C. §§1395-1395III). The entire SSA, as amended, is also available in a <u>compilation</u> from the Office of Legislative Counsel.

#### Regulations

States handle the regulation of health professionals. For licensure, states require health professionals to graduate from accredited schools deemed acceptable by state boards of medical and allied health examiners and to pass state-mandated independent examinations.

#### More Information

- HRSA, <u>Bureau of Health Workforce</u> (BHW), provides federal health professions grants and scholarship and loan programs.
- HRSA, <u>National Health Service Corps</u> (NHSC), offers scholarships and student loan repayments for those who agree to serve in federally designated health professional shortage areas.
- HRSA, National Center for Health Workforce Analysis, provides information on workforce data and analysis.
- HRSA, <u>Council on Graduate Medical Education</u> (COGME), provides assessment of physician workforce trends, training issues, and financing policies.
- <u>Accreditation Council for Graduate Medical Education</u> (ACGME), a private professional organization responsible
  for the accreditation of residency education programs, publishes the <u>ACGME Data Resource Book</u> with statistics
  on resident demographics, participating institutions, and program accreditation status.
- Association of American Medical Colleges (AAMC), a not-for-profit association representing all accredited U.S. and Canadian medical schools, publishes a number of <u>Workforce Data and Reports</u> on both the state and national level
- <u>Federation of State Medical Boards</u> represents state medical boards; resources include information on state requirements for medical licensure.

#### Further Assistance

For in-depth policy questions and analysis, please contact CRS Congressional Services at 7-5700.

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# **Footnotes**

- 1. U.S. Centers for Medicare & Medicaid Services (CMS), Office of the Actuary, *National Health Expenditures Fact Sheet*, <a href="https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html">https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html</a>
- 2. Organization for Economic Co-operation and Development (OECD), *Health at a Glance 2017: OECD Indicators*, 2017, <a href="http://www.oecd.org/health/health-at-a-glance-19991312.htm">http://www.oecd.org/health/health-at-a-glance-19991312.htm</a>. *U.S. Health in International Perspective: Shorter Lives, Poorer Health*, ed. Steven H. Woolf and Laudan Aron (Washington, DC: National Academies Press, 2013), <a href="https://www.nap.edu/catalog/13497/us-health-in-international-perspective-shorter-lives-poorer-health">https://www.nap.edu/catalog/13497/us-health-in-international-perspective-shorter-lives-poorer-health</a>. Irene Papanicolas, Liana R. Woskie, and Ashish K. Jha, "Health Care Spending in the United States and Other High-Income Countries," <a href="JAMA">JAMA</a>, vol. 319, no. 10 (March 13, 2018), pp. 1024-1039.
- 3. U.S. Office of Management and Budget, "Historical Tables—Table 15.1, Total Outlays for Health Programs: 1962–2023" in *Budget of the United States Government, Fiscal Year 2019*, February 12, 2018, <a href="https://www.whitehouse.gov/wp-content/uploads/2018/02/hist15z1-fy2019.xlsx">https://www.whitehouse.gov/wp-content/uploads/2018/02/hist15z1-fy2019.xlsx</a>.
- 4. The individual mandate was modified under the 2017 tax revision, <u>P.L. 115-97</u>, which was enacted on December 22, 2017. The law effectively eliminates the penalty associated with the individual mandate beginning in 2019 (i.e., the penalty is in effect through 2018). However, the 2017 tax revision does not make any other substantive changes to the statutory language establishing the mandate and its associated penalty. For more information, see CRS Report R44438, *The Individual Mandate for Health Insurance Coverage: In Brief*.
- 5. The federal government also has global (foreign) health programs and is a direct provider of health care through, for example, the military health care system, the Veterans Health Administration, the Indian Health Service, and the Federal Bureau of Prisons. These programs are beyond the scope of this report.
- 6. According to CRS Report RS20544, *The Office of the Parliamentarian in the House and Senate*, the House and Senate Parliamentarians "recommend the referral of most measures to committee, acting on behalf of the Speaker of the House or the presiding officer of the Senate. They refer measures on the basis of House and Senate rules and precedents that define committee jurisdictions" (p. 1).
- 7. U.S. Department of Health and Human Services (HHS), "Introduction: About HHS," *Strategic Plan FY 2018 2022*, <a href="https://www.hhs.gov/about/strategic-plan/introduction/index.html">https://www.hhs.gov/about/strategic-plan/introduction/index.html</a>.
- 8. HHS, "About the Department of Health and Human Services," *FY 2017 HHS Agency Financial Report* <a href="https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/fy-2017-hhs-agency-financial-report/management-discussion-analysis.html">https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/fy-2017-hhs-agency-financial-report/management-discussion-analysis.html</a>.

- 9. "HHS Agencies and Offices," at <a href="https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html">https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html</a> and "Programs & Services," at <a href="https://www.hhs.gov/programs/index.html">https://www.hhs.gov/programs/index.html</a>.
- 10.
  Data in this paragraph is taken from CMS, "National Health Expenditure Data: Historical," <a href="https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html">https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html</a>.
- 11. CRS Report RL32237, *Health Insurance: A Primer*.
- The National Academies of Sciences, Engineering, and Medicine provide expert scientific advice to the government "whenever called upon" by Congress or a government agency. The Academies do not perform original research; instead, panels consider problems of national importance and provide unbiased and authoritative advice. Their recommendations influence decision makers at all levels of government and the private sector. Although much of the work of the Academies comes from, and is funded by, Congress and federal agencies, the experts' deliberations are private and independent. See the Academies website for more information, <a href="http://www.nationalacademies.org/">http://www.nationalacademies.org/</a>. The Health and Medicine Division of the Academies was formerly known as the "Institute of Medicine."
- 13. Institute of Medicine and Committee for the Study of the Future of Public Health, Division of Health Care Services, *The Future of Public Health* (Washington, DC: National Academy Press, 1988).
- 14. World Health Organization, *World Report on Knowledge for Better Health*, Geneva, November 2004, <a href="http://www.who.int/rpc/meetings/wr2004/en/">http://www.who.int/rpc/meetings/wr2004/en/</a>.
- 15. Federal authority to regulate products in commerce is the basis for the Food and Drug Administration's regulation of food and medical products, as discussed in "Regulating Drugs and Devices."
- National Association of County and City Health Officials, "2016 National Profile of Local Health Departments," http://nacchoprofilestudy.org/wp-content/uploads/2017/04/ProfileReport Final3b.pdf.
- 17. The FDA does not handle all policy-relevant aspects of drugs. For example, the states are responsible for regulating the practice of medicine and pharmacy. The FDA does not oversee insurance coverage or pricing for drugs. For information on Part D drug coverage, see the "Medicare" section of this report.
- 18. CRS Report R45150, *Federal Research and Development (R&D) Funding: FY2019*.
- In recent years, the Department of Defense (DOD) has played a growing role in medical research. Examples include the U.S. Army Medical Department Research and Materiel Command, <a href="http://mrmc.amedd.army.mil">http://mrmc.amedd.army.mil</a>, and the Congressionally Directed Medical Research Program, <a href="http://cdmrp.army.mil">http://cdmrp.army.mil</a>.

Other federal agencies also support the education and training of the health workforce, including Department of Defense programs for health professionals working with active duty military, Department of Veterans Affairs programs for health professionals working with veterans, federal student assistance programs from the Department

of Education, and Department of Labor programs for high-growth occupations, including health care.