

Alliance for Health Policy Handbook

An introduction to the health policy
and health care ecosystem

The Alliance for Health Policy is a nonprofit, nonpartisan organization dedicated to helping policymakers and the public better understand health policy, the root of the nation's health care issues, and the tradeoffs posed by various proposals for change.

We believe a better health care system begins with a balanced exchange of evidence, experience, and multiple perspectives. To achieve this mission, we strive to educate and prepare the next generation of health policy leaders through collaborative learning and conversation.

The Alliance's *Health Policy Handbook* is designed to serve as a primer for congressional, executive branch and support agency staff, journalists, and others who are interested in a quick-study of the key foundations of health policy. This Handbook features a collection of six chapters, each devoted to one core health policy topic and supplemented by extensive resource lists.

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1 | Budget & Spending

| Overview

Budgetary and spending pressures heavily influence the design of policy changes in health care and frequently drive health reform discussions in the first place. Spending and deficit considerations often force policymakers to consider mechanisms to limit expenditures, scale back proposals, or identify budgetary offsets to balance new spending. Administration and congressional budget processes themselves also influence health policy. In a new administration and congress, the president's proposed budget and congressional budget resolutions are helpful markers

of spending and revenue priorities, policy visions, and areas of alignment or disagreement. In particular, the budget resolutions may include tools to help facilitate or place parameters on health policy changes. Stakeholders at the federal and state levels can also be significantly impacted by slight changes in health policy – and can alternatively push for new spending and defend against attempts to limit it as well. These budget realities shape the scope and financing of federal health care legislation, as well as state decisions on their Medicaid programs.

Background on U.S. Health Care Spending

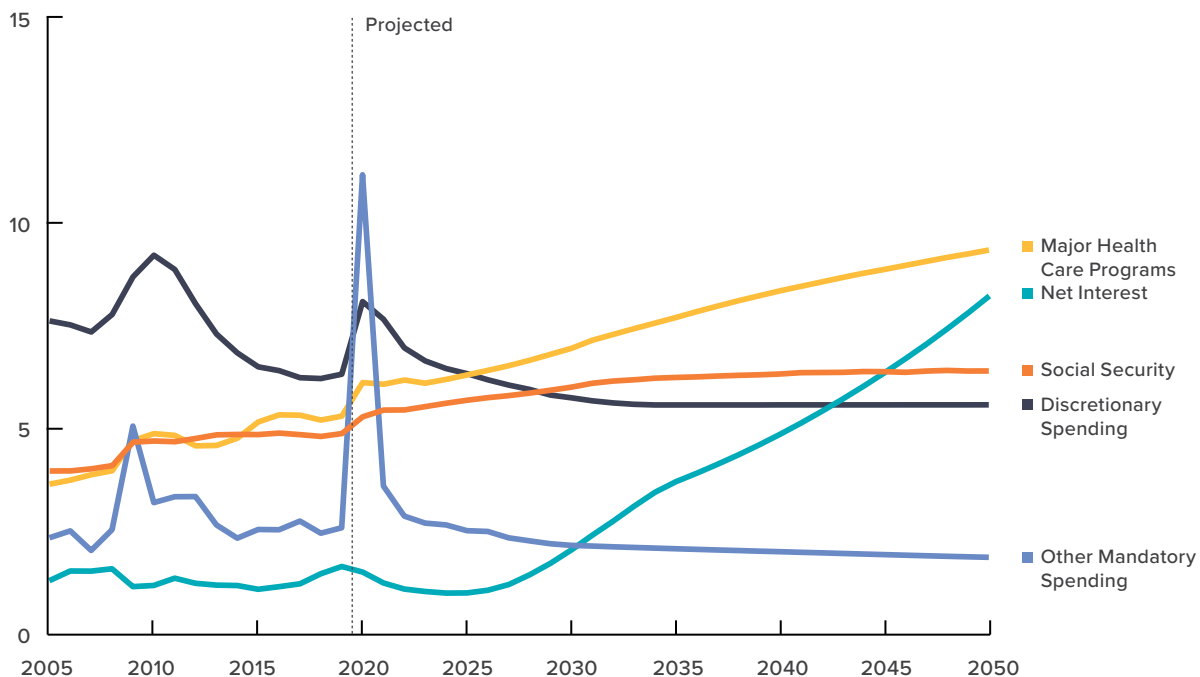
Health care spending accounts for a significant percentage of federal and state spending. [At the national level](#), the net cost of major health care programs has grown from 2.3% of Gross Domestic Product (GDP) in 1990, to 6.1% in 2020, and this proportion is projected to climb to 9.2% in 2050 absent any policy change (See Fig. 1.1). Medicare spending alone is projected to rise from [3.7%](#) of GDP in 2019 to

6.0% in 2044, and the **Medicare Hospital Insurance Trust Fund** – which is funded mainly through a dedicated payroll tax – is projected to be insolvent by [2024](#), meaning it will no longer have sufficient funds. The [growth](#) in federal health care spending is due both to rising per-person health care costs and, as the national population ages, an increase in the number of beneficiaries.

Fig. 1.1: Spending as a Percentage of Gross Domestic Product (2005-2050)

Federal spending grows from an average of 21.3 percent of GDP from 2010 to 2019 to an average of 29.3 percent from 2041 to 2050.

Percentage of Gross Domestic Product



Source: "The 2020 Long-Term Budget Outlook." Dahl, M, Demirel, D., Harris, E., et al. U.S. Congressional Budget Office. September 2020. Available at <http://allh.us/xfr6>.

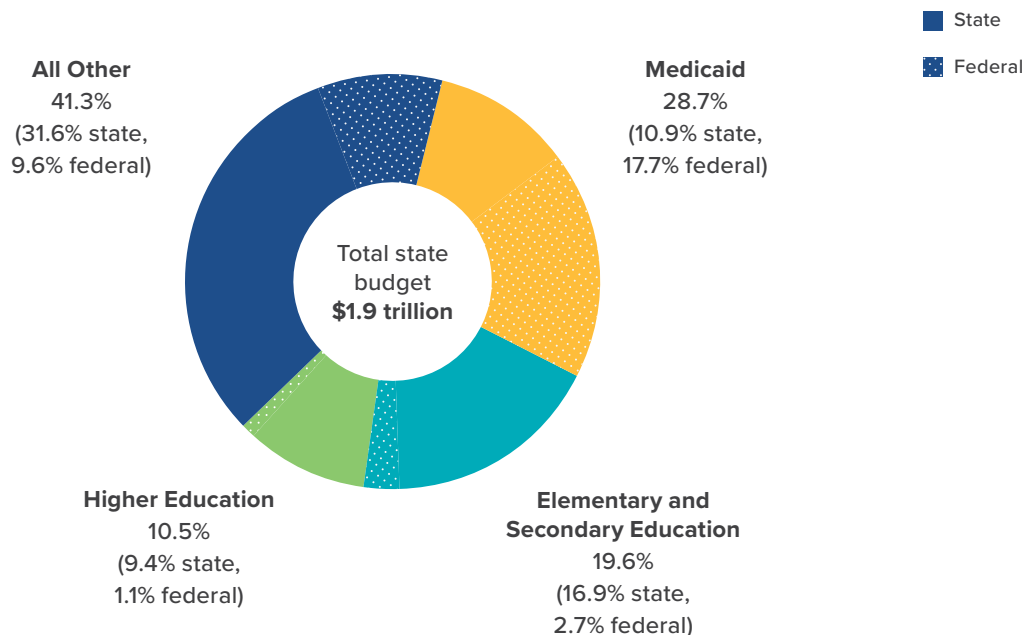
Discussions of the relationship between federal health care expenditures and the budget often rely on three overlapping, complex, and difficult-to-untangle terms: costs, prices, and spending. For the purposes of this Handbook, we define **costs** as the dollars or amount it takes for a health care entity, provider, or system to actually deliver a health care service. **Prices** – the dollars or amount charged to payers or individuals for health care services – are not necessarily the same amount as the cost. Finally, **spending** is typically thought of as the total expenditures or amount of money “going out the door” for health care, a function of both price and the level of utilization of services. These distinctions – further explored in Chapter 3 – can be fuzzy, and in the public debate, terms are often used interchangeably.

Even more complex are the impacts and pressures of high expenditures felt throughout the health care system, and by all stakeholders, including patients, providers, payers, purchasers, and the pharmaceutical industry. Thus, there is perennial tension in the health policy community about shifting spending and costs to and between these groups.

Similarly, examining spending provides only a partial view of how health care impacts the nation’s fiscal picture. In addition to direct spending on care, the federal government also subsidizes health care through the tax code via both subsidies and tax credits. The most significant tax expenditure in the Internal Revenue Code (IRC) is the exclusion of employer-sponsored insurance (ESI) premiums from taxable income, which effectively subsidizes health insurance for nearly half of all Americans. According to the Joint Committee on Taxation (JCT), in 2019 alone this subsidy resulted in \$169.6 billion in expenditures, or foregone revenue, for the federal government.

States are under even greater budgetary pressures given that their share of Medicaid spending, when federal funds are included, was estimated to be 28.7% (See Fig 1.2). The significant role of health care in the U.S. economy, and federal and state spending clearly illustrate why it is tied to nearly any discussion of budgets at both levels of government.

Fig. 1.2 Medicaid’s Share of State Budgets (2017)



Source: “Medicaid’s Share of State Budgets.” The Medicaid and CHIP Payment and Access Commission. 2017. Available at <http://allh.us/EXyg>.

Brief Overview of the Federal Budget Process

Historically, the budget process occurs annually, beginning with the president's proposed budget, usually sent to Congress in early February. The **president's budget** is essentially a detailed outline of spending levels for departments, agencies, and programs, as well as revenue proposals. It can be viewed as a marker for the Administration's policy, spending, and tax priorities.

The **congressional budget** process then begins with the House and Senate budget committees and their drafting of **budget resolutions** that set targets for discretionary spending, as well as targets for committees to move forward legislation that affects expenditures and revenues. The congressional budget resolution offers a blueprint for appropriations committees overseeing discretionary spending and other committees that may consider legislation that affects spending, revenues, or both.¹ A concurrent resolution is one that both chambers agree to and is more likely to be adopted when the same party controls both chambers. Budget resolutions are not sent to the president for approval, but are intended to guide congressional budgetary decisions.

Congress is supposed to pass a budget resolution annually by April 15. However, in recent years Congress has sometimes not passed, or even considered, one at all. In other years one or both chambers will pass their own budget, but are not be able to reach an agreement. When this occurs, the previous year's resolution remains in effect, or each chamber can set its own spending levels. Although budget committees oversee the process, all members of Congress and their staff play a role by holding hearings on the president's budget and considering and voting on budget resolutions on the floors of the respective chambers. A subsequent process of appropriations measures represents the mechanism by which actual funding levels are established and delivered to agencies and programs.

Neither the president's budget nor congressional budget resolutions have the force of law, but both

KEY BUDGET ISSUES FOR THE 117TH CONGRESS

- **Budget discussions** will be central to coverage expansions, drug pricing reform, and other significant health policy changes.
- The federal [debt limit](#) may need to be raised in July 2021.
- **COVID-19** has significantly [reduced government revenues](#), which is expected to impact state budgets in FY 2021–2022 and beyond, most notably for Medicaid programs. State fiscal needs, in turn, will affect federal legislation and spending.
- **Medicare Trust Fund** is approaching [insolvency](#).

play an essential role in how policy priorities and changes are funded and enacted. The president's budget lays out both broad administration priorities and specific policy changes and agency budgets for Congress to consider; however, the influence of those proposals depends on which party is in the majority. The congressional budget resolution is much less specific than the president's. However, these resolutions can include changes to House and Senate rules that make it easier to enact legislation consistent with the budget and more difficult to enact legislation inconsistent with the budget.

Budget resolutions also consist of enforcement mechanisms for appropriations bills, revenue bills, and [reconciliation](#) legislation, such as discretionary spending limits, pay-as-you-go rules or PAYGO, and sequestration. They include budget [points of order](#) (a claim that congressional procedure is being violated) that prohibit specific legislative or congressional actions – and are raised by members of Congress when legislation is being considered that violates these points of order (e.g., adhering to committee spending allocations). Last, congressional budget resolutions include deficit-neutral reserve funds. These funds allow spending levels to be adjusted, enabling legislation that is paid for to move forward without triggering points of order. Reserve funds are included not only to facilitate the passage of large-scale legislation, but also to highlight congressional policy priorities.

¹Note that budget resolutions are distinct from continuing resolutions (CR), which temporarily fund the government when annual appropriations bills have not been enacted.

Brief Overview of State Budget Processes

State budget processes and requirements are separate from the congressional process, but they can have a significant impact on federal spending. In most states, governors propose spending priorities and budgets, which are then voted on by state legislatures. Most governors have line-item veto authority on individual provisions. Perhaps most importantly, from a federal perspective, the [vast majority of states](#) – 46 states and

the District of Columbia (D.C.) – have balanced budget requirements. These balanced budget requirements vary across states, but [40 require](#) the governor to sign a balanced budget in which projected spending cannot exceed expected revenue.

As a result, state budgets must respond more quickly than the federal budget to changing fiscal conditions and pressures. The impacts of COVID-19 on states were predicted to be devastating. However, due to federal stimulus measures, and other personal, sales, and corporate tax collections, many states have seen an improvement in their revenue collection in fiscal year 2021. While governors' budget proposals were predicted to be reduced by as much as 20%, due to the above improvements, 2022 budget proposals

GLOSSARY OF TERMS

Budget Authority: Authority in appropriations or authorizing legislation that allows the government to incur immediate or future outlays of federal funds. Congress approves budget authorities for the federal government, which places a limit on how much federal agencies can spend or how much can be spent on a specific program or policy.

Budget Deficit: The difference between outlays and revenues over a given period of time, generally funded through bond issuances or borrowing.

Discretionary Spending: Government funding that can be adjusted annually for departments, agencies, and programs that occurs through the appropriations process – as opposed to mandatory spending (see below).

Federal Debt: The cumulative amount of borrowing financed by securities issued by the Treasury and sold to U.S. financial institutions, individuals, foreign private investors, and foreign central banks.

Mandatory Spending: Spending not controlled by annual appropriations, but occurring due to current law, such as Medicare and Medicaid programs. (Also known as entitlement spending.)

PAYGO: An abbreviation of “pay as you go” and a budget rule requiring that tax cuts and mandatory spending increases must be offset (i.e., “paid for”) by tax increases or cuts in mandatory spending. PAYGO does not apply to discretionary spending (spending that is controlled through the appropriations process).

Outlays: Actual cash flow to meet a federal financial obligation to make purchases, pay federal workers and contractors, provider transfers, or pay interest on the debt.

Revenues: Federal taxes, fees, and other collections that fund government spending.

Tax Credits: Amount removed or subtracted from taxes owed.

Tax Expenditures: Federal revenue losses resulting from Federal laws that exempt certain activities from taxation. A tax expenditure can serve as an alternative policy for spending or regulatory programs.

Tax Subsidy: Reduction in an individual's or organization's tax bill intended to reduce an item's cost. For instance, the exclusion of employer-sponsored insurance from taxable income offsets or reduces the cost of insurance to employees.

generally [did not see decreases](#). As with many things affected by the pandemic, there remains great uncertainty about the future. Given that Medicaid comprises a significant portion of state funding, [states are reporting](#) Medicaid budget issues will be among the most significant challenges in the coming year. These changing fiscal dynamics could place pressure on Congress and the administration to provide additional state fiscal relief – and understanding individual state fiscal pictures will be important in congressional debate and action on the economy.

Federal Budget Entities

The **House and Senate budget committees** were both established in The Congressional Budget and Impoundment Control Act of 1974. The committees' primary responsibilities are to draft annual concurrent budget resolutions that provide a blueprint for spending and revenue levels that impact the federal deficit and overall debt levels. Budget resolutions can also include instructions for congressional committees to draft reconciliation bills. Throughout the year, the Budget Committees track how legislation will affect the federal deficit and work with authorizing committees, including most standing committees, to understand how budget procedures may influence the design and passage of legislation in each chamber.

The 1974 Budget Act also established the **Congressional Budget Office (CBO)** to provide budgetary support to Congress. The CBO produces nonpartisan and independent analyses of the impact of legislation on the federal budget, as well as reports on economic issues, such as annual budget outlooks, to support the congressional budget process. Perhaps most importantly, CBO is the “scorekeeper” that attempts to quantify in concrete, detailed terms how legislative changes may impact the federal deficit, which makes their analyses critical for moving policy changes forward. In health care, a proposal's score can advance legislation or require the search for offsets (i.e., spending reductions or tax increases to raise revenue). These tradeoffs between costs and savings in health care

legislation create winners and losers – and can lead to intense negotiations with affected stakeholders seeking to advance, impede, or influence legislation.

Health care is perennially one of the most controversial topics the CBO must tackle. CBO does not make policy recommendations, but issues reports on how different policy actions may impact the federal spending or revenues, such as “Policies to Achieve Near-Universal Health Care Coverage” and “How CBO Analyzes Approaches to Improve Health Through Disease Prevention.”

Periodically, CBO issues a volume of [Budget Options](#) to reduce the deficit, which includes scores for mandatory, discretionary, and revenue policy proposals, including changes to Medicare and Medicaid. Given its bicameral and nonpartisan charge, the CBO must work equally with each chamber and party, but its health care analyses can be heavily scrutinized.

Another influential entity is the **Joint Committee on Taxation (JCT)** which supports both chambers of Congress on tax legislation. For instance, changes to the ESI exclusion would be evaluated or scored by the JCT. Last, the **Office of Management and Budget (OMB)**, which serves the administration as part of the Executive Branch, also assesses the impact of policy changes on the federal budget. However, their estimates and fiscal projections can differ from those of CBO. Policymakers can review the differences between the two by examining how their budget baselines differ, how economic assumptions vary, and whether their assessments of potential policy changes differ.

Federal Deficits, Debt, and Debt Limits

Federal debt and deficit dynamics significantly influence congressional spending. This often comes into play with health care legislation that would expand coverage or benefits. The **federal deficit** is [defined](#) as the difference, over a given period of time, between federal outlays and revenues – and dictates how much government borrowing must occur to close the gap.

In [fiscal year](#) 2020 (October 1, 2019–September 30, 2020), the federal deficit was [\\$3.1 trillion](#) – nearly 15 percent of GDP – and the largest since 1945. CBO estimates that fiscal year 2021 is on pace to have the [second-largest](#) in recent history.

The [federal debt](#) is the cumulative amount of federal borrowing, which is financed by securities issued by the Treasury and sold to U.S. financial institutions, individuals, foreign private investors, and foreign central banks. Increasing levels of federal debt can contribute to rising interest rates and increasing inflation depending on the circumstances, as well as to slower economic growth. In December 2020, the U.S. Treasury estimated that the federal debt held by the public totaled [\\$21 trillion](#), the highest level since just after [World War II](#). CBO [reported](#) that by the end of 2020, federal debt equaled 100.1 percent of GDP. [For historical context](#), the federal debt was 35 percent of GDP at the end of 2007, 70 percent in 2012, and 79 percent in 2019.

The **federal debt limit**, or debt ceiling, is set by Congress and constrains the amount of debt the Treasury can issue, either to the public or to itself through various trust funds. Because the debt limit is set in nominal dollars and debt continues to grow, Congress periodically raises and sometimes suspends the debt limit. In 2019, Congress and the Trump administration came to a budget agreement, including increasing the debt limit to \$22 trillion, and then suspending it until July 2021. At that point, Congress and the president will need to agree to raise or suspend the debt limit to keep the U.S. from defaulting on its debt. If changes are not made to revenues or spending, the debt is [expected to grow](#) significantly faster than the U.S. economy in the next decade – leaving Congress with a series of difficult tradeoffs to confront around the federal debt and debt limit.

Budget Reconciliation

Since 1980, Congress has used [budget reconciliation](#) to advance significant legislation, including health care legislation. Reconciliation is an expedited budgetary process that was intended to be used to bring federal spending, deficits, and debt in line with the amounts recommended in an approved congressional budget

resolution. While it was not intended to be used to enact significant policy change, reconciliation has been increasingly used over the years to move tax and other policy priorities forward by circumventing standard congressional rules and procedures. Reconciliation is particularly important in the Senate, where debate on a reconciliation bill is time-limited, and legislation requires only a simple majority (or 51 votes) to pass. However, the Senate also has unique statutory constraints on what can be included in reconciliation, known as the “Byrd Rule,” which limits the inclusion of extraneous, non-budgetary provisions that are subject to a point of order and can be struck from a bill.

In late 2010, reconciliation played an important role in the enactment of the Patient Protection and Affordable Care Act (ACA). The bulk of the law was passed through normal order in both chambers. However, before the House and Senate’s respective versions could be reconciled in a [conference committee](#) preceding a final vote, Senator Ted Kennedy (D-MA) passed away. A Republican won the special election to fill his seat, removing the 60th supermajority vote Senate Democrats needed to overcome a Republican filibuster and pass the ACA. In response, the Democrat-led House agreed to pass a version of the legislation identical to the measure already passed by the Senate, thus averting a subsequent, final vote that would have failed. Then immediately after, both chambers passed a budget reconciliation bill, which included amendments to the ACA incorporating key House priorities for the law and requiring only 50 votes to pass in the Senate.

Reconciliation has played an increasing role in enacting significant policy change – and its use could continue to grow as both parties have more recently used the expedited procedure to advance spending, tax, and policy priorities. It is worth noting that reconciliation tends to be used when one party controls both Chambers and the White House. However, future use of reconciliation could be affected if the Senate ever voted to eliminate the filibuster, which has been increasingly discussed in recent years. The elimination of the filibuster would both mitigate the need to rely on reconciliation and allow both parties to avoid the legislative challenges associated with its use.

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RESOURCES

Chapter 1: Budget & Spending

Listed by the order in which they appear in Chapter 1.

BACKGROUND ON U.S. HEALTH CARE SPENDING

The 2020 Long-Term Budget Outlook. <http://allh.us/dXfJ>

2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. <http://allh.us/8g9X>

The Outlook for Major Federal Trust Funds: 2020 to 2030. <http://allh.us/NKby>

Health Insurance Coverage of the Total Population. <http://allh.us/WKqg>

Overview of the Federal Tax System as in Effect For 2019. <http://allh.us/h6M9>

MACStats: Medicaid and CHIP Data Book. <http://allh.us/DyHq>

BRIEF OVERVIEW OF FEDERAL BUDGET PROCESS

Basics of Budget Reconciliation and the Connection to Health Policy. <http://allh.us/UAXK>

U.S. Senate: Glossary Term. <http://allh.us/eQGT>

STATE BUDGET PROCESSES

Balanced Budget Requirements: How States Limit Deficit Spending. <http://allh.us/pycw>

State Revenues Decline for First Time Since the Great Recession, With the Worst Still to Come. <http://allh.us/rfpU>

Summaries of Fiscal Year 2022 Proposed Budgets. <http://allh.us/YvGM>

State Medicaid Programs Respond to Meet COVID-19 Challenges. <http://allh.us/vdQq>

FEDERAL BUDGET ENTITIES

Congressional Budget Office: Budgets. <http://allh.us/64Nj>

FEDERAL DEFICITS, DEBT, AND DEBT LIMITS

Policy Basics: Deficits, Debt, and Interest. <http://allh.us/KmkM>

BUDGET RECONCILIATION

United States Senate Glossary Term. <http://allh.us/3ftQ>

Monthly Budget Review: Summary for Fiscal Year 2020. <http://allh.us/DXYa>

The 2020 Long-Term Budget Outlook. <http://allh.us/dXfJ>

Federal Debt: A Primer. <http://allh.us/vQGY>

Debt to the Penny. <http://allh.us/Tgq8>

Federal Debt: A Primer. <http://allh.us/vQGY>

Monthly Budget Review: Summary for Fiscal Year 2020. <http://allh.us/DXYa>

The 2020 Long-Term Budget Outlook. <http://allh.us/dXfJ>

Federal Debt: A Primer. <http://allh.us/vQGY>

The Budget Reconciliation Process: Timing of Legislative Action. <http://allh.us/Q6W7>

The Legislative Process: Resolving Differences. <http://allh.us/3RqE>

Box: Key Budget Issues for the 117th Congress

The Debt Limit: What You Need to Know. <http://allh.us/HAW8>

How much is COVID-19 hurting state and local revenues? <http://allh.us/rwNg>

Medicare Solvency Projections and Potential Policy Solutions. <http://allh.us/9qgA>

Box: Glossary of Terms

Tax Policy Center Briefing Book: What is PAYGO? <http://allh.us/vVnG>

2 | Coverage

Overview

America has a patchwork of policies and programs that broadly lead to people receiving insurance coverage through two mechanisms: Public programs (Medicaid, Medicare, Veterans Health Administration, TRICARE, Indian Health Service) or private coverage (employer-sponsored insurance plans or Affordable Care Act Marketplace plans) (See Fig 2.1). While the majority of Americans have health care coverage, the

United States has one of the highest uninsurance rates among Organization for Economic Cooperation and Development (OECD)¹ countries. An estimated 10.4% of Americans remain uninsured.

A central principle of insurance coverage financing is that the generosity of offered benefits is always a tradeoff with costs paid either by the person or by taxpayers. The cost of coverage for an individual

¹An intergovernmental economic organization with 37 member countries that, among other things, produces reports and data sets assessing various policy issues across the world. Learn more at <http://www.oecd.org/about/how-we-work/>.

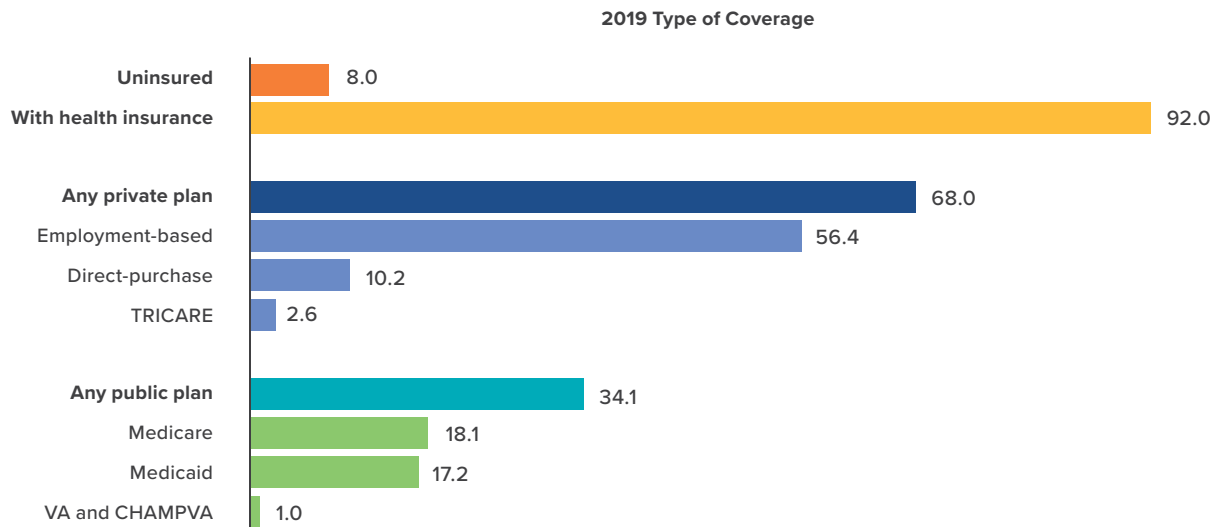
in the U.S. is mainly offset by the government through direct public arrangements or public subsidies (tax preferences for employers that provide coverage and premium subsidies for marketplace coverage). That said, individuals also bear financial responsibility to varying degrees, depending on the program. Therefore, even consumers with insurance are often underinsured, or have difficulty affording all of their health care costs, placing them at significant financial risk if they experience a serious illness.² Estimates find that half of those with employer-sponsored insurance (ESI) skipped or delayed care due to costs and the rate of underinsured Americans is only growing. These increases in the uninsured and underinsured populations, coupled with the impacts of COVID-19 on employment rates, have renewed public attention on, and policy interest in, addressing health care coverage and affordability issues.

Health Care Coverage Defined

Health care coverage is best understood in terms of payment for health care services. The cost of health care services can be expensive. The vast majority of Americans have some form of assistance in paying for health care services through a primary payer (the government directly or an insurer paid through an employer). Covered individuals typically have financial responsibility that includes monthly premiums, deductibles, co-pays, and coinsurance. The health care services available (benefits) and the financial obligations required of the individual receiving assistance from the payer capture the broader concept of health care coverage. Americans who do not have insurance coverage are generally described as being uninsured.

Fig. 2.1: Percentage of People by Type of Health Insurance Coverage (2019)

(Population as of March 2020)



Note: The estimates by type of coverage are not mutually exclusive; people can be covered by more than one type of health insurance during the year. Federal Employee Health Benefits (FEHB) is included in Direct-Purchase.

Source: "Health Insurance Coverage in the United States: 2019." Keisler-Starkey, K., Bunch, L. U.S. Census Bureau. September 15, 2020. Available at <http://allh.us/cavT>.

²Note that there is no generally agreed-upon standard for what designates underinsurance.

Types of Direct Government Coverage

Medicaid is the most extensive government coverage program in America, covering [more than 75 million people](#). The program is a federal-state partnership providing benefits to children, pregnant women, elderly adults, and people with disabilities. The Affordable Care Act (ACA) intended to transition Medicaid from a program based on categorical eligibility to a program that covered low-income individuals generally. Initially, the law required the states to expand coverage to low-income adults in exchange for a higher level contribution from the federal government. But in *National Federation of Independent Business v. Sebelius* (2012), the Supreme Court ruled that states could not be required to expand their Medicaid programs under the ACA. Consequently, covering low-income adults [remains an option](#) which states may embrace or forgo as they choose.

Each state and territory administers its own Medicaid program. Still, the benefit structure, individuals covered, and financial responsibility requirements are primarily determined by the federal government through statutory provisions. This includes a statutory

floor of requirements often referred to as “mandatory benefits.” States have flexibility working in conjunction with the federal government to tailor their Medicaid programs for the state’s particular needs. Thus, there is significant [variability](#) across each program. States are given the option to offer additional benefits and make benefits available to additional populations. States do so by applying to the [Centers for Medicare and Medicaid Services](#) and seeking formal approval for changes to their Medicaid program. Although federal [Medicaid funding](#) is considered mandatory and mostly open-ended entitlement spending, it is still subject to the annual budget and appropriations process – i.e., appropriated entitlement.

The Children’s Health Insurance Program (CHIP) provides health care coverage to [9.6 million](#) children in families with an income level too great for Medicaid eligibility. Benefits generally mirror those benefits provided through the Medicaid program. States have flexibility in determining the income range of children covered through CHIP. As is the case with Medicaid, CHIP is jointly funded by the federal government and the states. The federal portion of CHIP [funding](#) is mandatory spending and is usually appropriated several years at a time. Currently, the program is funded through Fiscal Year (FY) 2027.

Medicare is another extensive government coverage program with more than [60 million Americans](#). The program provides acute care coverage for seniors and

A central principle of insurance coverage financing is that the generosity of offered benefits is always a tradeoff with costs paid either by the person or by the taxpayers.

GLOSSARY OF TERMS

Premiums: Monthly amount individuals pay to health plans for a benefit period (usually one year). Total premiums are typically shared between individuals and their employers or government purchasers. Note, plans with the lowest premiums are not necessarily the best match for an individual as premiums, deductibles, and out-of-pocket costs are closely related. If one is lower, the others are typically higher.

Cost Sharing (Out-of-Pocket Costs): Expenses an individual will have to pay in a plan year that an insurer does not reimburse. Typically includes deductibles, coinsurance, and copayments for in-network, covered services. Most plans have an out-of-pocket maximum (the most you have to pay in a year). Premiums, payments for out-of-network costs, and non-covered services generally do not count towards that limit.

Deductibles: Fixed dollar amount during a benefit period that an individual must reach before an

insurer starts to pay for health care costs. This amount is on top of monthly premiums, as those monthly payments don't typically count towards a deductible.

Coinsurance / Copayments: Type of cost-sharing that an individual pays after meeting their deductible. Copayments are a fixed amount like \$20 or \$45. Coinsurance is a percentage (usually 10/90, 20/80, or 30/70) where an individual pays 20% of a charge, and their insurer pays the rest (80%). See this helpful [visual](#) of how deductibles, coinsurance, and out-of-pocket costs are interrelated.

Network: The facilities, providers, and suppliers your health insurer or plan has contracted with to provide health care services. These are considered in-network by your insurer. Out-of-network entities are facilities, providers, or suppliers that have not formally contracted with your insurer or plan. These providers are typically [more expensive](#) than in-network providers.

specific categories of Americans under 65 – people with disabilities, end-stage renal disease (ESRD), and amyotrophic lateral sclerosis (ALS). Roughly two-thirds of beneficiaries receive their coverage through Medicare's traditional fee-for-service program, which consists of three parts: [Part A](#) (inpatient hospital care, skilled nursing facility care, home health care, and hospice care), [Part B](#) (physician and other ancillary services in an outpatient setting), and [Part D](#) (coverage of prescription drugs). The other third of beneficiaries receive coverage through private insurance plans created through the Medicare Advantage program ([Part C](#)).

While Medicare does cover a broad range of services, it is important to note that dental, vision, hearing aids, and long-term services and supports are [not covered](#). The program is [funded](#) through general revenue and a dedicated payroll tax going into a trust fund, and for Parts B and D, beneficiary premiums. As described in Chapter 1 of this Handbook, the Medicare Trust Fund's ability to cover the program's promised benefits is projected to [fall short](#) in three to five years, likely creating significant pressure in budget negotiations in 2021 and beyond.

Other federal government coverage programs provide coverage of services for specific populations. The [Veterans Health Administration](#) (VHA) provides coverage for [9 million veterans](#). The [TRICARE system](#) provides coverage for over [9.5 million military personnel](#) and their families. The [Indian Health Service](#) (IHS) provides coverage for [2.7 million](#) American Indians and Alaska Natives in 574 federally recognized sovereign nations. The benefits provided and payment requirements for individuals covered under each of these programs are determined by federal statute.

Federal employees are eligible to receive coverage through the [Federal Employee Health Benefits](#) program (FEHB). Covering [9 million people](#), this program is the largest employer-sponsored plan in the world. FEHB is run by the Office of Personnel Management and makes a number of private insurance coverage options available to federal employees. The benefits provided and payment requirements for individuals covered under FEHB are determined by federal statute.

Every state government and many local governments have coverage arrangements for their collective [7.4 million employees](#). The benefits provided and payment requirements for individuals covered under those plans are determined by the state and local governments, consistent with applicable federal statutes.

Government-Subsidized Private Coverage

Individuals may also receive coverage through the [Affordable Care Act's Marketplace](#) for private insurance plans. Individuals eligible for coverage through Marketplace plans may also qualify for federal subsidies to lower premiums and out-of-pocket costs. The benefits provided and payment requirements for individuals covered through the Marketplace are determined by federal statute. The plans available to individuals are generally similar, but the specific cost of coverage can vary down to the county level. Despite reaching far fewer individuals than other key public programs, Marketplace coverage – its affordability and availability – has been, and will continue to be, a central focus for regulators and Congress over the next two years.

Employer-Based Coverage

[One hundred fifty-eight million Americans](#) in the workplace receive coverage through private insurance plans offered by their employer or union. Starting with the 1942 Stabilization Act, employer-based coverage [evolved](#) into the dominant form of health insurance for individuals in the workplace due to employers' tax incentive and the need to attract workers through robust benefits packages. These tax incentives are advantageous to both employers and employees. Employees are not subject to federal income and payroll taxes for the premiums paid by their employer, and employers

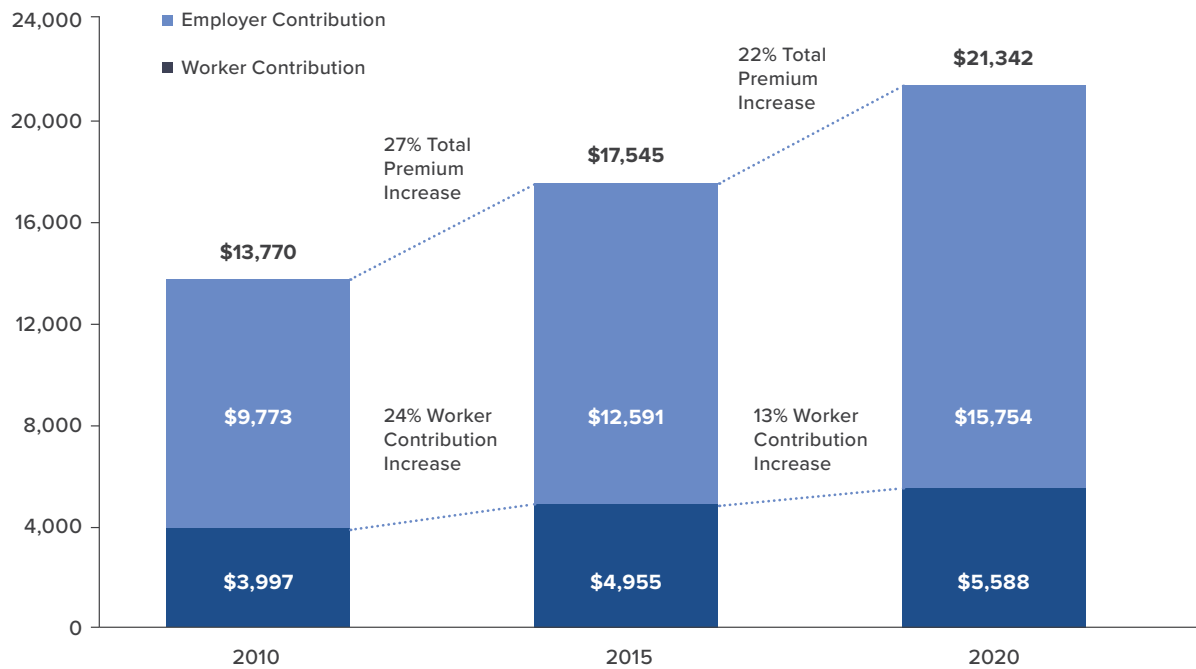
do not pay Social Security taxes on the premiums paid for health care coverage for their employees. More than [90% of large employers](#) (500 or more employees) make health care coverage available to their employees. Among smaller employers (less than 50 employees), barely half (52%) make health care coverage available to their employees.

The benefits provided through employer-based coverage are generally governed by the federal [Employee Retirement Income Security Act](#) (ERISA). The statute creates a general structure for employer-based coverage and exempts many employer plans from additional state regulation. As a result, many state-led changes and individual market changes do not affect ERISA plans.

KEY COVERAGE ISSUES FOR THE 117TH CONGRESS

- Despite new protections to mitigate “[surprise billing](#),” as well as short-term coverage affordability policies in the [American Rescue Plan Act](#), ongoing discussions about **addressing higher out-of-pocket costs** more generally in the form of premiums, co-pays, and deductibles are likely to intensify, especially for [moderate-income](#) individuals.
- During COVID-19, Congress and the administration took steps to **make telemedicine more [accessible](#)**. Providers and patient advocates will push for those changes to be retained indefinitely.
- Potential [movement](#) on the perennial issue of **enforcing mental health coverage [parity](#)**.
- Continued discussions about **reducing the overall uninsurance rate and achieving [universal coverage](#)**.

Fig 2.2 Average Annual Worker and Employer Premium Contributions for Family Coverage



Source: "2020 Employer Health Benefits Survey." KFF. October 8, 2020. Available at <http://allh.us/vHwC>.

The Uninsured

The vast majority of Americans (90%) do have some form of health care coverage. However, 29 million Americans are still without coverage. Most uninsured Americans are in families with at least one full-time worker. Half of the uninsured are in families with incomes below 200% of the Federal Poverty Level. Eighty-six percent of the uninsured are nonelderly adults. The uninsured are disproportionately [people of color](#).

Affordability remains a prime driver of the number of uninsured in America. While employed workers may be provided access to health care coverage, they may not be able to afford their share of the premiums. Medicaid eligibility for low-income individuals can vary by state, and in states where coverage through Medicaid is not available, low-income adults are more likely to be uninsured. More than two million Americans fall into a coverage gap affecting those with incomes higher than state Medicaid eligibility yet lower than the benchmark income necessary to qualify for Marketplace premium tax credits.

The Rising Cost of Coverage and Underinsurance

The cost of health care coverage remains an ongoing challenge for many Americans. In 2020, the average premium for an individual or family in an employer-based plan was \$7,470 and \$21,342, respectively. Premiums continue to increase faster than wages or inflation. Over the last five years, the average premium for family coverage has increased by 22%. Over the last ten years, it has increased by 55% (See Fig. 2.2).

Many Americans with health care coverage nevertheless struggle with the problem of underinsurance and growing financial requirements. Underinsurance is typically defined as when an individual has difficulty affording all of their health care costs. The [average](#) deductible for individual coverage has increased by 79% over the last decade. The increasing financial

requirements can impose a significant burden, especially for Americans with lower incomes, driving some to delay needed care because of the concern over out-of-pocket costs. Others who do utilize services can face escalating debt as a result.

Shared Responsibilities and Trade-Offs

It is a central tenet of health care coverage in America that the federal government largely offsets the cost of coverage for an individual. In direct government coverage arrangements, the federal government pays for a significant portion of the individual's health insurance. In employer-based coverage arrangements, the employer's share of the coverage is offset by a federal tax deduction and an employee benefits from tax exclusion. Directly or indirectly, the federal government is paying for almost [a third](#) of all health care spending.

That said, individuals also bear financial responsibility to varying degrees, depending on the program. In Medicaid, which is targeted to low-income individuals, financial requirements are nominal. In Medicare, individuals pay up to 20% of the cost of covered Part B benefits. Individuals can purchase supplemental Medigap coverage to insure against additional expenses, but do so out of their own pockets. Low-income Medicare recipients pay significantly less for their own care with subsidies provided by the Medicaid program. (See Chapter 6 of this Handbook for more information on this population.) The ACA Marketplace plans have subsidy structures designed around an individual being responsible for an estimated 30% of their cost of care.

Employer-based coverage has fewer restrictions on financial participation requirements. If an employer provides a uniform set of financial participation requirements for all employees, lower-income employees will be more financially challenged to fund their share of the coverage.

The design of the benefits provided and financial participation requirements in any coverage arrangement

Many Americans with health care coverage nevertheless struggle with the problem of underinsurance.

requires making trade-offs between coverage generosity and costs paid either by the person or by taxpayers. Many insurance programs also use [benefit design approaches](#) like limited provider networks, limitations on services, and utilization review. These tools can be used to reduce prices, control utilization, or both, therefore keeping costs in check without requiring beneficiaries to pay more. But aggressive use of those benefit design tools can only go so far before there is consumer backlash. The Patients' Bill of Rights debates of the early 2000s were in response to benefit limitations. Eventually, coverage arrangements return to the question of how much covered individuals should be expected to contribute financially. The more an individual is required to pay, the greater the likelihood that the individual will face the problem of underinsurance. In turn the conflict between health care costs and other living expenses becomes more acute. The costs to an individual can be lowered considerably by greater financial participation from the government. That, of course, requires additional taxpayer resources.

The effort to find an acceptable balance between government subsidization of health care costs and individuals' financial requirements in paying for health care costs eventually drives the policy conversation to consider health care costs (See Chapter 1 of this Handbook for more information on health care costs and spending). The interconnected nature of coverage and costs necessitates they both be considered simultaneously in policy conversations.

This Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with generous support from Arnold Ventures.

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Box: Glossary of Terms

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3 | Provider Rates

Overview

As discussed in Chapter 1 of this Handbook, budgetary pressures are spurring policymakers at every level to examine the drivers of high spending. In 2018, spending on hospitals and physicians accounted for [33 and 20 percent](#) respectively of U.S. national health expenditures (NHE) – or, over half of all health care spending (See Fig.3.1). Further, a [recent analysis](#) found that the U.S. spends an average of \$6,624 per person on inpatient and outpatient services compared to \$2,718 per person in comparable countries. This trend exists [despite](#) the U.S. having shorter average hospital stays and fewer physician visits per capita. Thus, a comprehensive discussion of health care spending must examine spending on, and payment rates for, hospital and physician services.

For various reasons, rates for the same service can vary significantly across Medicare, Medicaid, and commercial plans, and also across states and regions. Additionally, underpayment for some services such as primary care, and overpayment for others, is a recurring issue. The impacts of high health spending and irregular provider rates are often felt most acutely by individuals and households through higher out-of-pocket costs or [unexpected bills](#) (so-called “surprise billing”). As health care spending rises and consumer issues come into sharper focus on the national stage, states and federal agencies are interested in understanding provider rates and the outcomes we pay for.

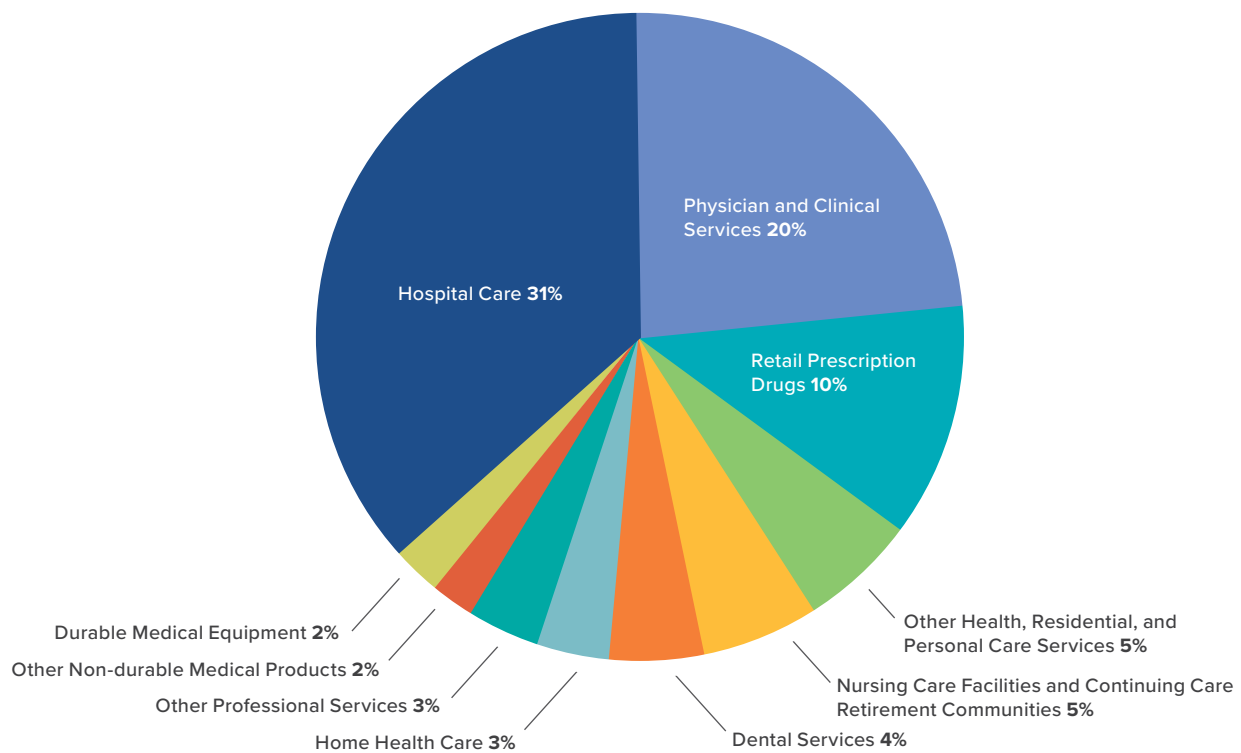
Provider Payments in Medicare

“Health care provider” is a broad term that encompasses the various people, entities, or companies that deliver a health care service to patients. These may include nurses, medical equipment, outpatient

surgery clinics, etc. This Handbook focuses primarily on hospital and physician payments.

The Medicare program relies primarily on fee-for-service (FFS) payments to hospitals and physicians made

Figure 3.1 Health Spending by Type of Service or Product (2019)



Source: “National Health Expenditures 2019 Highlights.” U.S. Centers for Medicare & Medicaid Services. December 16, 2020. Available at <http://allh.us/N9bM>.

through prospective payment systems. The Centers for Medicare and Medicaid Services (CMS) establishes a base payment rate for a unit of service. The hospital and physician payment systems – formally named the [Inpatient Prospective Payment System](#) (IPPS), the [Outpatient Prospective Payment System](#) (OPPS), and the [Medicare Physician Fee Schedule](#) (MPFS) – are updated annually through a notice of proposed

rulemaking (NPRM) process. These rules are usually submitted in the spring and summer for a comment period, and finalized in the fall. Implementation for these rules is meant to start the next fiscal year or calendar year, depending on the rule's schedule.¹ Together, [these systems](#) establish how much Medicare will pay for more than 745 hospital diagnosis-related groups (DRGs) and 8,000 [HCPCS/CPT](#) codes.

GLOSSARY OF TERMS

Inpatient Care: Treatment received only when a physician formally admits someone to a typically more specialized health care entity such as a hospital. Inpatient status ends when a physician formally discharges the patient.

Outpatient Care (or Ambulatory Care): Clinics, doctor's offices, urgent care centers, walk-in labs, and ambulatory surgery centers are considered outpatient settings. Care in an emergency department is usually considered outpatient, even though they are typically connected to a hospital.

Hospital Inpatient Services vs. Hospital Outpatient Services: Hospital inpatients typically are severely ill or have suffered severe trauma. Still, inpatients can receive more routine services such as non-emergency surgeries, x-rays, and infusion therapies. Conversely, people can obtain more routine care ([such as diagnostic and treatment services](#)) at a hospital, but be considered outpatients. The admittance distinction impacts how insurance plans will [pay for them](#). Inpatient care is usually more expensive than outpatient care.

In-Network: The facilities, providers, and suppliers a health insurer or plan has contracted to provide health care services. These entities are only considered in-network for a given insurance plan as payers create their own networks on a plan by plan basis.

Out-of-Network: Any facility, provider, or supplier that has not formally contracted with an insurer or accepted their negotiated rates. These providers are typically [more expensive](#) than in-network providers.

Fee-for-Service (FFS): Payment system in which clinicians and facilities are paid for each service performed and do not typically account for care management or coordination. The majority of the U.S. health care system is based on FFS payments.

Value-Based Payments (VBP): Payment systems that attempt to move away from the FFS system and pay providers based on quality, cost of care, and other outcome metrics. There are various [approaches](#) and [demonstrations](#), including pay-for-performance and alternative payment models (APMs).

¹Medicare rules are either fiscal year or calendar year rules. For example, IPPS is effective October (fiscal year) and OPPS is effective January 1 (calendar year).

Underpayment for some services such as primary care, and overpayment for others, is a perennial issue.

However, underpayment for some services such as primary care, and overpayment for others, is a perennial issue. Given that these annual rules affect many health care stakeholders, they are contentious, as small updates or revaluing of services can change total expenditures by billions. Medicare payment changes occur via regulation and within the parameters that Congress passed to establish the payment systems. Stakeholders approach congressional staff to discuss the impacts of proposed payment changes on providers, services, and technologies – and place pressure on CMS to advance or pull back proposed changes – or even to reverse or delay payment changes via legislation.

Note that in 2015 Congress passed the Medicare Access and CHIP Reauthorization Act ([MACRA](#)) that established two new “[pathways](#)” or methodologies for calculating payment updates for physician services: the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payment Model (APM). While both aim to gradually link payment to the value of care delivered, the programs have been difficult to implement and may significantly reduce physician payments in the coming few years. If this is the case, physicians and other stakeholders are likely to continue pushing Congress to intervene – either to hold or blunt the cuts’ impacts in MIPS or extend bonus opportunities for those in the Advanced APM pathway.

While less is known about payment rates for hospitals and providers participating in the Medicare Advantage (MA) program, recent studies have found that they

generally mirror those of Medicare FFS. Experts attribute this to several facts, including MA plan rates are based on Medicare FFS spending, restrictions against balance billing for MA patients treated by out-of-network providers, and greater acceptance among plans, [hospitals](#), and [providers](#) of alignment in rates across the two. With [one in three](#) Medicare beneficiaries joining Medicare Advantage plans, changes to the program and provider payment rates can have significant budgetary impacts.

For more information on how Medicare provider payment functions, visit Medicare Payment Advisory Commission (MedPAC)’s [Payment Basics](#) page.

Provider Payments in Medicaid

States have significant flexibility in setting provider payment rates in their Medicaid programs, yet there are general federal requirements. [Rates](#) must be consistent with the efficiency, economy, and quality of care, and be sufficient to supply access to care and benefits equivalent to the general population in the same geographic area. Payments can be made either through FFS, in which providers are paid directly for services received by beneficiaries, or through managed care plans, in which states pay managed care

plans for each beneficiary enrolled in the plan. The managed care plan then pays providers for the services they deliver to beneficiaries. While [over 80%](#) of Medicaid beneficiaries receive some benefits or care through managed care, the majority of high-cost populations and delivery of high-cost services still occurs in FFS. Thus the majority of state spending still occurs through FFS arrangements.

[Under FFS](#), states use various methods (approved by CMS) to set inpatient payment rates, including reimbursement based on reported costs, number of hospital days, or diagnosis-related groups (DRGs). States have the latitude to set payments for physician services, with most using a fee schedule as with Medicare and commercial payers. In addition, states also make [supplemental payments](#) in both FFS and managed care systems that are both separate and on top of services rendered. These payments aim to support quality or

delivery system reform initiatives or may attempt to adjust total reimbursement for facilities that serve a complex patient population (rural or safety-net).

The Medicaid and CHIP Payment and Access Commission (MACPAC) [estimated](#) that, on average, Medicaid FFS physician payment rates are two-thirds that of Medicare payment rates. As a result, there have been long-standing concerns that low Medicaid payment rates discourage provider participation in the program and can limit beneficiary access to care. However, once supplemental payments for hospitals and nursing facilities are taken into account, the ratio of Medicaid to Medicare payments [evens out](#), and, in some states, Medicaid payment to hospitals may be higher.

For more information on how Medicaid provider payment functions, visit MACPAC's [Provider Payment](#) and [Delivery Systems](#) pages.

KEY PROVIDER PAYMENT ISSUES FOR THE 117TH CONGRESS

- During COVID-19, Congress and the Administration took steps to **make telemedicine more accessible** by increasing payment rates for remote care and offering [regulatory flexibilities](#). Providers and patient advocates are pushing for many of these changes to be retained indefinitely. However, Congress will likely weigh how to balance expanding access to telehealth with concerns about waste, fraud, and abuse.
- Conversely, several issues across the next two years could increase scrutiny over **how provider payment rates are set and how they could be limited**, including federal and state budget pressures, the Medicare Hospital Trust Fund's potential [insolvency](#), and calls for greater transparency about the results of the [emergency financial aid](#) given to provider entities during the pandemic.
- Appeals from constituents and patient advocates are likely to intensify about **addressing high consumer out-of-pocket costs** beyond surprise billing, including lowering premiums, co-pays, and deductibles. Some policy approaches to reduce out-of-pocket costs involve reducing or capping provider and hospital rates.
- Data demonstrating **a growing differential between commercial, Medicare, and Medicaid provider payment rates** and consolidation as a primary driver will pressure policymakers to examine federal policy levers that could address these issues across all markets.

Provider Payments in Commercial Plans

Commercial plans set payment rates for providers primarily through negotiation with providers in a given region. While many commercial payers have based their payment systems – and even payment levels – on Medicare, several factors influence negotiated payment rates. These include the number of enrollees in the plan (their market share), geography, and relative size, or market concentration, of payers versus hospitals and physician practices in a given area. A market with one or two dominant insurers will have more negotiating power for lower rates relative to a different market with several payers and a more dominant health system with the ability to negotiate higher payment rates.

Historically, payment rates between commercial plans and providers are also not usually public. [Experts note](#) that this can impede the identification of high-value providers and can contribute to price increases without public scrutiny. For years, states have been implementing [all-payer claims databases](#) (APCDs) to advance cost transparency, better understand geographic variations in price and utilization, and track healthcare spending trends, among other goals. APCDs are [large databases](#) used to collect medical, pharmacy, and usually dental claims, as well as eligibility and provider files from private and public payers. Nearly [20 states](#) have APCDs, with five more in the implementation phase. Yet data collected is typically incomplete, as only a handful of these state APCDs make the data public, and states cannot require federally regulated plans – typically large employer plans – to submit data. State cost transparency efforts are growing – and will continue to influence congressional discussions on price transparency for providers.

For more information about how commercial plan provider payment functions, see this Congressional Research Service [report](#), as well as this America's Health Insurance Plans' [Guide to Understanding Health Plan Networks](#).

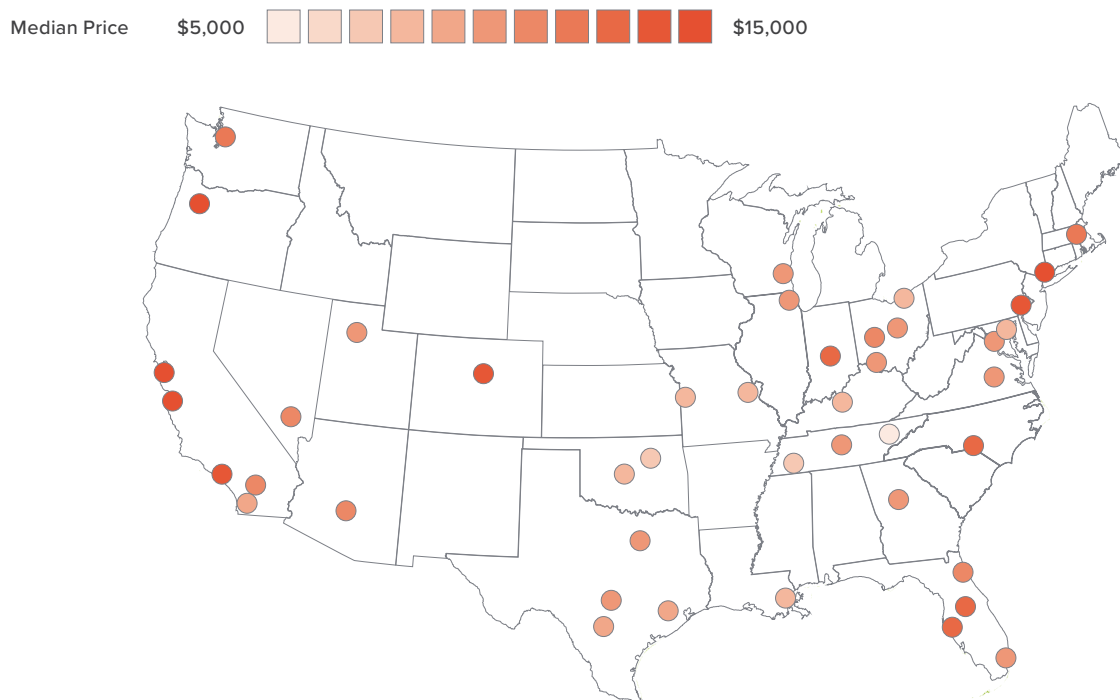
Given the various factors that can affect commercial plan and provider negotiations, there is significant variability in payment rates depending on a market's characteristics.

Provider Rate Disparities Between Private and Public Payers

Given the various factors that can affect commercial plan and provider negotiations, there is significant variability in payment rates depending on a market's characteristics. A [2020 study](#) by the Health Care Cost Institute found that the average commercial costs for medical professional services range from 98% of Medicare in Alabama to 188% of Medicare in Wisconsin. Across the country, prices paid for inpatient and medical care have been rising rapidly. Among large employer plans, the cost of inpatient admissions for

Figure 3.2: Example of Price Variation Across Metropolitan Areas (C-Section Delivery, 2017)

C-section delivery prices varied from \$5,142 (Knoxville, TN) to \$21,890 (San Francisco, CA).



Source: "Past the Health Marketplace Index, Volume 1: Exploring the Actual Prices Paid for Specific Services by Metro Area." Kennedy, K., Clayton, E., Johnson, B., et al. Health Care Cost Institute. November 2020. Available at <http://allh.us/URXM>.

surgical care almost doubled from \$25,054 to \$47,345 from 2008 to 2018 and from \$11,545 to \$21,395 for medical care over the same time period. While prices are rising everywhere, they vary widely (See Fig. 3.2). For example, the average cost of an inpatient admission for those in large employer plans ranged from \$18,392 in St. Louis to \$31,744 in San Diego.

A recent study also examined the relationship between Medicare and commercial physician payments and estimated that a \$1.00 increase in Medicare payments was associated with a \$1.16 increase in commercial payments to physicians. The study illustrated the impact of Medicare on commercial payments and underscores why policymakers often view the Medicare program as a lever for commercial market changes. Neither growth in provider rates nor geographic variations in costs are

new – but the pressure may be greater than before given the impacts on all markets and individual and family premiums and cost-sharing.

The price differential among payers – with commercial rates being higher than Medicare and Medicaid – has been studied extensively, especially in the hospital sector. However, there are concerns that the disparities in payments have increased in recent years (See Fig. 3.3). A study of ESI plans recently found that in 2017, employers and private insurers paid 247% of what the Medicare program would have paid for services at the same facilities – up from 224% in 2016 and 230% in 2017. These studies may increase calls for price transparency or an examination of how Medicare can be a lever to reduce differentials between government and commercial rates.

State and Federal Policy Activity on Provider Costs

The last few years have seen an increase in state activity and national discussion on hospital and physician pricing. States have been more active on the issue and are implementing several policy changes. Policy approaches fall into broad themes, including market-based policies, consumer transparency efforts, and shifting to pay for performance or value-based payment systems.

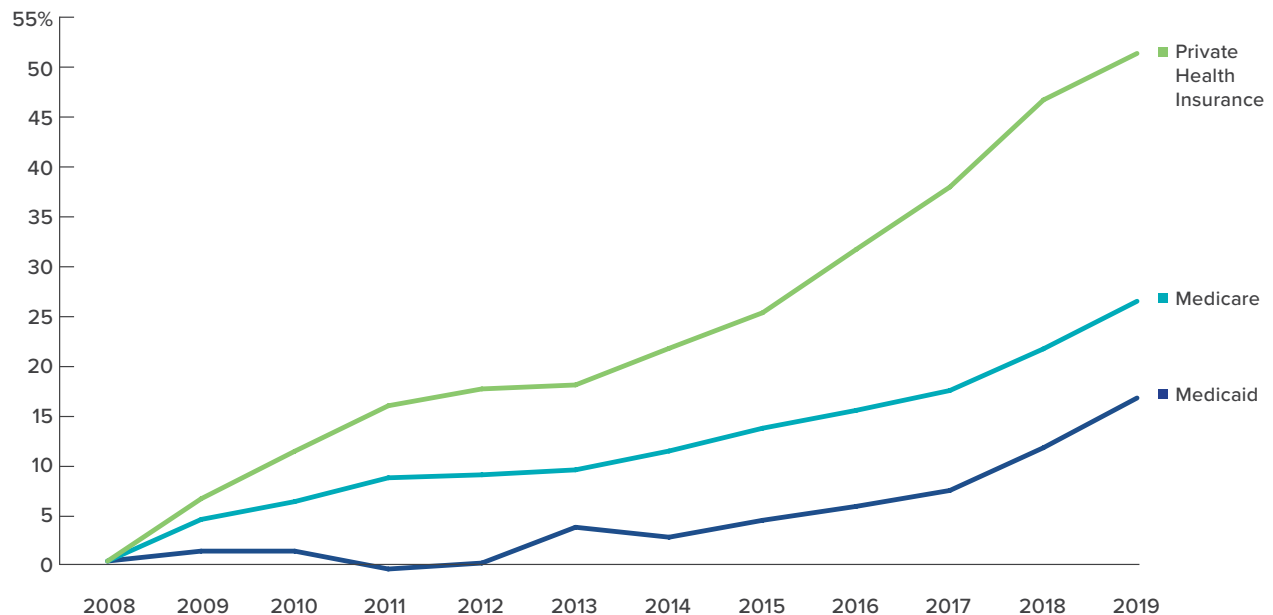
Some states have been working with CMS and the Center for Medicare & Medicaid Innovation (CMMI) to

address high spending by shifting payments systems to [value-based models](#). These initiatives attempt to, among other things, pay providers based on the total cost of care and/or outcomes metrics. [Maryland](#) is the only state in the country to use an all-payer rate-setting system for hospital services, which has evolved considerably since its inception in the 1970s. States are also using the Affordable Care Act Marketplaces to address provider pricing via public options – although their design varies widely from state to state. [Washington](#) is the first state to implement a public option-type approach, which caps provider and facility payments at 160% of Medicare costs (excluding pharmacy benefits).

[Health care market consolidation](#) (i.e., mergers, acquisitions, and other affiliations that reduce the number of competitors in a health care market) is often cited as

Fig 3.3 Cumulative Growth in Per Enrollee Spending by Private Insurance, Medicare, and Medicaid (2008–2019)

On a per enrollee basis, private insurance spending has grown much faster than Medicare and Medicaid spending.



Source: “How has U.S. Spending on Health Care Changed Over Time?” Kamal, R., McDermott, D., Ramirez, G., et al. Peterson - KFF Health System Tracker. December 23, 2020. Available at <http://allh.us/njYK>.

a noteworthy driver of hospital and physician pricing issues. [Examples of state options](#) to address the impacts of provider consolidation include, collecting data via APCDs, creating [independent](#) or [multi-agency](#) review commissions, controlling costs by restricting facility fees, and tying rates for public purchasers to Medicare rates.

While state initiatives and experimentation are essential, policy discussions and changes must occur at both levels. State policymakers may better understand local market considerations, but lack some of the broader policy levers and options available to the federal government.

At the national level, recent congressional and administrative approaches have focused on increasing [price transparency](#) and addressing “surprise bills.” In [2019-2020](#), one in five insured individuals received a “surprise bill” or unexpected bill from an out-of-network provider, which spurred greater scrutiny over provider payment practices. Debate throughout the 116th Congress led to surprise billing legislation passing at the very end of 2020. The [new law](#) prohibits providers from billing patients more than in-network cost-sharing for emergency and specific non-emergency care. Despite these new protections, ongoing discussions about addressing higher out-of-pocket costs more generally in the form of premiums, copays, and deductibles are likely to intensify.

On January 1, 2021 – after [extensive litigation](#) from the hospital industry – a new CMS rule on [hospital price transparency](#) took effect requiring hospitals to publish consumer-friendly lists of their charges for their 300 most “shoppable services” – including minimum and maximum rates negotiated with private payers. The rule applies to hospitals, excluding ambulatory surgery centers and individual providers not employed by a hospital. Additionally, in October 2020, a [complementary rule](#) was finalized imposing new transparency requirements on most group health plans (employer-sponsored health plans) and health insurers in the individual and group markets. Congress and CMS will face ongoing pressure to strengthen the enforcement of these rules and broaden its scope.

These state and federal actions will influence future policymaking – at least with continued calls for measures to address out-of-pocket costs. If Congress feels the pressure to respond to rising costs for commercially and publicly insured patients, then efforts could broaden for federal policymakers to identify options to address pricing issues by leveraging Medicare, the ACA Marketplaces, or other national oversight mechanisms.

This Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with generous support from Arnold Ventures.

While state initiatives and experimentation are essential, policy discussions and changes must occur at both the state and federal levels.

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4 | U.S. Food and Drug Administration

Overview

The **U.S. Food and Drug Administration (FDA)** is one of the 11 [operating divisions](#) within the United States Department of Health and Human Services (HHS). It ensures “the safety and efficacy of human and veterinary drugs, biologic products, and medical devices,” along with ensuring the safety of the food supply chain, cosmetics, and devices that emit radiation, that are [marketed or sold](#) in the U.S. The FDA also has responsibility for the regulation of tobacco products. It carries out this authority by reviewing manufacturers’ applications to sell these items in the

United States. The FDA does not consider price in its approval process, nor is the agency involved in setting prices for any medical product on the market. However, FDA approvals come with market exclusivity periods which are closely tied with how drugs are priced (you can learn more about drug pricing in this Handbook’s Chapter 5).

The FDA balances pressures from multiple constituencies – to make products available in a timely manner, but also to ensure that they are safe and

efficacious if used as indicated. The agency is under constant pressure to ensure that critical innovations (such as COVID-19 vaccines) are available to the public as expeditiously as possible. Of course, it is impossible to know whether an innovation is important before subjecting it to the very testing that can delay its availability. To carry out its work of determining whether products are safe and efficacious for the public, the agency relies, to a significant extent, on [funding](#) provided in the form of [user fees](#) paid by those products' producers.

Background

The federal role in regulating food and drugs dates back to the [nineteenth century](#). The predecessor to the Food and Drug Administration was the Bureau of Chemistry, created within the Department of Agriculture in [1862](#). The bureau was given its first modern regulatory functions over the pharmaceutical market in the 1902 Biologics Control Act and the 1906 Pure Food and Drugs Act. In 1927, the bureau

Table 4.1: Definitions of Drugs, Including Biological Therapeutics

Type of Drug or Therapy	Definition
Innovator or Originator Drugs	The first drug with a specific set of active ingredients to receive FDA approval and can be granted fixed-term exclusivity, which delays or prohibits approval of competitor drugs.
Generic Drugs	A drug that is comparable to an innovator drug in dose, strength, route of administration, quality, performance, and intended use. More >>
Biologic	A large or complex molecule drug that is made in a living system and can contain proteins, glycoproteins, nucleic acids, cells, or tissues. More >>
Biosimilar	A biologic that is highly similar to a previously licensed innovator biologic; sometimes referred to as a follow-on biologic. More >>
Gene Therapies	A subset of biologics that involves inserting DNA into a cell to correct a mutation that causes disease. More >>
Cell Therapies	Live cells that originate from a patient or a donor are transferred into a patient – a biologics subset. More >>
Specialty Drugs	Drugs that treat complex diseases (such as hepatitis C, cancer, and multiple sclerosis) – often requiring specific handling or administration and frequently, with a high price tag. More >>

was reorganized and its regulatory entity became the Food and Drug Administration. The Food, Drug, and Cosmetic Act of 1938, for the first time, required drug manufacturers to submit safety data to the FDA for evaluation. The agency started evaluating for efficacy in 1962. Currently, the agency is organized into seven centers and 13 offices.

The term “drug” encompasses a wide range of substances used to diagnose, cure, mitigate, treat, or prevent disease. The term includes small molecule drugs and therapeutic biological products, which payers may cover under different benefits. Different types of drugs have different approval processes, distinct market characteristics, and face different pricing and cost challenges. Table 4.1 provides some basic definitions for various drugs and therapeutic biological products.

Four Stages of a New Drug Review Process

The FDA reviews every drug and device that is marketed in America. The process for an innovator (or new) drug requires the manufacturer to go through

four stages to prove the drug’s safety and efficacy (See Fig. 4.1).

In the first stage of the drug approval process, a drug sponsor develops a new molecular entity and then begins pre-clinical development. The process is likely to include initial testing on animals. The sponsor must then submit to the FDA an *Investigational New Drug* (IND) application before it can move to clinical trials on humans. The IND proposes a plan for evaluating the drug and a summary of the preclinical data collected to that point. Human clinical testing can start 30 days after IND submission unless the FDA objects and imposes a clinical hold.

In the second stage, the sponsor engages in clinical trials. In the first phase of clinical trials, the sponsor will work with a small group of individuals, often a dozen or so healthy volunteers, to test how the drug is absorbed, metabolized, and affects the body (i.e., pharmacokinetics and pharmacodynamics). In the second phase, the sponsor works with a larger group of volunteers, perhaps up to a hundred or so patients with the disease in question, to test the drug for safety and perhaps provide the first hint of efficacy. In the third phase, which is not mandatory, the sponsor will expand to an even larger group of patients, hundreds or even thousands of individuals, to test the drug’s efficacy compared to a placebo or other standards of care. The sponsor continues to gather safety data as well.

Fig 4.1 Drug Development and FDA Marketing Approval Process Steps



Source: “FDA Could Improve Designation Review Consistency; Rare Disease Drug Development Challenges Continue.” Dicken, J., Crosse, M., Copeland, R., et al. U.S. Government Accountability Office. November 2018. Available at <http://allh.us/f6vy>.

KEY FDA ISSUES IN 2021

- Preparing for [reauthorization](#) of user fee programs in 2022.
- Increased scrutiny on regulatory efficiency and availability of new therapies given faster than normal COVID-19 vaccine development.
- Uses of [real-world evidence](#) apart from post-market surveillance.
- Scope of products the agency is regulating, such as diagnostic tests, digital health, and nicotine/e-cigarettes.
- Continued [implementation](#) of the [21st Century Cures Act](#) (which, among many other things, aims to streamline the drug, biologics, and device approval process) and potential discussion of “[Cures 2.0](#)” legislation.

In the third stage, the drug sponsor submits a *New Drug Application* (NDA) to the FDA. The NDA is the sponsor’s formal request to have the FDA approve the drug for marketing and distribution in the United States. FDA scientists review the NDA inclusive of all the data collected by the sponsor from its use anywhere in the world, and approve the drug’s manufacturer-written labeling that summarizes all of that data. The FDA also inspects the facilities where the drug will be manufactured. When all of these separate steps have been concluded to the FDA’s satisfaction, the drug is approved for sale in the U.S. market for a particular disease or indication.

In the fourth stage, the FDA continues to work with the drug sponsor to [monitor](#) the drug for side effects that may occur while on the market (also known as post-market surveillance). Prescribers and consumers can bring any [adverse events](#) that occur with the use of the drug to the FDA’s attention. If evidence emerges that an approved drug is safe and effective for additional clinical uses, manufacturers can submit a streamlined application (“[efficacy supplements](#)”).

This streamlined approval is not to be confused with [off-label uses](#), i.e., unapproved uses for an approved drug.

Generic Drug Review Process

Generic drugs do not have to go through the extensive efficacy and safety trials expected of the innovator drug. A generic drug goes through an [Abbreviated New Drug Application](#) process in which the generic sponsor is required to prove that the generic drug is bioequivalent to the innovator drug. If the generic sponsor can meet that benchmark, it does not have to conduct costly and duplicative clinical trials to establish the generic drug’s safety and efficacy. This abbreviated process allows generic drugs to come to the market faster. Generic drugs are usually cheaper because there are typically multiple generic manufacturers, and FDA-approved generic drugs are generally automatically interchangeable at the pharmacy level for their brand-name drugs (see chapter 5 of the Handbook for more details).

Biologic and Biosimilar Drug Review Process

Unlike chemically synthesized drugs, **biologic** drugs are complex combinations of sugars, proteins, or nucleic acids that are usually produced by living cells and tissues. Innovator biologics require an approval process called [Biologics License Application](#) (BLA) that mirrors the NDA process. **Biosimilar** drugs are meant to replicate an existing biologic drug’s clinical outcome and therefore go through a more [extensive review process](#) than generic drugs. The goal of the approval process is to show that the biosimilar drug has a similar structure to a reference innovator drug and can be expected to have no clinical differences.

Device Review Process

The FDA has broad authority over any **device** used in the care of a person or animal. While a popsicle stick and a tongue depressor may look like similar pieces of wood, only a tongue depressor is considered a device under the FDA's authority because it is intended to be used for clinical purposes.

The FDA divides medical devices into [three classes](#) and the approval process for each varies depending on the assigned class of the device in question.

Class I devices (tongue depressors) pose the lowest risk to the patient and are simply registered with the FDA without any formal review. **Class II** devices pose a moderate risk and require clearance from the FDA. Most Class II devices reach the market by submitting a 510(k) application that shows they are substantially equivalent to another already legally marketed device.

Class III devices have the greatest potential risk to the patient, and new Class III devices require premarket approval from the FDA, going through a process similar to those for new drugs or biologics.

New technologies have made the device field even more complex in recent years, especially when a device is used in combination with a drug or biologic. Software, for example, has historically been excluded from the FDA's approval process as a medical device. However, software that is diagnostic and is

connected to a hardware medical device is subject to the approval process. As artificial intelligence and machine learning advance, the FDA's challenge in determining what is and is not a medical device will only grow more complicated.

Expedited Approval and Emergency Use Authorizations

The FDA has the authority to [expedite](#) the development and review process for drugs, biologics, and devices deemed to fill an unmet medical need or offer better health outcomes. There are [four mechanisms](#) that alter the process – fast track and breakthrough product designations change the administrative procedures of the review, accelerated approval designation modifies the clinical evidence needed in an application, and priority review designation accelerates the FDA application review start date. Additionally, in public health emergency situations, the Secretary of Health and Human Services and FDA may utilize **Emergency Use Authorization (EUA)** to permit the use of unapproved medical products or unapproved uses of approved medical products to provide medical countermeasures. Recent issuances of EUAs were in December 2020 and February 2021 to allow use of vaccines against COVID-19.

As artificial intelligence and machine learning advance, the FDA's challenge in determining what is and is not a medical device will only grow more complicated.

Dietary Supplements

The FDA oversees dietary supplements like it does foods; however, there is no approval process requiring dietary supplements to show efficacy or safety. One of the FDA's roles is to ensure that a dietary supplement's intended effect is not misrepresented to the public.

What the FDA Does Not Do

The FDA is statutorily charged with approving products under its jurisdiction if they are (1) safe and efficacious when used as indicated and (2) if their benefits outweigh their risks. The FDA does not engage in any effort to evaluate comparative effectiveness between any two drugs or devices. The FDA does not have the authority to require product sponsors to show comparative effectiveness with other products that treat the same condition. However, most clinical trials treat their control group with the current standard of care. The agency also does not oversee the practice of medicine and pharmacy – which are state-based and govern how medicines are used in practice.

The FDA also does not consider the pricing of any drug or device as part of its review process, and subsequently most products going through FDA review do not have a price attached as they are yet to be approved for marketing in the U.S.

The FDA does not determine whether a drug or device will be covered by insurance or other payers. The FDA approves a drug or device for use by the public for a specific indication, although physicians may prescribe off-label for additional disease or conditions as they are covered by state-based medical licenses and the practice of medicine. Payers determine whether to cover a drug or device within the terms of their insurance programs. While FDA approval makes coverage highly likely for private insurers, it is not a certainty, and coverage can vary depending on the availability of multiple

GLOSSARY OF TERMS

Patent: Granted by the U.S. Patent and Trademark Office and provides for the protection of property rights, for example, in the active ingredient of a drug. The term of the patent is 20 years from the date of application.

Exclusivity: Prohibits the approval of competitor drugs by the FDA. All new drugs get five years of exclusivity from their FDA approval date. However, different types of exclusivities are intended to provide additional incentives for the production of certain types of drugs.

Safety: “Often measured by toxicity testing to determine the highest tolerable dose or the optimal dose of a drug needed to achieve the desired benefit.” A safe drug does not mean that there are no side effects, but benefits outweigh the potential risks of side effects and that the drug is not toxic. Safety trials may also identify adverse events (injury resulting from medical intervention).

Efficacy: Performance of an intervention under ideal and controlled circumstances.

Effectiveness: Performance of an intervention under real-world conditions.

medicines, including generics, for any given condition. However, FDA approval generally guarantees coverage by Medicaid (if manufacturers choose to participate), and specific categories of drugs are also required to be covered by Medicare Part D plans. For drugs not subject to guaranteed Medicare coverage, Part D plans have their own review processes for determining if an approved drug or device should be covered.

User Fee Acts

In 1992, Congress passed the first Prescription Drug User Fee Act (PDUFA), in part, as a response to drug manufacturer and patient advocate complaints about delays in the FDA approval process. The act's solution was to require manufacturers to pay a [user fee](#) at the time of the NDA submission, which the FDA then used to increase staffing to address pending applications.

The User Fee Act's purview for originator drugs has since been expanded to include user fees for animal drugs, generic drugs, biosimilars, and medical devices. The whole Act (and its amendments for other drug/device types) is subject to renewal every five years. The process of writing the legislation to extend the act is carefully negotiated between the industry and the FDA, with results presented to Congress for approval. Through the negotiations, each of the parties, as well as stakeholder groups like patient advocates, are trying to achieve improvements they see as being in their interests.

Patents v. Exclusivity and the Hatch Waxman Act

[Patents and exclusivity](#) are similar in concept in that they relate to how long a new drug can be on the market before the drug can be replicated and sold by competitors. Still, they are distinct and governed by different statutes and parts of the government. A **patent** is granted by the U.S. Patent and Trademark Office and provides for the protection of property rights, for example, the active ingredient of a drug. The term of the patent is 20 years from the date of application, regardless of the drug's FDA approval status.

Exclusivity prohibits the approval of competitor drugs by the FDA. All new drugs get five years exclusivity from their date of approval by the FDA. However, there are different types of exclusivities intended to provide supplemental incentives for the production of certain types of drugs. For instance, drugs for rare diseases (sometimes called orphan drugs) receive an exclusivity of seven years, and drugs tested in children receive an

additional six months added to their existing exclusivity. Additional exclusivities may be limited to an [individual indication](#) rather than the entire product.

The first generic drug to the marketplace can earn a 180-day period of exclusivity from other generic entrants, which encourages generic manufacturers to challenge brand-name manufacturers' patents so they may be the first to bring competition to the market. Patent terms and exclusivity periods may or may not co-occur.

Many of these provisions were initially established in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the [Hatch-Waxman Act](#), which intended to preserve the incentives that bring innovator drugs to the market while allowing a streamlined process for the approval of generic drugs. The Act provided for patent extensions to account for clinical testing and regulatory review periods and minimum competition-free periods for drugs without patents. In addition, a streamlined process was formalized to bring generic competition to the market after the exclusivity period. The FDA publishes a compendium of approved drugs with therapeutic equivalents (generics), commonly referred to as the Orange Book (for the orange cover from its original printing). The Orange Book lists key patent and exclusivity information for drugs approved by the FDA.

In theory, patent terms and exclusivity periods reward innovators for bringing new drugs to the market by allowing them to charge monopoly prices while preventing competitors from immediately copying their products. When the exclusivity period expires, competition from generic drugs benefits consumers by bringing down the cost of prescription drugs. [Patent-related protection](#) from generic competition can often extend past 20 years because brand-name manufacturers may obtain numerous patents on multiple aspects of their drug, including its formulation, salt forms, and uses (method patents).

Chapter 5 of this Handbook goes into more detail about the many facets and actors that impact the final cost and price of prescription drugs, as well as the various financing challenges and opportunities.

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How FDA Approves Drugs and Regulates Their Safety and Effectiveness. <http://allh.us/7DfG>

5 | Prescription Drug Financing

Overview

Prescription drug financing and pricing may be the most complicated issue in health care. There is substantial debate over the affordability of drugs for patients, private payers, and government programs in recent years. Many facets and actors impact the final cost and price of drugs to payers and patients, including: Research and development costs of – and the exclusivity afforded to – a new drug, manufacturing costs, and the impact of pharmacy benefit manager (PBM) negotiations on patient cost-sharing rebates and discounts. While [spending](#) on prescription drugs

constituted about 14% of overall national health expenditures in 2018, [one in four](#) Americans reported difficulty affording their medications. Additionally, as scientific advancement allows for more complex specialty drugs and potentially curative cell and gene therapies to enter the market, both the policy community and consumers are growing more concerned about how to pay for those drugs.

[Drug pricing](#), therefore, is an area ripe for [policy option](#) discussions. There are growing questions

about the tradeoffs between innovation and prices charged in the U.S. relative to other countries – and whether prices reflect the drugs’ value to health. [States](#) have moved faster than the federal government to establish boards to examine price increases and to regulate PBMs, among other actions. The policy community has also expressed increasing interest in learning from and incorporating international drug pricing approaches. These activities are likely to influence continued national debate and potential action building in the 117th Congress on legislation considered and passed in the last session.

Background

The term “**drug**” encompasses a wide range of **substances** used to diagnose, cure, mitigate, treat, or prevent disease. The term includes small molecule drugs and large molecule biological products, which can have distinct market characteristics and face different pricing and spending challenges. Chapter 4 of this Handbook defines different drugs and therapeutic biological products and describes their approval processes by the U.S. Food and Drug Administration (FDA), as well as the basics of patent terms and exclusivity periods.

Figure 5.1 summarizes the United States’ prescription drug distribution system, the major entities, and how funds and services flow between them.

Multiple federal laws have created and impacted the current prescription drug development pipeline, pharmaceutical marketplace, and drug coverage programs, including:

- **1983 Orphan Drug Act:** Provides incentives to develop drugs for rare diseases.
- **1984 Drug Price Competition and Patent Term Restoration Act ([Hatch-Waxman Act](#)):** Intended to streamline generic drug approval process. (Discussed in more detail in Chapter 4.)
- **1990 Omnibus Drug Reconciliation Act:** Authorized the [Medicaid Drug Rebate Program](#) (MRDP) which aims to expand prescription drug coverage for low-income patients.

- **2003 [Medicare Prescription Drug, Improvement, and Modernization Act \(MMA\)](#):** Authorized the Medicare Part D program which aims to expand prescription drug coverage for seniors.
- **2010 Affordable Care Act (ACA):** Changed the structure of [MRDP](#), established a [biosimilar](#) approval pathway, and closed the Part D [donut hole](#).
- **2016 [21st Century Cures Act](#):** Aims to, among many other things, streamline the drug and device approval process.

The federal government covers prescription drugs for patients through two main health insurance programs – Medicare (through Parts B and D) and [Medicaid](#). Almost all [employer health plans](#) include prescription drug benefits, and individual marketplace plans must include drugs as one of the ten essential health benefits. (Note that private plans do not necessarily cover all drugs.) Similar to provider payment rate variation (as discussed in Chapter 3), [net prices](#), [spending](#), and ultimately patient out-of-pocket costs can vary significantly across different programs and payers. Many reasons drive this variation including the fact that these programs target different patient populations, use formularies differently, and are subject to different statutory requirements and regulations. For sake of brevity, we have focused on the Medicare drug benefit (Parts B and D) in this chapter.

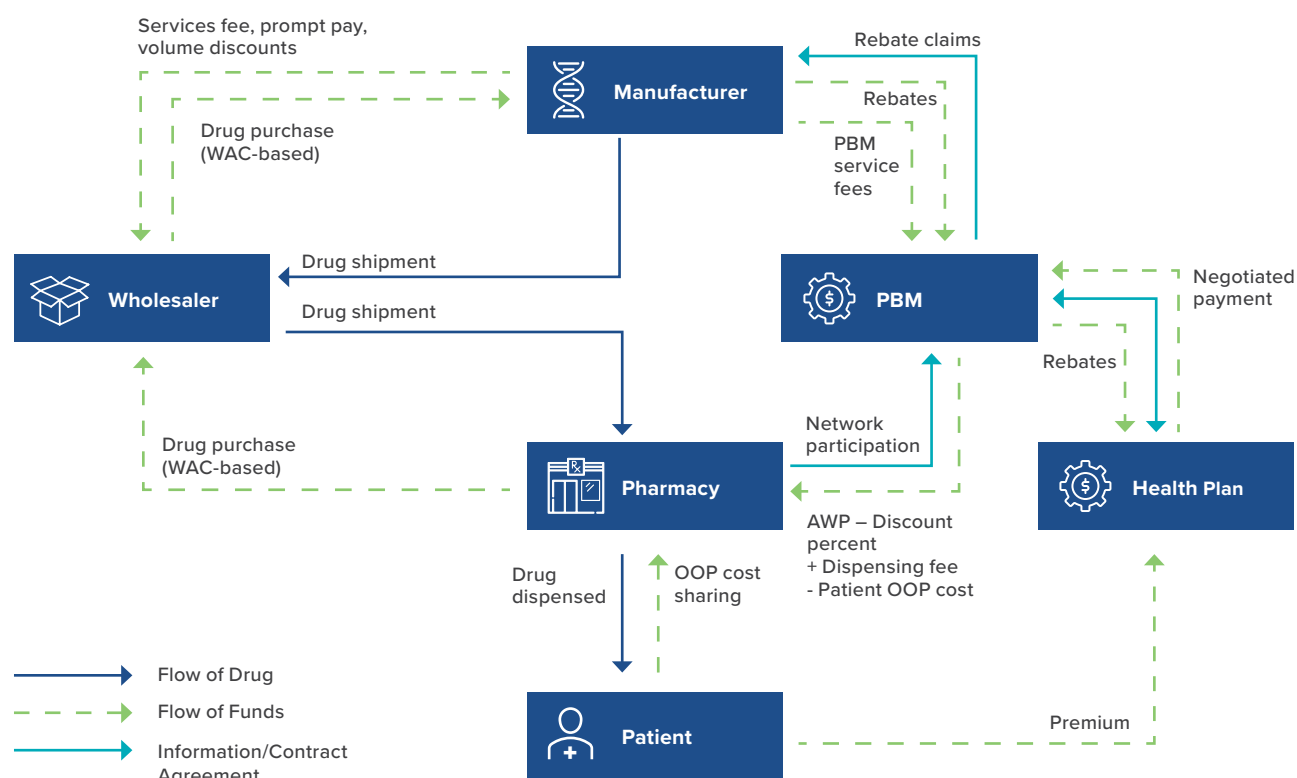
Drug Pricing Incentives in the Medicare Program

The Medicare program provides coverage for **out-patient drugs** prescribed to Medicare beneficiaries through Parts B and D. The Medicare Part B benefit covers drugs that are administered in a physician’s office setting. By contrast, the Part D program provides coverage for prescription drugs typically dispensed by retail pharmacies. Each program uses distinct mechanisms to pay for drugs covered under each benefit and face different spending and affordability challenges.

Drugs provided through the Part B drug benefit are reimbursed based on the average sale price (ASP) of the drug plus a 6% add-on payment to cover drug administration fees. Medicare Part B does not negotiate drug prices with brand-name manufacturers. Since the add-on payment increases as the ASP increases, there have been concerns that this creates incentives for physicians to administer higher-priced drugs. In the last several years, both CMS and Congress have proposed and considered changes to the ASP payment structure to address the arrangement's potentially inflationary nature. They have also contemplated other approaches to contain Part B spending, including paying an amount derived from international prices, and penalties paid by manufacturers to Medicare if prices grow faster than inflation.

Medicare Part D, Medicare's retail prescription drug benefit, was established in 2003 with the enactment of the Medicare Modernization Act (MMA). Funded with federal subsidies and beneficiary premiums, benefits are offered through private plans – either stand alone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA-PD) plans. The MMA included a “non-interference” provision that prohibits the government from interfering with negotiations between plans and drug manufacturers, or from requiring specific formularies or price structures for payment of the drugs. However, the law does include some drug coverage requirements on all Part D plans, including coverage of at least two drugs in each therapeutic class and nearly all drugs in six protected classes. In concept, insurers work to negotiate between manufacturers to drive the

Fig 5.1 Understanding the Prescription Drug Supply Chain



Source: “Follow the Pill: Understanding the Prescription Drug Supply Chain.” Olsen, M, Nam, D, Getachew, B. et al. Avalere. May 20, 2020. Available at <http://allh.us/BrTf>.

cost of drugs down for beneficiaries. Nevertheless, there has been a marked increase in the number of high-cost specialty drugs and drugs with prices rising faster than inflation. As a result, Part D beneficiary [premiums](#) and out-of-pocket costs are also [increasing](#). In 2017, [60%](#) of the drugs covered by Medicare Part D reported list price increases larger than inflation.

The Part D benefit structure may create incentives that lead to higher costs for Medicare. Primarily, the current structure of the Part D benefit may create financial incentives for plans to not manage costs for beneficiaries as closely, especially those with high drug costs. There are also concerns that the Part D benefit current structure could incentivize manufacturers to set a higher initial launch price for drugs. The benefit's structure may also discourage any efforts among manufacturers to limit year-to-year inflationary increases among drugs without any competition in their class. In response, policymakers are considering structural changes to the Part D benefit designed to address these issues, especially plan incentives, to encourage more efficient management and cost control.

Financing Challenges

In 2018, spending on drugs constituted 14% of overall national health expenditures. However, spending has increased in recent years, with retail prescription drug spending growing by [27%](#) between 2012 and 2016 – faster than other health expenditures categories. This growth [was attributed](#) to a surge in new specialty drugs coming to market in 2014. While spending slowed in 2016 and 2017, [CMS projects](#) that drug spending will increase by five to six percent between 2021 and 2028. Spending on prescription drugs is driven by brand-name drugs, which make up about [10%](#) of all prescriptions, but nearly [80% of spending](#). Policymakers should recognize that overall spending data may hide conflicting trends driven by the kind of drugs being studied, the conditions they treat, and consequently, their impact on individual patients' out-of-pocket costs. For example, recently a significant portion of spending growth has been [attributed](#) to a surge in new specialty drugs, with per

GLOSSARY OF TERMS

List Price: The price a manufacturer sets for a drug before discounts and rebates.

Net Price: The price of a drug after discounts and rebates are taken into account.

Rebate: A negotiated discount that payers are able to obtain from pharmaceutical companies due to purchasing volume and level of influence on drug product choice.

Average Sales Price (ASP): A manufacturer's reported average price for physicians, hospitals, and other purchasers of a drug. Inclusive of most discounts and rebates and only used for Medicare Part B drug payments.

Average Wholesale Price (AWP): A list price that does not reflect actual sales prices inclusive of discounts and rebates. Medicare payment for certain vaccines and blood products are based on a percent of AWP instead of ASP.

Wholesale Acquisition Cost (WAC): A price from a manufacturer to a wholesaler that is also related to the list price, but not the actual price of a drug. Used for new single-source drugs (brand-name drugs that do not have a generic) where average sales price data are not yet available. Usually lower than AWP.

capita growth in specialty drugs outpacing overall drug spending trends. Since 2014, prices for brand specialty drugs have increased by [57%](#), while generic drugs' prices fell by [35%](#).

As evidenced above in Fig 5.1, the prescription drug supply chain is complex and many interconnected factors drive spending and prices. We have chosen to focus on the costs of bringing new drugs to market and the role of rebates in this chapter as these drivers impact all federal programs and private drug benefit plans.

KEY DRUG COST ISSUES FOR THE 117TH CONGRESS

- Growing affordability issues for Medicare beneficiaries for Part B and Part D drugs.
- Financing for very high-cost drugs that may be curative or very effective.
- Role of PBMs in managing drug formularies and how rebates affect list prices for drugs.

Cost of Innovation and Bringing Drugs to Market

The question of how much biomedical innovation costs is often brought up in discussions over how drugs are priced and their impact on federal, state, and household budgets. Unfortunately, estimates of the cost to bring drugs to market vary widely depending on the study, companies examined, and data used. For instance, a [2016 study](#) of multinational biopharmaceutical companies estimated that research and development (R&D) costs were \$2.6 billion per approved drug. In contrast, a [2020 study](#) on research and development costs for drugs approved by the FDA estimated that the median cost to bring a new drug to market was \$985 million. The methodologies and sources of data can vary widely from one study to another resulting in wide ranges of estimates.

The path from discovering a new potentially medicinal compound to FDA approval can be [long](#), taking an average of 10-15 years, with the final five years or so accounting for human clinical trials. It can also be much shorter than that, particularly for highly effective new therapies and precision medicines. After discovery, sponsors must successfully navigate preclinical and clinical research consisting of three trial phases. Of the drugs that enter the clinical research phase, only

[25-30%](#) advance from Phase 3 trials. After completing clinical research, *New Drug Applications* (NDAs) or *Biologics License Applications* (BLAs) are submitted to the FDA for approval. Timelines for reviewing applications range from six months for priority reviews to 10 months for standard reviews. Pharmaceutical manufacturers are [required](#) to conduct post-market surveillance with Phase 4 studies that assess drugs' effectiveness and their long-term effects.

The [National Institutes of Health](#) (NIH), is one of the eleven operating divisions of the U.S. Department of Health and Human Services, and, with an annual budget of [\\$41.7 billion](#), is a major funder of basic and translational science, including drug innovation. In addition to funding basic science that supports drug development, a recent study found that an estimated [25%](#) of newly approved drugs had late-stage development links to NIH funding or academic medical centers. Discussion around research and development costs also raises the question of which taxpayer-funded programs contributed to any given drug's discovery process, and how that contribution should factor into its future market pricing.

Role of Pharmacy Benefit Managers' Rebates and Discounts

[PBMs](#) came to prominence in the 1980s, playing a role in negotiating drug prices with manufacturers on behalf of insurers. PBMs manage prescription drug benefits for insurers by developing formularies, negotiating rebates and discounts from manufacturers, and contracting with pharmacies which are reimbursed for drugs dispensed to beneficiaries (See Fig 5.2). Patient [benefits](#) can include home delivery of medications, adherence programs, and managing high-cost specialty medications.

PBMs use rebates to drive lower prices, with the volume of drugs purchased used as a lever to encourage larger

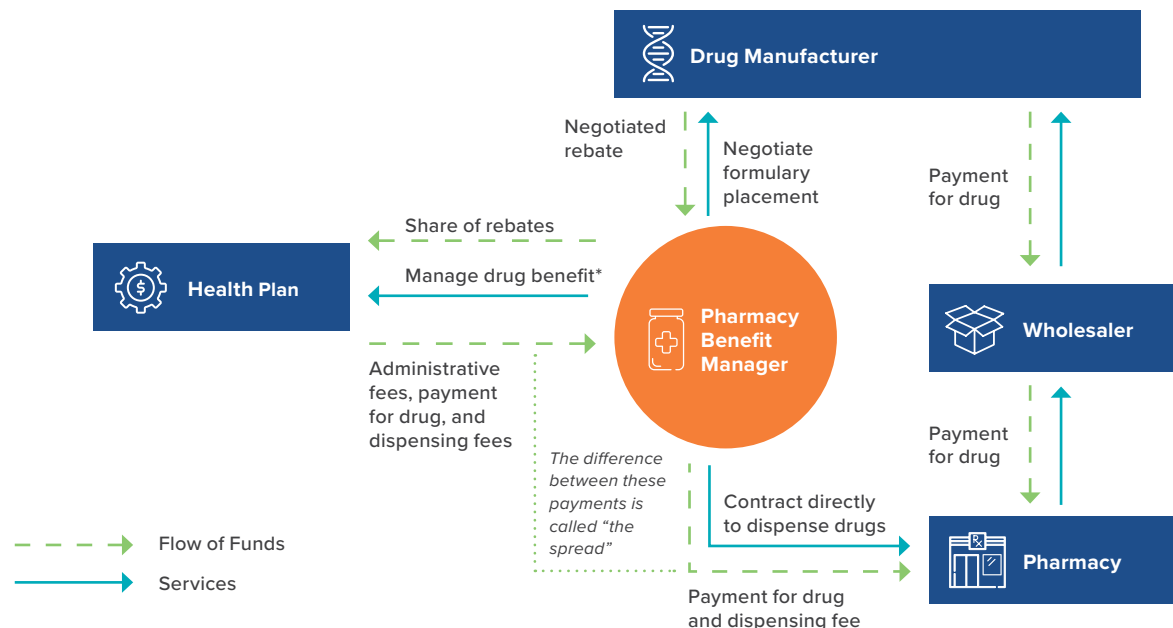
rebates. In exchange for their efforts, PBMs typically retain some portion of the savings achieved. Positioned between manufacturers and insurers, they are in the “middle” of the transaction chain.

One of the side effects of using rebates is that it can lead to higher overall health spending, potentially by increasing list prices, which are paid for by the uninsured and those with insurance that base cost-sharing on list prices. PBMs receive rebates that are often calculated as a percentage of list price (the price of a drug that is set by the manufacturer). Some critics say this creates a perverse incentive for PBMs to favor more expensive drugs or drugs with larger rebates. This has also raised questions of whether these rebates contribute to manufacturers raising their list prices to offset larger rebates to PBMs. Unfortunately, data can support both arguments (and furthermore, data is somewhat hard to come by as many entities consider it proprietary information). A Pew study found that manufacturer rebates grew from \$39.7 billion in 2012 to

\$89.5 billion in 2016. However, a survey of insurers and PBMs found that PBMs passed a greater percentage of rebates back to insurers – increasing from 78 to 91% over the same period.

PBMs have also been at the center of controversies related to generic drug pricing. In negotiating prices for drugs, PBMs can use a model called “spread” pricing, in which a PBM charges an insurer *more* than it pays the pharmacy for a drug and then retains the difference. While these are voluntary agreements between PBMs and payers, there are increasing concerns about how this spread pricing practice may be driving up prices for generic drugs – which are usually far less expensive than brand-name drugs – and in turn may be driving up costs for insurers, premiums, and government programs. In 2019, CMS restricted the practice within the Medicaid program, but spread pricing is still used in the commercial market. Calls for greater transparency on rates and requirements to pass on rebates to insurers or patients are likely to continue.

Fig 5.2 Role of Pharmacy Benefit Managers in the Prescription Drug Supply Chain



Source: “Pharmacy Benefit Managers and Their Role in Drug Spending.” The Commonwealth Fund. April 2019. Available at <http://allh.us/nj4h>.

International Approaches to Drug Financing

The U.S. paying more for prescription drugs relative to counterparts in other developed countries is not new. Calls for prescription drug reimportation to reduce costs for Americans date back decades. However, the current drug pricing debate has renewed interest in how other developed countries approach drug pricing and financing. These countries use a range of tools to support their drug pricing and

financing approaches, including health technology assessments that examine the clinical benefits of a drug, negotiating drug prices, setting limits on post-approval price increases, and using reference pricing. Some of these tools are described in more detail in Table 5.1, below. These or similar options are being discussed for potential adoption in the U.S. Note that many countries employ multiple options or approaches for drug pricing depending on the type of drug and its level of competition in the market.

This Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with generous support from Arnold Ventures.

Table 5.1 Overview of International Approaches to Drug Financing

Pricing/Financing Approach	Description
External Reference Pricing	Setting prices for drugs by taking into account what other countries pay , which can lower the price of drugs depending on the countries used in the analysis
Internal Reference Pricing	Setting prices based on payments for clinically comparable products , however, cannot be used for drugs without any comparable alternatives
Value-Based Pricing	Setting prices based on an assessment of the value , including clinical benefits of a drug
Negotiation	Setting prices with manufacturers using reference prices or value assessments

Source: "Payment Policies to Manage Pharmaceutical Costs." Docteur, E., Lopert, R. The Pew Charitable Trusts. March 2017. Available at <http://allh.us/Bpnr>.

RESOURCES

Chapter 5: Prescription Drug Financing

Listed by the order in which they appear in Chapter 5.

OVERVIEW

Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. <http://allh.us/UbxC>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

Frequently Asked Questions About Prescription Drug Pricing and Policy. <http://allh.us/uw6d>

Prescription Drug Pricing. <http://allh.us/rRXN>

2021 State Legislative Action to Lower Pharmaceutical Costs. <http://allh.us/JNCY>

BACKGROUND

Drugs@FDA Glossary of Terms. <http://allh.us/eF9D>

Orphan Drug Act: Background and Proposed Legislation in the 107th Congress. <http://allh.us/jXvG>

The Hatch-Waxman Act: A Primer. <http://allh.us/Ew7u>

Medicaid Prescription Drug Pricing and Policy. <http://allh.us/TgbD>

Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. <http://allh.us/qVkd>

What Happens to Medicaid Drug Policy if the ACA is Overturned? <http://allh.us/uehW>

Health Policy Brief: Biosimilars. <http://allh.us/Byhw>

Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead. <http://allh.us/rCx9>

The 21st Century Cures Act (Division A of P.L. 114-255). <http://allh.us/URcY>

Medicaid's Prescription Drug Benefit: Key Facts. <http://allh.us/jpRa>

2020 Employer Health Benefits Survey. <http://allh.us/Bnfb>

A Comparison of Brand-Name Drug Prices Among Selected Federal Programs. <http://allh.us/NkB8>

How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid? <http://allh.us/UJTc>

DRUG PRICING INCENTIVES IN THE MEDICARE PROGRAM

Part B Drugs Payment Systems. <http://allh.us/MpTE>

Medicare Part D Prescription Drug Benefit. <http://allh.us/QDCA>

Negotiation of Drug Prices in Medicare Part D. <http://allh.us/j4xb>

General Drug Categories. <http://allh.us/np8c>

An Overview of the Medicare Part D Prescription Drug Benefit. <http://allh.us/9t4h>

Assessing Drug Price Increases in Medicare Part D and the Implications of Inflation Limits. <http://allh.us/hBdt>

The Prescription Drug Landscape, Explored.

<http://allh.us/VRTf>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

National Health Expenditure Projections 2019–28. <http://allh.us/XUhg>

Why Are Prescription Drug Prices Rising and How Do They Affect the U.S. Fiscal Outlook? <http://allh.us/Exhd>

Medicine Spending and Affordability in the United States. <http://allh.us/hpJ3>

What Are the Recent and Forecasted Trends in Prescription Drug Spending? <http://allh.us/wWA8>

COST OF INNOVATION AND BRINGING DRUGS TO MARKET

Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. <http://allh.us/dwtb>

Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. <http://allh.us/XVQu>

The Pharmaceutical Drug Development Process. <http://allh.us/J3BD>

National Institutes of Health: About NIH.

<http://allh.us/AGuR>

National Institutes of Health: Budget. <http://allh.us/hX3K>

Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study. <http://allh.us/j63p>

ROLE OF PHARMACY BENEFIT MANAGERS' REBATES AND DISCOUNTS

Pharmacy Benefit Managers. <http://allh.us/vngQ>

The Value of PBMs. <http://allh.us/3EfK>

Pharmacy Benefit Managers and Their Role in Drug Spending. <http://allh.us/nj4h>

The Prescription Drug Landscape, Explored. <http://allh.us/VRTf>

Pharmacy Benefit Managers and Their Role in Drug Spending. <http://allh.us/nj4h>

CMS Issues New Guidance Addressing Spread Pricing in Medicaid, Ensures Pharmacy Benefit Managers are not Up-Charging Taxpayers. <http://allh.us/wCuV>

Box: Glossary of Terms

Medicare Part B Drug Average Sales Price. <http://allh.us/dpuN>

Medicare Part D Prescription Drug Benefit. <http://allh.us/QDCA>

Use of Average Sales Price Payment Methodology. <http://allh.us/WGbJ>

6 | Dual Eligible Beneficiaries

Overview

Low-income older adults and people with complex needs who are eligible for both Medicare and Medicaid are sometimes referred to as “[dual eligible](#).” An estimated [12 million](#) dually eligible beneficiaries were enrolled in Medicare and Medicaid in 2019. Dually eligible individuals are typically low-income individuals over 65, or those diagnosed with [End-Stage Renal Disease \(ESRD\)](#) or another disability. They often experience socioeconomic vulnerability and have various complex care needs, such as multiple chronic conditions, functional limitations, and behavioral health conditions. This group typically

represents the [highest need](#), and highest cost beneficiaries within both programs. Therefore, policies directed at this population should in theory have a high impact in reducing costs and improving care, but in reality are very complicated to design and implement; any policy change would involve altering two very large government programs.

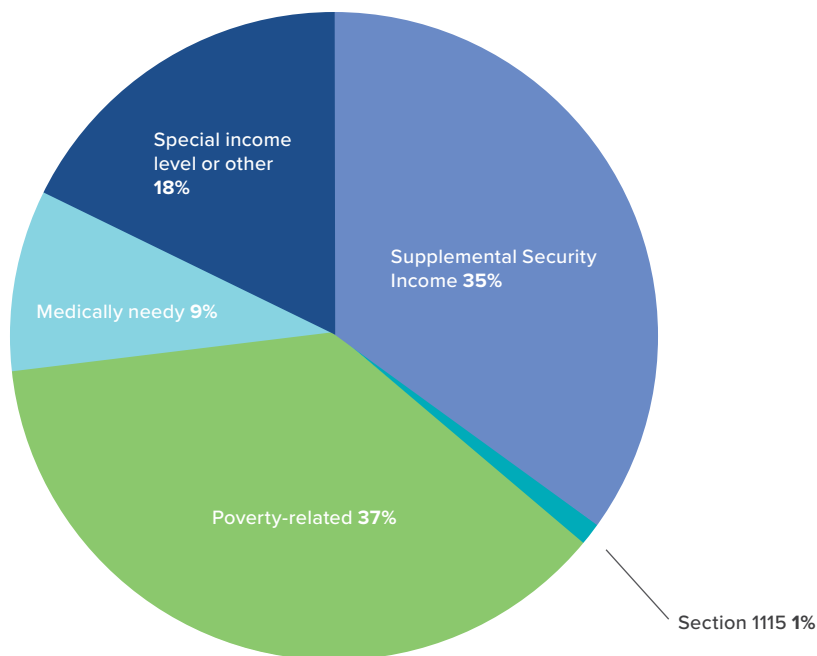
Generally, Medicare covers medical services for dual-eligible beneficiaries, and Medicaid covers certain services not provided by Medicare, including [long-term services and supports \(LTSS\)](#) and some

behavioral health benefits. Medicaid also offers financial assistance to these low-income beneficiaries to pay Medicare premiums and cost-sharing. Federal and state policymakers have long grappled with strengthening coordination between Medicare and Medicaid to improve quality and outcomes for dual-eligible beneficiaries and reduce both programs' costs. That said, there is significant diversity within the duals population. Further, because meaningful change in this area requires policymakers to make changes to both Medicare and Medicaid, dual eligible-focused policies require careful consideration of both programs as well as the populations' characteristics. See *Chapter 2 of this Handbook for more information on Medicare and Medicaid programs and the basics of health care coverage.*

| Eligibility

For an individual to be dually eligible for both Medicare and Medicaid, they must meet the statutory criteria for both programs. Medicaid eligibility varies by state, which means a Medicare beneficiary might be dually eligible in one state, but not in another. There are two broad dual eligibility groups. *Partial benefit dual eligible individuals* are those only eligible for assistance paying for some of their Medicare premiums and cost-sharing. *Full benefit dual eligible individuals* qualify for help paying for all Medicare cost-sharing and premiums, as well as for the full range of Medicaid benefits. The partial benefit eligibility category is further broken out by the level

Fig 6.1 Share of Dually Eligible Population by Medicaid Eligibility Pathways



Source: "Eligibility." Medicaid and CHIP Payment and Access Commission. 2018. Available at <http://allh.us/k4Ug>.

of cost-sharing and premium assistance people are eligible for. The federal government sets income and asset floors for each of these categories; however, states have the flexibility to provide support above these levels, and many do.

Individuals become [eligible](#) for the Medicare program through one of three pathways: Age, ESRD, or disability. Medicare provides health insurance coverage to nearly all adults over age 65 and younger individuals who qualify through other conditions. To be eligible for Medicare based on a disability, an individual must have a history of contributing to the Medicare program through payroll tax, and a qualifying medical condition. Individuals with disabilities may qualify for Medicare based on their own work history or based on a spouse's or parent's work history. Roughly 42% of dual eligibles qualify for Medicare through the disability criteria.

Individuals become eligible for the Medicaid program based on federal requirements that states must follow (mandatory [eligibility categories](#)), or based upon additional requirements that states may choose to cover (optional eligibility categories) (See Fig 6.1).

Benefits

Medicare benefits include inpatient hospital care, skilled nursing facility care, home health care and hospice care (Part A), physician and other ancillary services in an outpatient setting (Part B), and coverage of prescription drugs (Part D). Medicare Part A and B benefits are offered through traditional fee-for-service or private managed care plans (Part C Medicare Advantage), and Part D is administered through managed care plans. The benefits may include service limitations and a requirement for individual financial participation through premiums, copays, and deductibles.

The Medicaid program provides additional services not covered by Medicare, including long-term stays in a nursing home. The Medicaid program may provide extra benefits at the discretion of each state, such as [home and community-based services](#) (HCBS) or transportation services, that Medicare does not cover. The Medicaid program also provides additional financial

support for Medicare premiums, copays, and deductibles of individuals dually eligible for both programs.

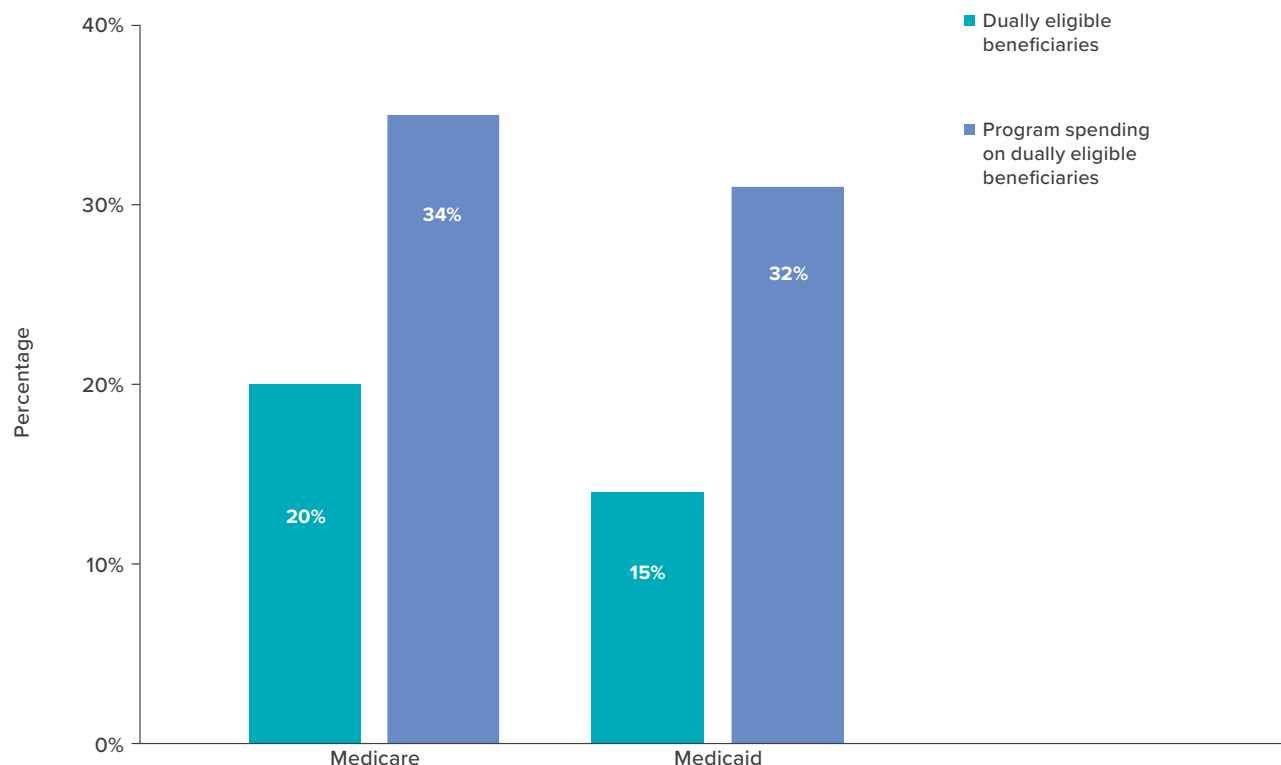
Divisions between the two programs may compromise patient care by complicating coordination across providers. For example, a patient's acute care provider paid by Medicare may have difficulty accounting for or following up on their patient's chronic or non-medical needs, covered by Medicaid. This disconnect is particularly challenging in periods of care transition, such as, for example, when a patient has a hospital stay (Medicare) before being discharged to their home or institution where they may need LTSS (Medicaid).

Additionally, different program rules can create stress, administrative burden, and waste for beneficiaries around the coordination of benefits. Cost-shifting across the two programs – and the different levels of government that take the lead on each program – is a persistent issue. [Appeals processes](#) also differ between the two programs, as do care coordination and coverage for services that allow beneficiaries to transition back to the community after an inpatient stay. The lack of program alignment and fragmented coverage also means that one program may not take actions that would result in savings in the other program – and there can be incentives to cost shift. Last, cost-sharing policies [differ across states](#), with studies indicating that beneficiaries in states with higher cost-sharing face access issues. Finding ways to provide more integrated benefits and services to these individuals in a more cost-effective manner is a perennial challenge for policymakers.

The Demographics and Economics of the Dually Eligible

In 2019, **12.3 million individuals** were enrolled in Medicare and Medicaid. Dually eligible individuals have several demographic characteristics that distinguish them from non-dual Medicare beneficiaries. [Dually eligible individuals](#) are more likely to be female and persons of color, be in poor health, experience more activity of daily living (ADL) limitations, and are more likely to be

Fig 6.2 Dually Eligible Beneficiaries as a Share of All Medicare and Medicaid Beneficiaries and Spending by Program (2013)



Source: “Integrating Care for Dually Eligible Beneficiaries: Background and Context.” The Medicaid and CHIP Payment and Access Commission. June 2020. Available at <http://allh.us/wk9e>.

living alone or in a facility. They are also prone to have social risk factors that lead to poor health outcomes, including homelessness, food insecurity, lack of transportation, and low health literacy levels.

Individuals dually eligible for Medicare and Medicaid account for a disproportionate amount of the spending in those programs (See Fig. 6.2). In the calendar year 2013 (which is “the most recent year of comprehensive data for both programs” according to MACPAC, as data completeness and accuracy are a perennial issue), combined spending on dually eligible individuals was \$312.4 billion (See Fig. 6.3). Of that total, 62% was from the Medicare program.

Beyond some of the characteristics outlined above and the eligibility pathways that all dual beneficiaries must meet, there is significant diversity within the population that limits simplistic policy solutions. A dually eligible individual may be a person under 65 with a disability living in the community who only needs a limited amount of HCBS, or a relatively healthy low-income senior who needs additional financial assistance provided by the Medicaid program to pay for Medicare coverage. An individual who is dually eligible may be under 65, profoundly disabled, and living in a facility, or a frail elder with numerous health conditions requiring significant attention.

The Challenge of Two Programs Serving One Population

For federal and state policymakers facing budgetary challenges, the disproportionate cost of dually eligible individuals will continue to drive efforts to address the challenges of providing efficient, quality care to those individuals. This is of increased importance to state policymakers as the [Medicaid program](#) will have many individuals who similarly utilize extensive services but are not dually eligible. The focus of policy solutions continues to be on integrating care across the services provided by both programs (particularly acute care and LTSS) as well as ones that will have the highest impact in reducing costs and improving care to the most medically needy, high cost individuals.

The Impact of Long-Term Services and Supports

Long-Term Services and Supports (LTSS) differs from both acute and post-acute care services and can range from a home health aide assisting someone with activities of daily living for a couple of hours a day (an example

of [HCBS](#)) to intensive nursing care for persons needing 24-hour supervision (an example of institutional care).

The Medicare program provides a 100-day benefit for LTSS. The provision of LTSS for both dually eligible individuals and Medicaid beneficiaries without Medicare [falls mainly to the states](#) and the [Medicaid](#) program. The expense of the LTSS benefit is significant for state Medicaid programs. Nationwide, the LTSS benefit accounts for [32%](#) of Medicaid spending. In Iowa, New Hampshire, and North Dakota, the LTSS benefit accounts for more than half of all Medicaid spending in each state. These spending trends drive states to seek [creative solutions](#) to provide HCBS and potentially delay the use of the more expensive institutional benefit.

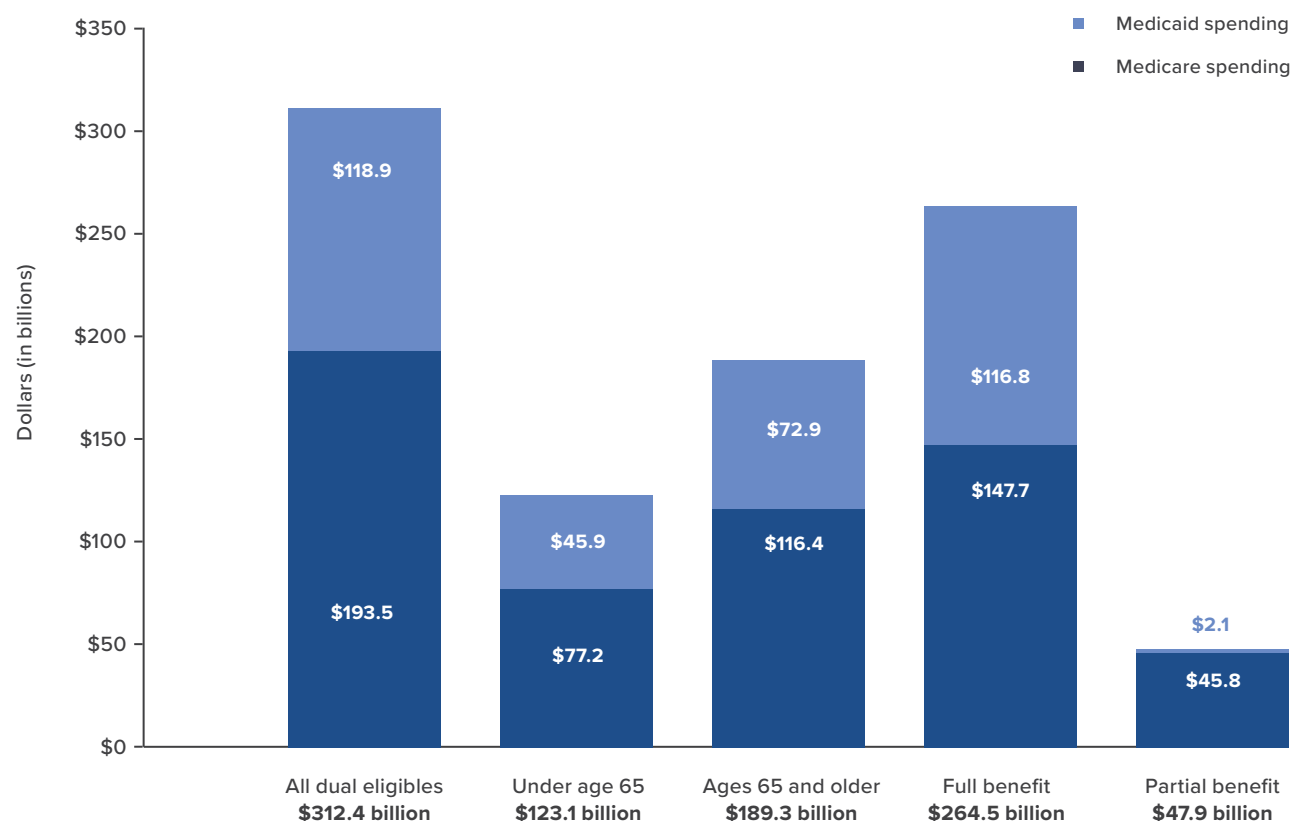
The Challenge of Behavioral Health Integration

An additional challenge faced by states in treating the dually eligible population is the simultaneous need for [behavioral health services](#) (including mental health and substance use care). Medicare beneficiaries age 65 and over are [increasingly likely](#) to report having a behavioral health disorder, and Medicare beneficiaries under 65 are significantly more likely to need behavioral health services.

Those patients needing behavioral health services are also more likely to need treatment for a chronic physical condition. Medicare spending for individuals needing

There is significant diversity within the population that limits simplistic policy solutions.

Fig 6.3 Medicare and Medicaid Spending on Dual-Eligible Beneficiaries (2013)



Source: "Databook: Beneficiaries Dually Eligible for Medicare and Medicaid." Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission. January 2018. Available at <http://allh.us/xaJN>.

behavioral health services is roughly two times greater than spending for the average Medicare beneficiary.

Efforts at Integration

A significant problem in providing care for the more expensive dually eligible individuals is the complicated nature of the interactions between two separated programs with their own complex set of rules. Much of the work over the last decade has focused on creating

mechanisms to better integrate Medicare and Medicaid programs for dually eligible individuals.

In 2010, the Affordable Care Act (ACA) authorized an office within the Centers for Medicare and Medicaid Services (CMS), now known as the Federal Coordinated Health Care Office, or Medicare-Medicaid Coordination Office (MMCO). To date, there are three types of integrated models: Financial Alignment Initiative, Dual Eligible Special Needs Plans, and Program of All-inclusive Care for the Elderly.

The Financial Alignment Initiative (FAI), a demonstration authorized in the ACA, is testing a capitated Medicare-Medicaid Plans (MMPs) model and a Managed Fee-for-Service (MFFS) model in several states. Early

[analyses](#) indicated that the FAI is associated with lower emergency department (ED) use and hospitalizations, but has had mixed impacts on the use of other services, such as nursing facility admissions, and beneficiary experience. Beneficiaries reported varying experiences with care coordinators. In some cases, beneficiaries had not been actively connected to a care coordinator and were not aware they had one. [Effects on spending](#) are also unclear, with some studies finding savings to Medicare, but no information on Medicaid. Eleven states are participating in the FAI, and while results have been mixed, there may be discussion in Congress and at CMS about building on the lessons learned from this effort.

Another integration approach has been Medicare Advantage [Dual Eligible Special Needs Plans](#) (D-SNPs), permanently authorized by Congress in 2018. These managed-care plans target individuals who are dually eligible for both programs and attempt to better coordinate and integrate services. These plans work with both the federal and state government to provide seamless integration of benefits to the beneficiary. An [estimated 2.6 million beneficiaries](#) are enrolled in D-SNPs – or 20% of all dual beneficiaries. As a result, there is growing interest in their effectiveness at coordinating benefits and care. [Research indicates](#) they are associated with lower rates of hospitalization and readmission. Still, results are mixed on the use of ED and LTSS services – and most studies cannot assess the impact on Medicaid spending.

One approach states take is to implement [managed LTSS](#) (MLTSS) programs, a type of managed care plan,

Medicare beneficiaries age 65 and over are increasingly likely to report having a behavioral health disorder.

and connect it with these D-SNPs to assist with coordination across the two programs. There is limited data on the [success of MLTSS](#), but a [growing number](#) of states are employing this strategy.

[Program of All-inclusive Care for the Elderly](#) (PACE), permanently established in 1997, is another means of providing comprehensive and integrated care for dually eligible people. PACE offers medical and social services to older adults living in the community (non-institutional). Unfortunately, PACE programs only serve [49,000 beneficiaries](#) or less than 1% of duals in 31 states.

This Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with generous support from Arnold Ventures.

GLOSSARY OF TERMS

[Activities of Daily Living \(ADL\)](#): Basic self-care activities that persons must perform on a day-to-day basis to live independently, including eating, bathing, using the toilet, and dressing. The inability to accomplish essential activities of daily living may lead to unsafe conditions and poor quality of life.

[Long-Term Services and Supports \(LTSS\)](#): Range of health and health-related services (including support with ADL) for individuals who lack the capacity due to a physical, cognitive, and/or mental disability or condition.

[Multiple Chronic Conditions \(MCC\)](#): People who live with two or more physical or behavioral

conditions that last one year or more and require ongoing care. Common chronic conditions include high blood pressure, asthma and/or COPD, heart disease, and diabetes. MCCs exacerbate symptoms, complicate care plans, and are costly to address. Over 25% of Americans have MCCs, and over 75% of the duals population experience MCCs.

[Home and Community-Based Services \(HCBS\)](#): Care delivery model that allows patients to receive health services in their home or a local setting rather than a typically higher-cost institutional setting. Offerings include intensive, round-the-clock care through more wrap-around services such as caregiver support, home-delivered meals, and employment supports.

RESOURCES

Chapter 6: Dual Eligible Beneficiaries

Listed by the order in which they appear in Chapter 6.

OVERVIEW

People Dually Eligible for Medicare and Medicaid. <http://allh.us/RCQv>

MACPAC: Dually Eligible Beneficiaries. <http://allh.us/73Vn>

End-Stage Renal Disease (ESRD). <http://allh.us/W4x8>

Care Needs for Dual-Eligible Beneficiaries.

<http://allh.us/VPA7>

Overview of Long-Term Services and Supports.

<http://allh.us/VQuF>

Who is the Dual-Eligible Population and Why is Change Needed? <http://allh.us/EpXR>

ELIGIBILITY

Dually Eligible Individuals – Categories.

<http://allh.us/4tkw>

Who is Eligible for Medicare? <http://allh.us/kM3g>

MACPAC: Eligibility. <http://allh.us/k4Ug>

BENEFITS

MACPAC: Home and Community-Based Services.

<http://allh.us/fy4e>

MACPAC: Third Party Liability. <http://allh.us/QjXE>

Integrating Care for Dually Eligible Beneficiaries:

Background and Context. <http://allh.us/wk9e>

THE DEMOGRAPHICS AND ECONOMICS OF THE Dually ELIGIBLE

MACPAC: Dually Eligible Beneficiaries. <http://allh.us/73Vn>

Data Book: Beneficiaries Dually Eligible for Medicare And Medicaid. <http://allh.us/7xyu>

Integrating Care for Dually Eligible Beneficiaries:

Background and Context. <http://allh.us/wk9e>

Data Book: Beneficiaries Dually Eligible for Medicare And Medicaid. <http://allh.us/7xyu>

Medicaid: Data Completeness and Accuracy Have Improved, Though Not All Standards Have Been Met.

<http://allh.us/hgEN>

MACPAC: Dually Eligible Beneficiaries. <http://allh.us/73Vn>

Duals Demystified: Actions to Drive Quality, Outcomes, and Value for the Dual Eligible Population.

<http://allh.us/yYWP>

Faces of Dually Eligible Beneficiaries: Profiles of People with Medicare and Medicaid Coverage.

<http://allh.us/4w9a>

THE CHALLENGE OF TWO PROGRAMS SERVING ONE POPULATION

MACPAC: Medicaid Spending in Context.

<http://allh.us/qQC9>

THE IMPACT OF LONG-TERM SERVICES AND SUPPORTS

Long-Term Services and Supports Expenditures on Home & Community-Based Services. <http://allh.us/TkVU>

Who Pays for Long-Term Services and Supports?

<http://allh.us/g4eF>

MACPAC: Long-Term Services and Supports.

<http://allh.us/kvqr>

An Overview of Long-Term Services and Supports and Medicaid: Final Report. <http://allh.us/NF3X>

Long-Term Services and Supports Rebalancing Toolkit.

<http://allh.us/PkXM>

THE CHALLENGE OF BEHAVIORAL HEALTH INTEGRATION

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Behavioral Health Care and the Medicare Program.

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About the Medicare-Medicaid Coordination Office.

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Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps.

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Managed Long Term Services and Supports.

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Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution.

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Box: Glossary of Terms

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