Alliance for Health Policy Handbook

An introduction to the health policy and health care ecosystem

ALLIANCE FOR HEALTH POLICY

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.

1 | Budget & Spending

Overview

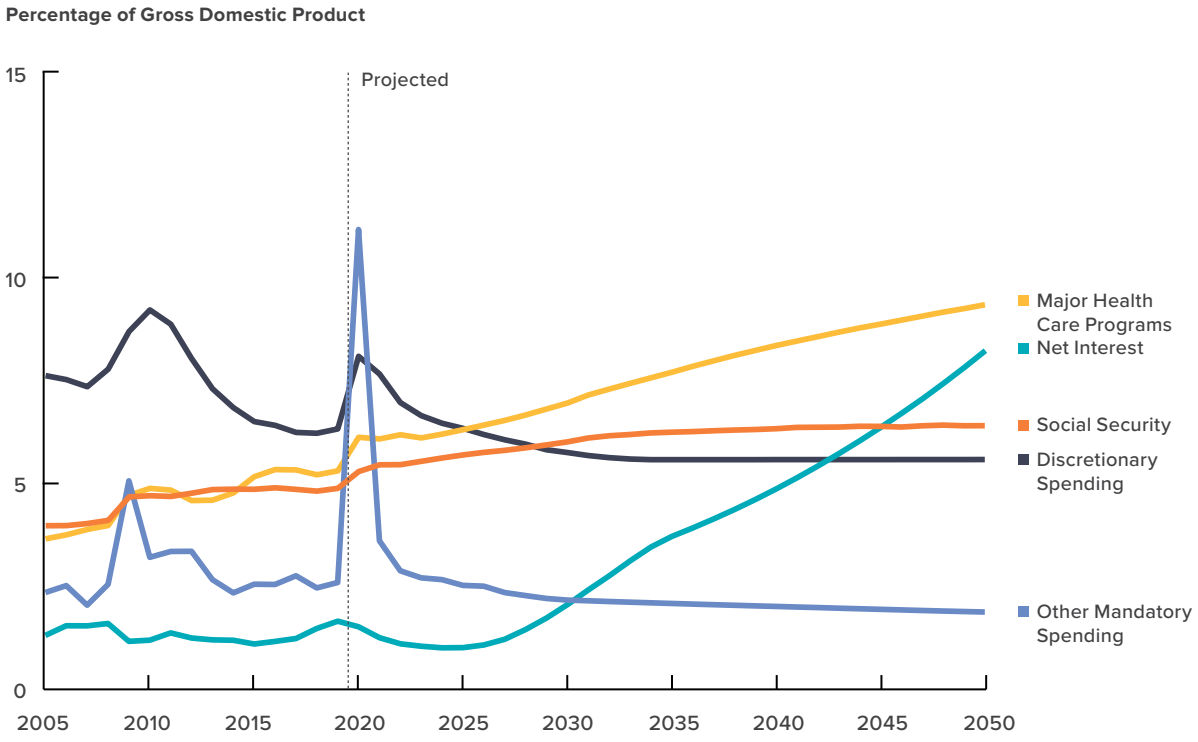
Budgetary and spending pressures heavily influence the design of policy changes in health care and frequently drive health reform discussions in the first place. Spending and deficit considerations often force policymakers to consider mechanisms to limit expenditures, scale back proposals, or identify 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.



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.

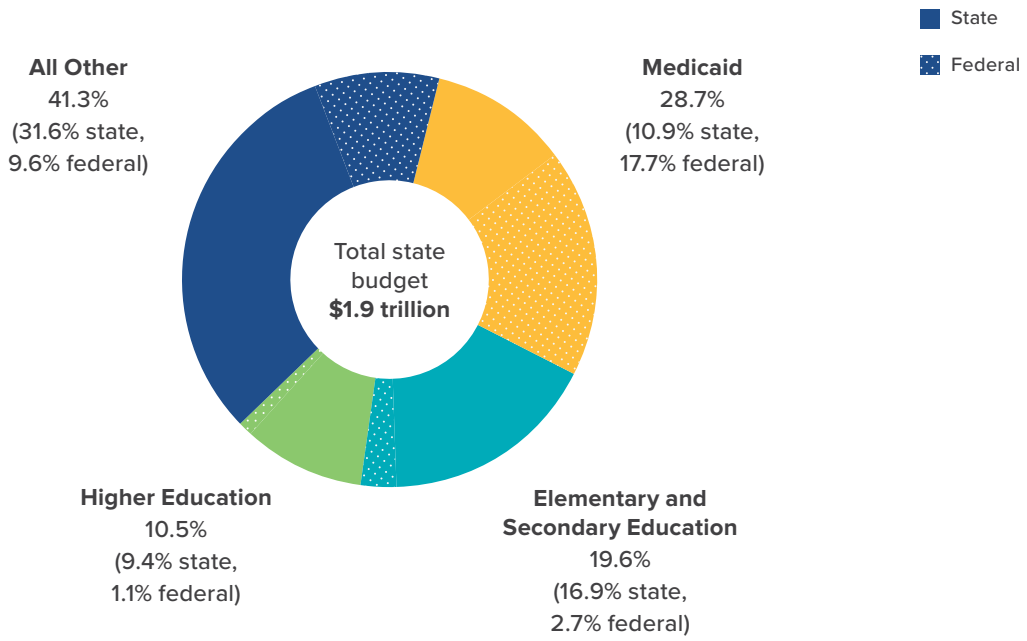
Discussions of the relationship between federal health care expenditures and the budget often rely on three overlapping, complex, and difficult-to-untangle terms: costs, prices, and spending. For the purposes of this Handbook, we define **costs** as the dollars or amount it takes for a health care entity, 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 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.

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.

[1]Note 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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Editor: Robb Lott

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/WKgq

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

[1]An 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/.

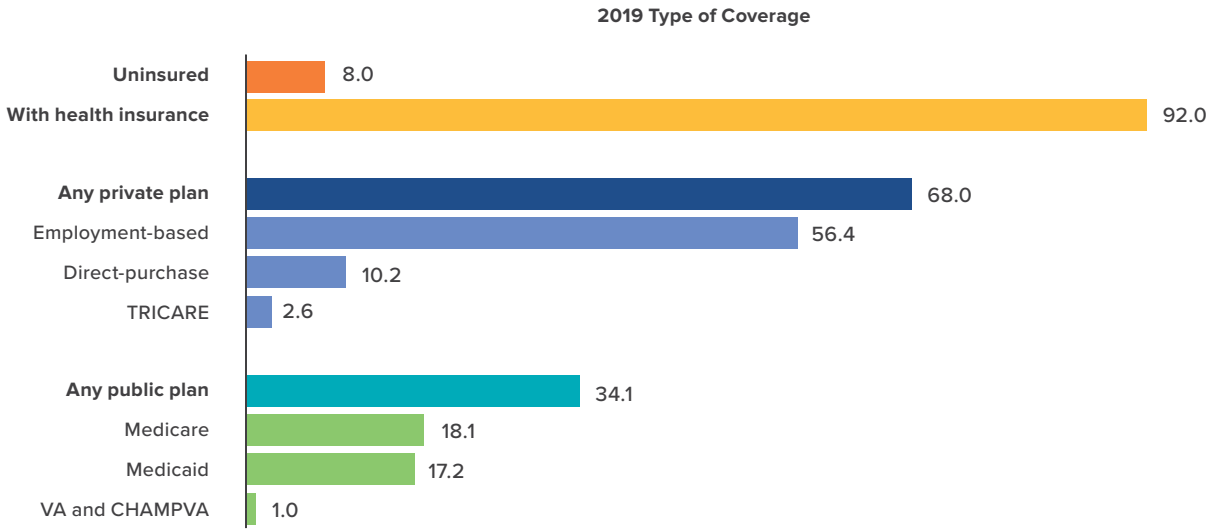
in the U.S. is mainly offset by the government through direct public arrangements or public subsidies (tax preferences for employers that provide coverage and premium subsidies for marketplace coverage). That said, individuals also bear financial responsibility to varying degrees, depending on the program. 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.

[2]Note 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

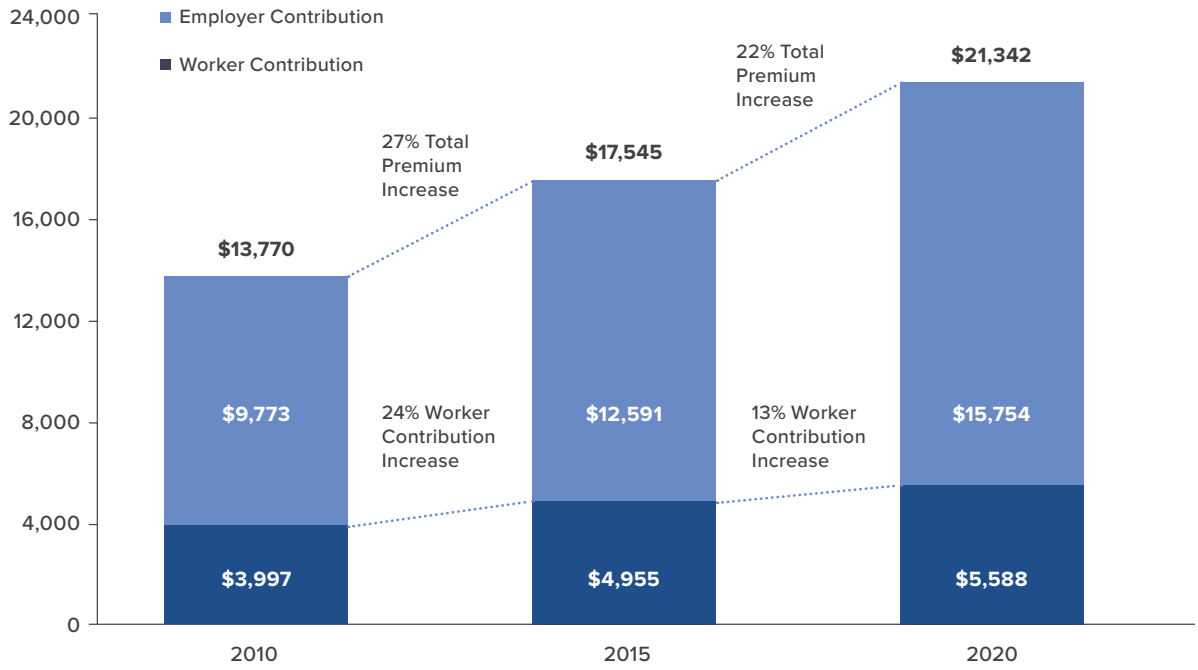
One hundred fifty-eight million Americans in the workplace receive coverage through private insurance plans offered by their employer or union. Starting with the 1942 Stabilization Act, employer-based coverage evolved into the dominant form of health insurance for individuals in the workplace due to 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.

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

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 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.

CHAPTER 2 of the Health Policy Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with support from Arnold Ventures.

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Editor: Robb Lott

RESOURCES

Chapter 2: Coverage

Listed by the order in which they appear in Chapter 2.

OVERVIEW

Key Facts about the Uninsured Population. http://allh.us/6aHu

Kaiser Family Foundation/LA Times Survey Of Adults With Employer-Sponsored Insurance. http://allh.us/erJR

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Veterans Health Administration. http://allh.us/49Tc

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Indian Health Service. http://allh.us/jwex

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State Employee Health Benefits, Insurance and Costs. http://allh.us/AeFB

GOVERNMENT-SUBSIDIZED PRIVATE COVERAGE

Overview of Health Insurance Exchanges. http://allh.us/ymbr

EMPLOYER-BASED COVERAGE

Health Insurance Coverage of the Total Population. http://allh.us/ymbr

The Employer-Health Insurance Connection an 'Accident of History'. http://allh.us/Xdw8

Employee Benefits in The United States—March 2020. http://allh.us/jrqv

Summary of the Employee Retirement Income Security Act (ERISA). http://allh.us/BjEM

THE UNINSURED

Health Insurance Coverage of the Total Population. http://allh.us/ymbr

Who Are the Remaining Uninsured, and Why Do They Lack Coverage? http://allh.us/kuyV

THE RISING COST OF COVERAGE AND UNDERINSURANCE

Average Family Premiums Rose 4% to $21,342 in 2020, Benchmark KFF Employer Health Benefit Survey Finds. http://allh.us/QpGC

SHARED RESPONSIBILITIES AND TRADE-OFFS

National Health Expenditures 2019 Highlights. http://allh.us/N9bM

Benefit Designs: How They Work. http://allh.us/cb8J

Box: Glossary of Terms

(HealthCare.gov) Premium. http://allh.us/qTkp

(HealthCare.gov) Out-of-Pocket Costs. http://allh.us/afKG

(HealthCare.gov) Deductible. http://allh.us/afKG

(HealthCare.gov) Coinsurance. http://allh.us/my7q

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Box: Key Coverage Issues for the 117th Congress

Unpacking the No Surprises Act: An Opportunity to Protect Millions. http://allh.us/crPF

How the American Rescue Plan Will Improve Affordability of Private Health Coverage. http://allh.us/aqJQ

Road to Universal Coverage: Addressing the Premium Affordability Gap. http://allh.us/FpEa

Telehealth: Delivering Care Safely During COVID-19. http://allh.us/E9jW

Beyond COVID-19: 4 Other Key Health Issues Congress Recently Addressed. http://allh.us/vpr8

Mental Health Parity in the US: Have We Made Any Real Progress? http://allh.us/q6RF

Examining the Continuum of Coverage Proposals. http://allh.us/XFQr

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.

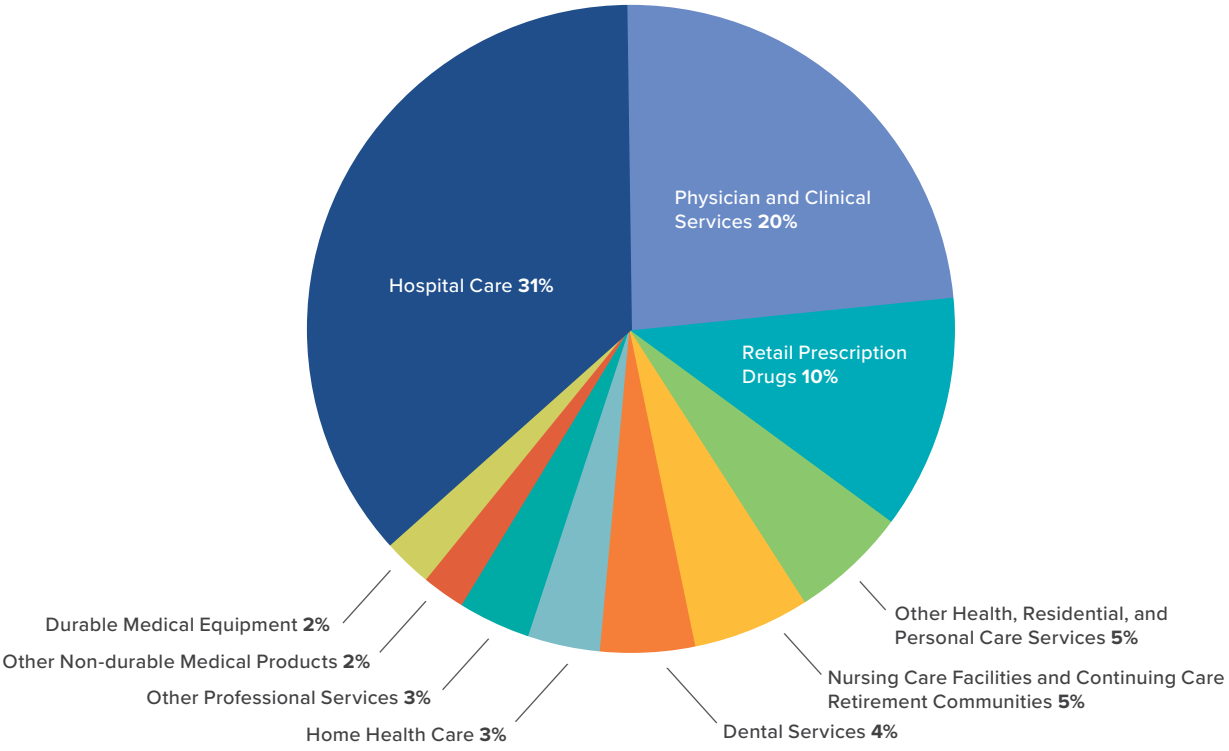
For various reasons, rates for the same service can vary significantly across Medicare, Medicaid, and commercial plans, and also across states and regions. Additionally, underpayment for some services such as primary care, and overpayment for others, is a recurring issue. The impacts of high health spending 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

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.

made 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).

[1]Medicare 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 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.

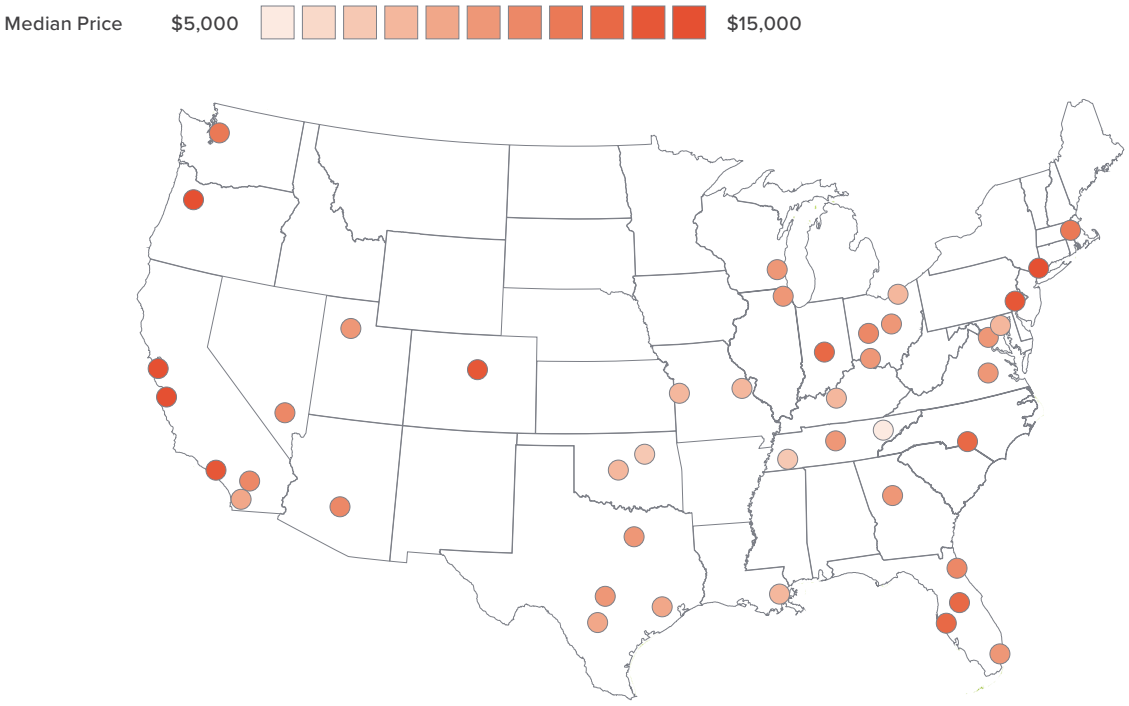
Given the various factors that can affect commercial plan and provider negotiations, there is significant variability in payment rates depending on a market's characteristics.

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

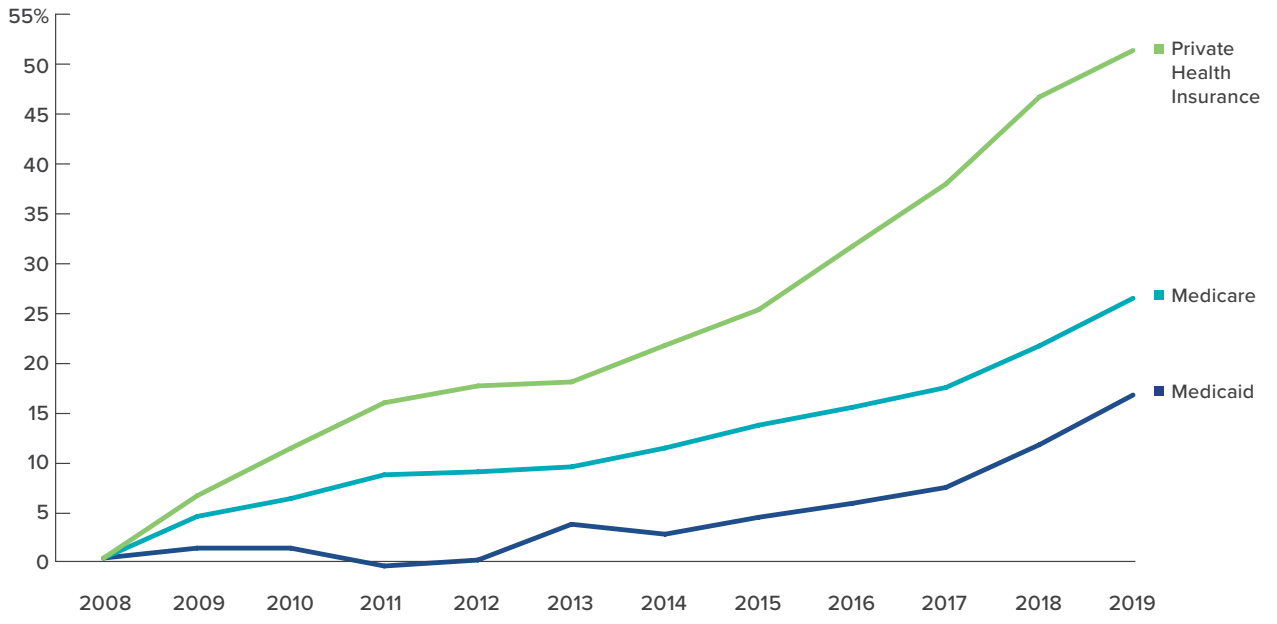
The last few years have seen an increase in state activity and national discussion on hospital and physician pricing. States have been more active on the issue and are implementing several policy changes. Policy approaches fall into broad themes, including market-based policies, consumer transparency 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 a noteworthy driver of hospital and physician pricing

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.

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.

CHAPTER 3 of the Health Policy Handbook was organized by the Alliance for Health Policy in partnership with Health Affairs, and made possible with support from Arnold Ventures.

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Editor: Robb Lott

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

RESOURCES

Chapter 3: Provider Rates

Listed by the order in which they appear in Chapter 3.

OVERVIEW

National Health Expenditures 2019 Highlights. http://allh.us/N9bM

What Drives Health Spending in the U.S. Compared to Other Countries. http://allh.us/T8mM

US Statistics on Surprise Medical Billing. http://allh.us/Hhe8

PROVIDER PAYMENTS IN MEDICARE

Acute Inpatient PPS. http://allh.us/Wjah

Hospital Outpatient PPS. http://allh.us/hBpr

Physician Fee Schedule. http://allh.us/VFwn

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The Basics of All-Payer Claims Databases. http://allh.us/fB9F

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Surprise Billing in Private Health Insurance: Overview and Federal Policy Considerations. http://allh.us/kTwX

A Consumer Guide to Understanding Health Plan Networks. http://allh.us/BwYD

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Health Care Cost Institute: Wide Variation in Commercial Prices vs. Medicare Rates Across & Within U.S. States. http://allh.us/6PWq

How Costly Are Common Health Services in the United States? http://allh.us/JC94

In the Shadow of a Giant: Medicare's Influence on Private Physician Payments. http://allh.us/XYJc

Nationwide Evaluation of Health Care Prices Paid by Private Health Plans. http://allh.us/GfVJ

STATE AND FEDERAL POLICY ACTIVITY AND PROVIDER COSTS

Innovation Models. http://allh.us/8fxK

Maryland All-Payer Model. http://allh.us/GcBC

Engrossed Substitute Senate Bill 5526. http://allh.us/pPyw

Addressing Consolidation in the Healthcare Industry. http://allh.us/HJ7T

State Policies to Address Vertical Consolidation in Health Care. http://allh.us/E8JM

Commissioning Change: How Four States Use Advisory Boards to Contain Health Spending. http://allh.us/dqDY

A Lesson from States: Curtailing Anticompetitive Health Care Consolidation. http://allh.us/xhrw

Price Transparency: Requirements for Hospitals and Health Plans. http://allh.us/J7hx

US Statistics on Surprise Medical Billing. http://allh.us/Hhe8

Unpacking the No Surprises Act: An Opportunity to Protect Millions. http://allh.us/crPF

Trump Administration Finalizes Transparency Rule for Health Insurers. http://allh.us/DmGt

Hospital Price Transparency. http://allh.us/Uh9C

Transparency in Coverage Final Rule Fact Sheet (CMS-9915-F). http://allh.us/P9Jr

Box: Glossary of Terms

Outpatient Hospital Services. http://allh.us/fJFR

Are You a Hospital Inpatient or Outpatient? http://allh.us/GPF3

Glossary of Health Coverage and Medical Terms. http://allh.us/j9Wc

Alternative Payment Models: The APM Framework. http://allh.us/yUq7

Innovation Models. http://allh.us/8fxK

Box: Key Provider Payment Issues for the 117th Congress

Pandemic Flexibilities in Long-Term Care. http://allh.us/Jykm

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

An Expert Discussion on the Provider Relief Fund. http://allh.us/GDPb

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.

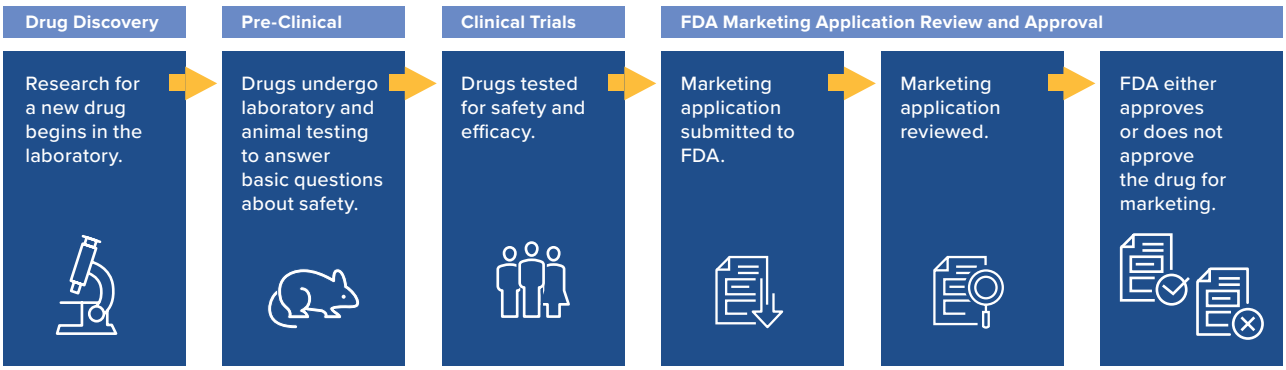
Four Stages of a New Drug Review Process

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 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.

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.

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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Editor: Robb Lott

RESOURCES

Chapter 4: U.S. Food & Drug Administration

Listed by the order in which they appear in Chapter 4.

OVERVIEW

HHS Organizational Chart. http://allh.us/WKPh

What Does FDA Regulate? http://allh.us/hpwJ

The Food and Drug Administration (FDA) Budget: Fact Sheet. http://allh.us/6fcK

FDA User Fee Programs. http://allh.us/Yafe

BACKGROUND

When and Why Was FDA formed? http://allh.us/79wk

FDA History. http://allh.us/xWq7

FDA Overview Organization Chart. http://allh.us/r6RK

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

FOUR STAGES OF A NEW DRUG REVIEW PROCESS

The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective. http://allh.us/7mDA

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

The Sentinel System—An Overview of FDA's Tools For Assessing Medical Product Safety And Gathering Real-World Evidence. http://allh.us/UWDt

What is a Serious Adverse Event? http://allh.us/vjhu

New and Expanded Uses of Already FDA-Approved Drugs. http://allh.us/PaDc

Understanding Unapproved Use of Approved Drugs "Off Label". http://allh.us/gM9m

GENERIC DRUG REVIEW PROCESS

Abbreviated New Drug Application (ANDA). http://allh.us/TB8q

BIOLOGIC AND BIOSIMILAR DRUG REVIEW PROCESS

Development & Approval Process (CBER). http://allh.us/qc7D

Biologics and Biosimilars: Background and Key Issues. http://allh.us/XGj3

DEVICE REVIEW PROCESS

Overview of Device Regulation. http://allh.us/KRHx

EXPEDITED APPROVAL AND EMERGENCY USE AUTHORIZATIONS

Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review. http://allh.us/EypF

How FDA Approves Drugs and Regulates Their Safety and Effectiveness. http://allh.us/yu6v

Emergency Use Authorization. http://allh.us/Kn9g

USER FEE ACTS

FDA User Fee Programs. http://allh.us/Yafe

PATENTS V. EXCLUSIVITY AND THE HATCH WAXMAN ACT

How Can I Better Understand Patents and Exclusivity? http://allh.us/3rhP

Repurposing Existing Drugs for New Uses: A Cohort Study of the Frequency of FDA-Granted New Indication Exclusivities Since 1997. http://allh.us/Pv9e

The Hatch-Waxman Act: A Primer. http://allh.us/nbMC

Drug Pricing and Pharmaceutical Patenting Practices. http://allh.us/nQef

Table 4.1

Drugs@FDA Glossary of Terms. http://allh.us/fPF7

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

Biosimilars. http://allh.us/9QYA

Cellular & Gene Therapy Products. http://allh.us/kdyx

Congressional Research Service: Specialty Drugs—Background and Policy Concerns. http://allh.us/7MNh

Box: Key FDA Issues in 2021

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments. http://allh.us/8WKv

Real-World Evidence. http://allh.us/pC9u

21st Century Cures Act. http://allh.us/MckV

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

Building Upon the Promise of 21st Century Cures: The Cures 2.0 Concept Paper. http://allh.us/PdTm

Box: Glossary of Terms

United States Patent and Trademark Office. http://allh.us/cWNY

Frequently Asked Questions on Patents and Exclusivity. http://allh.us/AmWu

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.

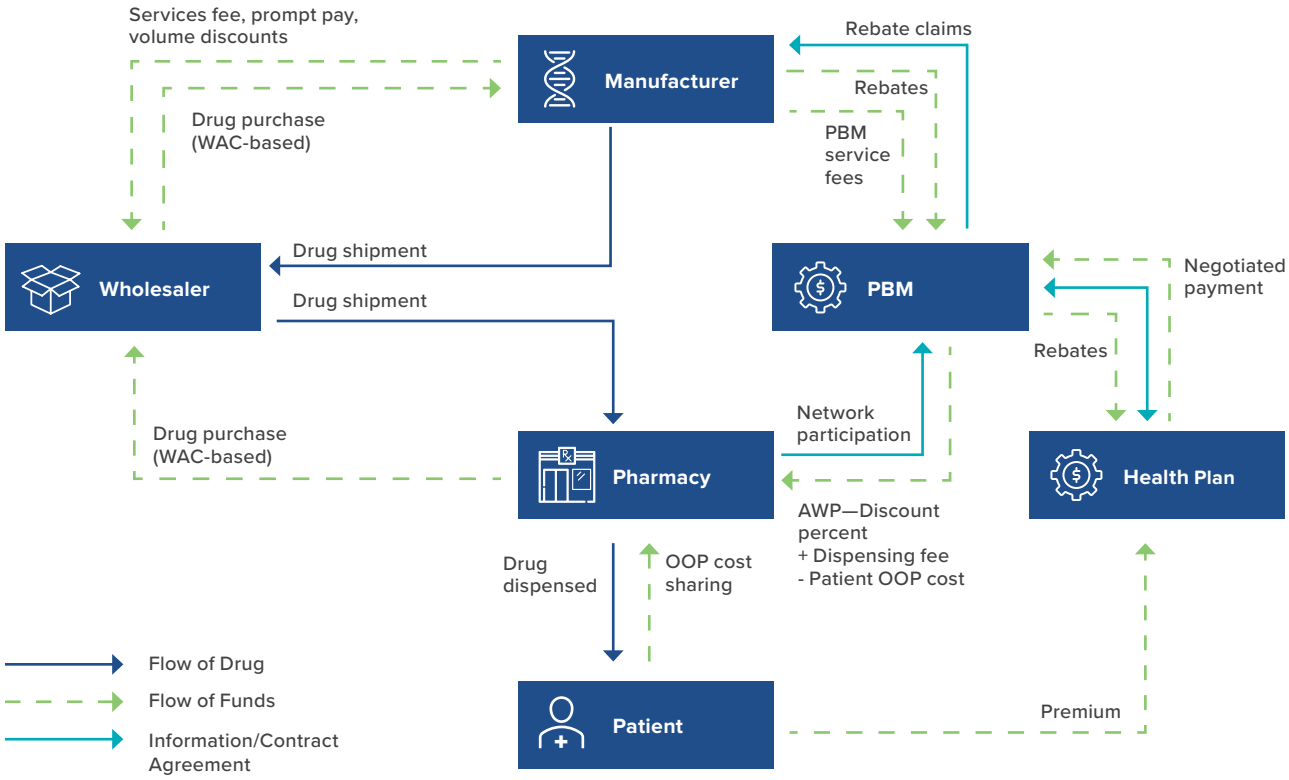
Drug Pricing Incentives in the Medicare Program

The Medicare program provides coverage for outpatient 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 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.

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.

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.

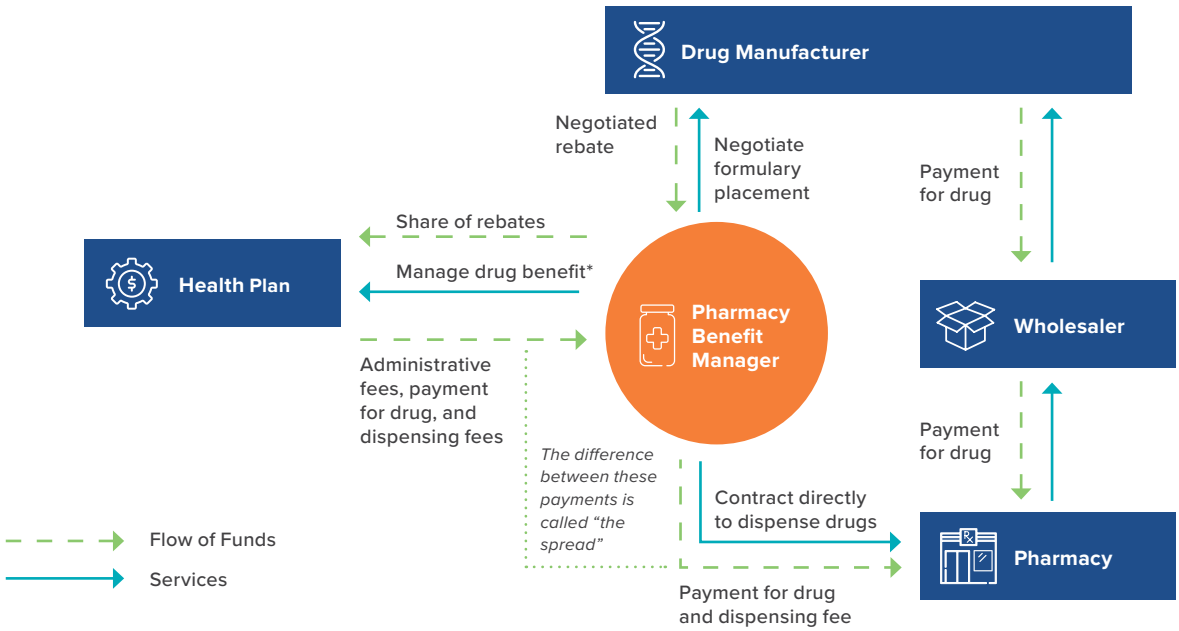
PBMs use rebates to drive lower prices, with the volume of drugs purchased used as a lever to encourage larger

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.

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Editor: Robb Lott

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.

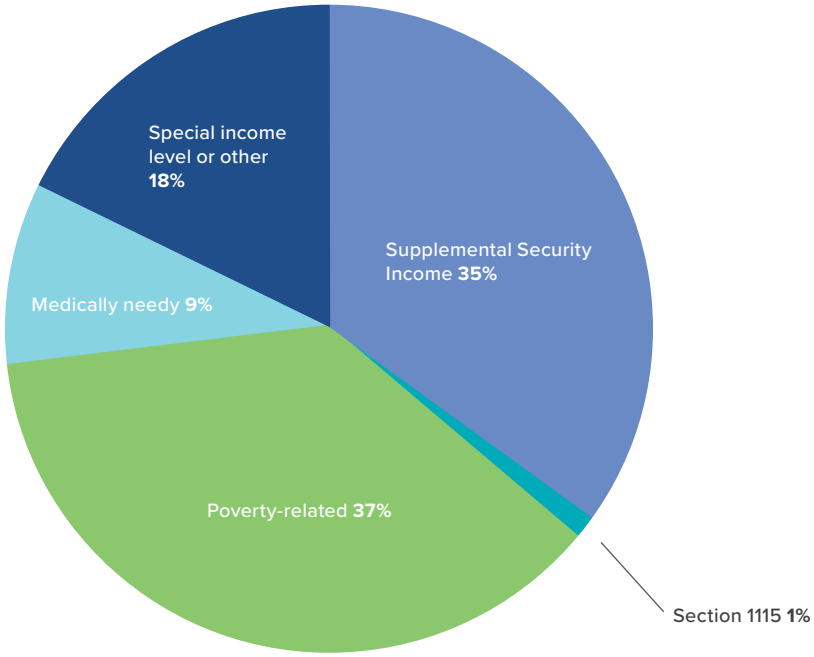
Generally, Medicare covers medical services for dual-eligible beneficiaries, and Medicaid covers certain services not provided by Medicare, including long-term services and supports (LTSS)

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.

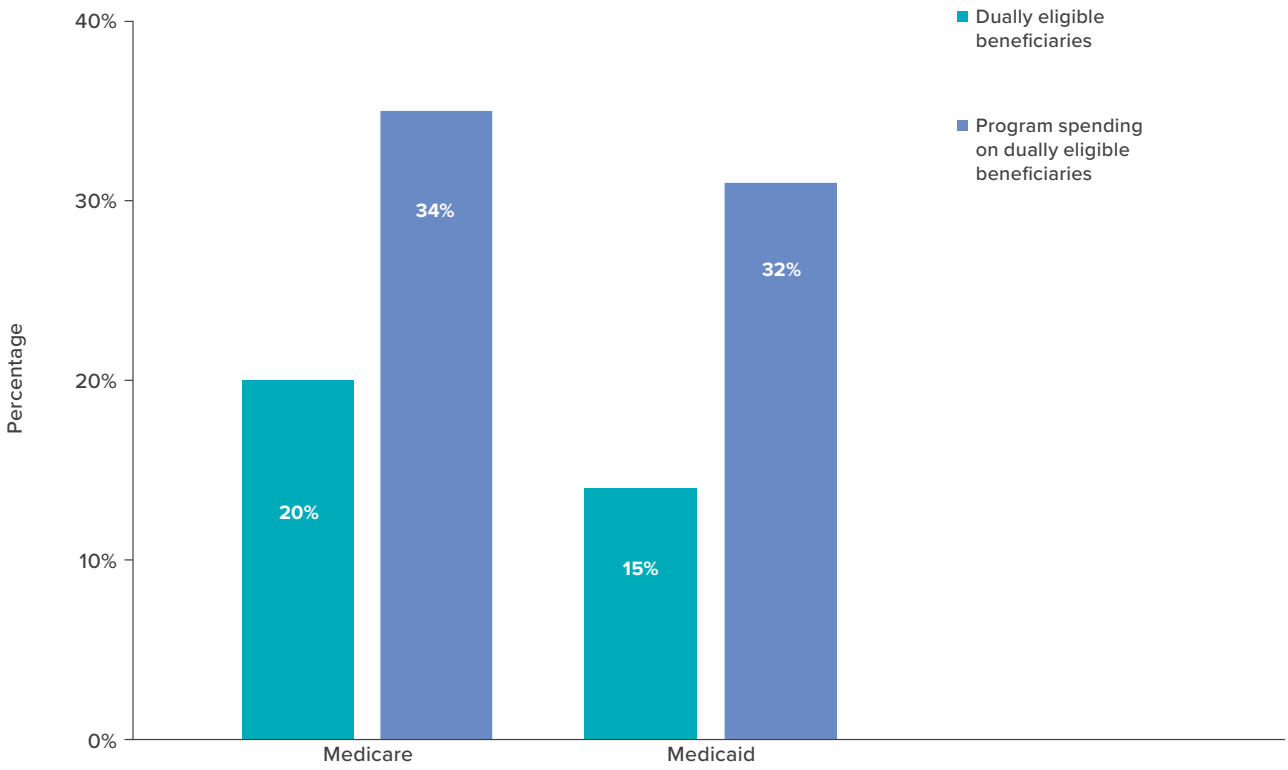
Divisions between the two programs may compromise patient care by complicating coordination across providers. For example, a patient's acute care provider paid by Medicare may have difficulty accounting for or following up on their patient's chronic or non-medical needs, covered by Medicaid. This disconnect 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.

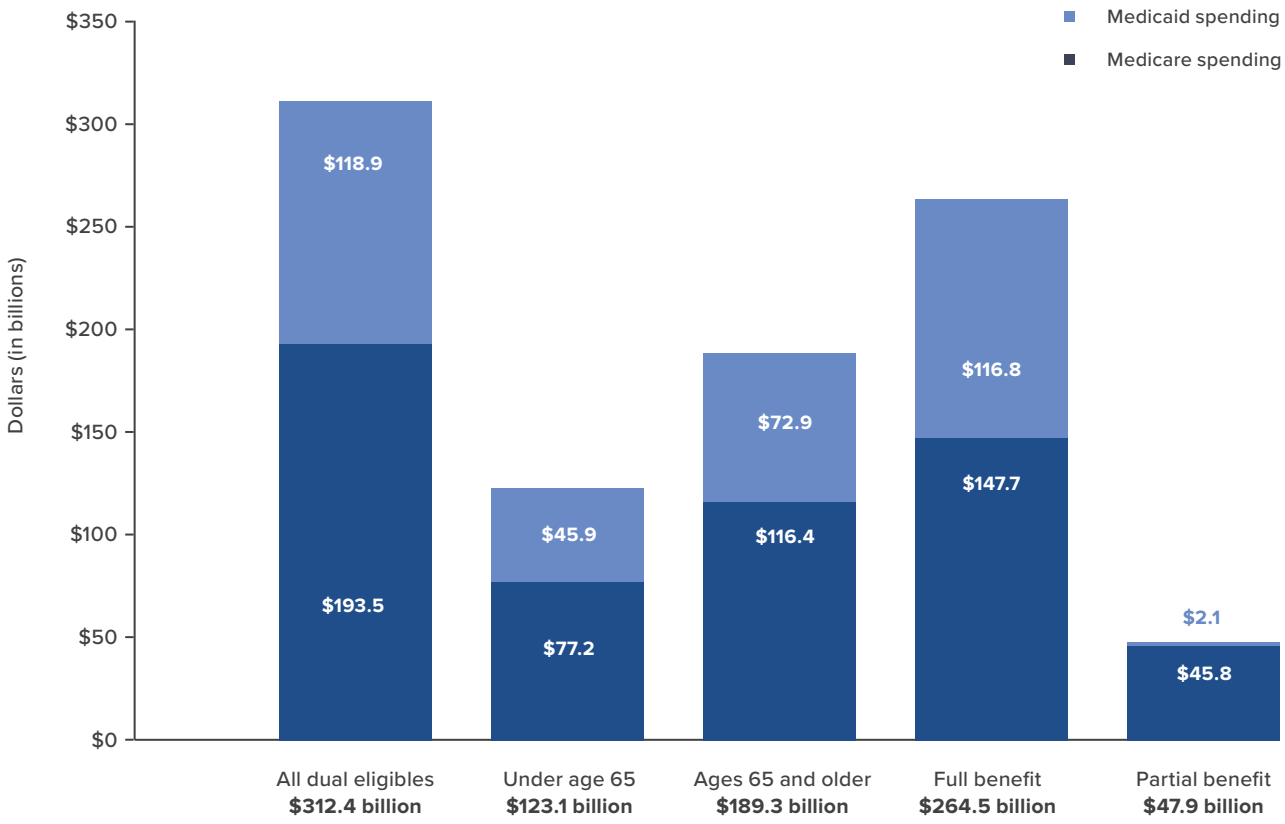
The Challenge of Behavioral Health Integration

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 findings 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, 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.

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

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Authors: Purva Rawal, Ph.D / Rodney L. Whitlock, Ph.D.
Editor: Robb Lott

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

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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

Behavioral Health in the Medicaid Program—People, Use, and Expenditures. http://allh.us/nuCY

Behavioral Health Care and the Medicare Program. http://allh.us/TjJF

EFFORTS IN INTEGRATION

About the Medicare-Medicaid Coordination Office. http://allh.us/6FGB

Financial Alignment Initiative (FAI). http://allh.us/c9vm

Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps. http://allh.us/ypJc

Integrating Care Through Dual Eligible Special Needs Plans (D-SNPs): Opportunities and Challenges. http://allh.us/fgAk

Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps. http://allh.us/ypJc

Integrating Care for Dually Eligible Beneficiaries: Background and Context. http://allh.us/wk9e

Managed Long Term Services and Supports. http://allh.us/ht6A

Managed Long-Term Services and Supports: Status of State Adoption and Areas of Program Evolution. http://allh.us/YKJe

MACPAC: Managed Long-Term Services and Supports. http://allh.us/evaN

Programs of All-Inclusive Care for the Elderly Benefits. http://allh.us/FnE9

Integrating Care for Dually Eligible Beneficiaries: Background and Context. http://allh.us/wk9e

Box: Glossary of Terms

Overview of Long-Term Services and Supports. http://allh.us/VQuF

Multiple Chronic Conditions Research Network. http://allh.us/rXfC

MACPAC: Home and Community-Based Services. http://allh.us/fy4e

Implications of Inflation Limits. http://allh.us/hBdt

7 | The Mental Health Care and Substance Use Treatment System

Where We Are, Where We Need To Be

Overview

Like the broader health care system in the United States, mental health services and funding are decentralized. Treatment plans usually entail a mix of medications, providers, therapy approaches, and social services. Factors such as provider type, care setting, payer, and government regulations can all influence a patient's experience in seeking, receiving, and affording care.

The median delay between the onset of mental health symptoms and a person's first contact with a health care provider for treatment is **11 YEARS**.

Despite similarities and interconnections with the U.S. physical health care system, the mental health care system and its substance use treatment system can seem more siloed, impenetrable, cost-prohibitive, or culturally taboo.

As a result, each year millions of Americans with mental illness do not get any treatment. Indeed, the median delay between the onset of mental health symptoms and a person's first contact with a health care provider for treatment is 11 years. Barriers to getting mental health care in the U.S. include unaffordable cost, even with insurance coverage; trouble understanding where to go for help; stigma; inconvenience; and logistical burdens like lack of time or transportation.

An enlightened and transformed U.S. mental health care system would offer people with a diversity of conditions and severities not only access to mental health care and substance use treatment, but also sustained opportunities to recover and thrive. Legislative initiatives, program development, financial investment, and treatment innovations all hold promise for improving mental health care, with many valid perspectives on specific changes.

This primer surveys the mental health care system as it exists today, including critical shortcomings, and introduces opportunities for policy change. The facts and concepts are paired with traits—or hallmarks—that characterize excellence for a future, transformed version of the system.

The hallmarks, defined by a diverse set of leaders convened throughout 2022 by the Alliance for Health Policy, include:

1. Magnitude and Parity—A magnitude of improvement that is far-reaching, on par with the expansive needs of Americans
2. Access—Accessibility for patients
3. Coordinating and Integrating Care—Coordination and integration among physical health care, human services, and other systems
4. Developing a Sustainable Mental Health Care Workforce
5. Building Equity, Inclusivity, and Cultural Relevance for All—especially for historically underserved groups
6. Innovative in Delivering and Paying for Care
7. Measured for Quality

More about the Hallmarks and the experts and process convened by the Alliance is available at Mental Health in America.

Contents

BACKGROUND: THE SYSTEM TODAY

Consumers of Mental Health Services

In 2020, at least 57 million youth and adults in communities across the United States received mental health services or substance use treatment. Separate estimates show an additional 43,700 people sought mental health care in residential treatment settings, while more than 475,000 people with a history of mental illness who reside in jails and prisons report receiving some treatment while serving time. Another 59,000 active-duty military personnel report receiving monthly mental health care through the U.S. military health system. The total mental health care system spans specialty and general medical providers, inpatient and outpatient settings, virtual care, prescription medication, school counseling, juvenile justice programs, child welfare services, and more.

However, mental health conditions are more widespread than treatment. Among adults with any mental illness, nearly 31 percent—16.1 million people—judged they needed treatment or counseling at least once in the past year, but did not receive it. Seven million of those patients had serious mental illness (disorders that are more severe), and 2.6 million of them received no mental health care all year. Studies estimate that between 50 to 80 percent of children who need mental health services receive none. This "treatment gap" affects Americans of all ages, races, genders, sexual orientations, geographies, and disability statuses, with some of the greatest disparities between need and access falling on people with low incomes, in rural areas, racial minorities, and LGBTQ people.

Providers

Although some patients get mental health treatment from primary care providers like family physicians and internists, mental health is the focus for several other types of providers. Core services are diagnosis, counseling or talk therapy, and prescribing medications, with various occupations trained and licensed to deliver some or all categories of care.

Prescribers:

- Psychiatrists
- Advanced-practice psychiatric nurses
- Psychiatric physician assistants
- Psychiatric pharmacists can prescribe in some states

Prescribers have the most-advanced degrees in the mental health care workforce. Psychiatrists have medical degrees, and psychiatric pharmacists hold doctoral degrees in pharmacy. Physician assistants and advanced-practice nurses have master's or doctoral degrees. All prescriber roles are state-licensed. Psychiatrists, advanced-practice nurses, and psychiatric physician assistants can diagnose and counsel in addition to prescribing.

Non-prescribers practicing independently:

- Clinical psychologists
- Clinical social workers
- Marriage and family therapists
- Professional mental health counselors
- Substance abuse counselors

These practitioners counsel clients independently and most can diagnose and treat mental illness. Substance abuse counselors can diagnose only in some states. All roles are state licensed, and education requirements vary. Clinical psychologists have doctoral degrees. Clinical social workers, marriage and family therapists, and professional mental health counselors usually have master's degrees.

Professional roles that do not typically practice independently:

- Psychiatric aides and technicians
- Peer support specialists
- Paraprofessionals like case managers, outreach specialists, community health workers, or parent aides
- Recovery coaches
- Psychiatric rehabilitation specialists

Training, certification, and licensure vary across states and roles in this category. These positions often serve crucial outreach, navigation, and coordination roles.

Facilities

In addition to delivering mental health and substance use treatment services in primary care and specialist private practices, providers also work in and with dedicated mental health care facilities.

Those include:

- Public and private psychiatric hospitals
- General hospitals with separate psychiatric units
- U.S. Department of Veterans Affairs medical centers
- Residential treatment centers for children and adults
- Community mental health centers, including county clinics
- Outpatient, day treatment, or partial hospitalization mental health facilities
- Multi-setting (non-hospital) mental health facilities

Funding Treatment and Services

In 2015, the most recent year with comprehensive data available, all spending on mental health care and substance use treatment in the United States totaled $212 billion.

- Mental health service spending—$156 billion
- Substance use treatment spending—$56 billion

PUBLIC FUNDING

Public spending—divided among federal, state, and local governments—was the largest source of funding for services and treatment.

Medicaid and Medicare are mandatory spending programs, required to fund benefits for every person who qualifies. Medicaid is jointly administered by states and the federal government; Medicare is a federal program.

Other state and local spending includes state psychiatric hospitals, county clinics, and other programs.

Other federal spending includes treatment provided by the Department of Veterans Affairs, Department of Defense, and the Indian Health Service, among others. This spending also includes block grants administered by the Substance Abuse and Mental Health Services Administration (SAMHSA)—a branch of the U.S. Department of Health and Human Services (HHS) tasked with advancing behavioral health.

The Community Mental Health Services Block Grants and Substance Abuse Prevention and Treatment Block Grants are non-competitive grants to states, with substantial flexibility in how states spend the dollars on prevention, treatment, recovery support, and other services. These sources are reauthorized at legislated intervals, with spending levels negotiated in the appropriation process.

PRIVATE FUNDING

Private spending—divided among private insurance, out-of-pocket spending, and other private sources—comprised somewhat under half of funding for services and treatment in 2015.

Private insurance includes employer-sponsored health coverage and individual health plans. Out-of-pocket spending includes deductibles, copayments, and payment for services not covered by insurance. Private philanthropy is one example of other private sources.

Table 7.1 Public and Private Funding Breakdown

PUBLIC FUNDING	Mental Health Services	Substance Use Treatment
Medicaid	$38 billion	$14 billion
Medicare	$25 billion	$1.7 billion
Other state and local spending	$18 billion	$10 billion
Other federal spending	$9 billion	$6.2 billion
Total Public Spending	**$90 billion**	**$31.9 billion**
Percent of all Spending	**58 percent**	**57 percent**

PRIVATE FUNDING	Mental Health Services	Substance Use Treatment
Private insurance	$43 billion	$16 billion
Out-of-pocket	$17 billion	$5.5 billion
Other private sources	$6 billion	$2.5 billion
Total Private Spending	**$66 billion**	**$24 billion**
Percent of all Spending	**42 percent**	**43 percent**

ANALYSIS: IDENTIFYING GAPS, ENVISIONING A FUTURE AROUND HALLMARKS OF EXCELLENCE

Magnitude and Parity

Currently, mental health care and substance use treatment services are somewhat detached from physical health care. In addition, the complexity of the field and the social stigma of mental illness can make the search for care a daunting, isolating experience. These difficulties are ironic considering the tremendous natural overlap and interaction between mental wellbeing and physical health, personal relationships, educational attainment, work experiences, and more.

Mental health and substance use conditions were the top cause of disability in the United States in 2015. People with severe mental illness die 10 to 20 years earlier than the general population. Very common, unavoidable stressors such as financial problems, or the death of a loved one can aggravate a mental illness, and mental health or substance use conditions can cause problems with work, school, and relationships. One's quality of life is inextricably linked to good mental health.

Unaddressed mental health problems can have devastating consequences for individuals and society. This gap in care creates enormous social and economic costs. As such, efforts to improve the system need to reach deeply and widely across sectors.

These are just some of the concrete elements of the system that diverge from standards in the physical health care system and require improvement:

ATTITUDES ABOUT MENTAL ILLNESS AND SUBSTANCE USE DISORDERS

Prejudice and discrimination, or stigma, attached to mental health and substance use disorders are widespread and interfere with people's successful treatment for those conditions. A 2018 national survey showed 65 percent of people believe alcoholism is caused by "bad character," 49 percent would not want a person with schizophrenia as a neighbor, and 40 percent would not want a person with depression to marry into their family.

Social stigma can cause patients to avoid treatment; believe they will not recover; lose opportunities for work, education or housing; and, as health care providers themselves are not immune to discriminatory thinking, receive poor physical or mental health treatment, for mental illness.

COVERAGE LIMITS

Despite robust parity laws that protect mental health and substance use treatment benefits in many types of coverage, there are exceptions. Medicaid generally will not pay for care in "institutions for mental disease" (IMDs), facilities that provide diagnosis, treatment, or care to people with mental illnesses, including substance use disorders. Medicare will pay for no more than 190 days of in-patient care in psychiatric hospitals over the lifetime of a beneficiary. Some states have formed Medicaid 1115 waivers to permit payment for care in IMDs and closer coordination with community-based services. Federal legislation has been introduced, but not yet passed as of fall 2022, that would remove the 190-day limit in Medicare.

ROUTINE, PREVENTIVE CARE

Although physical preventive care is common for healthy people, and providers are generally reimbursed for the services, interventions to prevent mental health or substance use problems from becoming disorders are generally not reimbursed. If a patient's concerns are "subclinical"—not having a mental health or substance use diagnosis—the provider typically cannot be paid by the insurer.

KEY MENTAL HEALTH CARE AND SUBSTANCE USE TREATMENT LAWS

1973 AND 1975

Section 504 of the Rehabilitation Act of 1973 followed by the *Individuals with Disabilities Education Act* guarantee free access to an appropriate public education for children with disabilities including some mental health conditions

1990

Americans with Disabilities Act is civil rights legislation that prohibits discrimination against people with disabilities, including mental illnesses

1993

Family and Medical Leave Act allows employees to take unpaid leave without losing their jobs when they cannot work due to their own or a family member's serious health condition—including mental illness—or substance use treatment

1996

Mental Health Parity Act eliminates annual or lifetime dollar limits on mental health benefits that are less favorable than the same type of limits imposed on medical or surgical benefits among large group health plans

2008

Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Act (MHPAEA) requires group health plans and self-insured plans with more than 50 workers to cover behavioral health services on par with medical and surgical services

2008

Medicare Improvements for Patients and Providers Act began applying parity in out-of-pocket costs to Medicare coverage of outpatient mental health services

2010

Patient Protection and Affordable Care Act (ACA) extended MHPAEA to individual-market plans and certain small-group market plans, as well as Medicaid alternative benefit plans

2016

21st Century Cures Act created federal leadership roles and initiatives that focus on mental health and substance use treatment. The law created or codified the Assistant Secretary for Mental Health and Substance Use role, the Center for Behavioral Health Statistics and Quality, the Interdepartmental Serious Mental Illness Coordinating Committee, and the National Mental Health and Substance Use Policy Laboratory

2018

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act required state Children's Health Insurance Programs (CHIP) which provide mental health and substance abuse treatment benefits to comply with MHPAEA parity requirements, and it expanded telehealth services in Medicare for such treatment.

More details on many of these laws and others are available on the SAMHSA website.

Access

Removing the obstacles to finding and affording mental health services or substance use treatment is about more than convenience; it is vital for access to care.

The median 11-year delay in first accessing treatment after experiencing mental health symptoms partly reflects that about 50 percent of people with a mental health condition first developed it in childhood, when conditions are difficult to communicate or identify. Fear and stigma about getting treatment, complexity in the health care system, lack of affordability, and scarcity of suitable providers also keep people from accessing mental health care. Building a truly accessible system of mental health care and substance use treatment will simplify processes for patients, include roles for education and public safety sectors, invest in the mental health care workforce, and diversify sources of assistance for patients.

SPECIALIZED PATHWAYS TO CARE

Calling a provider's office for an appointment is just one of the ways people initiate care. For example, education and policing are two systems that regularly identify mental health care or substance use treatment needs.

Law enforcement experts estimate that as many as 7 to 10 percent of police interactions involve persons with mental disorders. Without thoughtful diversion programs, police often see arrest as the only option for resolving public disturbances or risks of physical harm around mental health crises. The result is that people with severe mental illness are jailed at a rate four to six times greater than the general population, with about 2 million people with serious mental illness put in local jails each year.

A "co-response" approach—teams of law enforcement and mental health professionals who work together to respond to crisis calls—is an alternative that operates on some scale in 46 states. The goal of the model is to refer people with mental illness to treatment rather than jail. Outcome data is mixed and difficult to collect due to the fragmentation across and within health and criminal justice systems, but feedback on programs implementing the model is promising.

Other alternatives include the Crisis Intervention Team model, a police-based response that relies on officers with specialized training in de-escalating mental health crises, and the Mobile Crisis Team model, in which medics, crisis counselors, and peer-support workers provide stabilization and referral resources, generally without participation from police.

Elementary and secondary schools are also major pathways to mental health care. At most, only half of children with mental health conditions get care, but when they do, they are just as likely to receive services through schools than from community-based providers. Among all students, 11 to 12 percent have accessed care via an education system, compared to 7 percent who have seen specialty providers and 4 percent who have seen general medical providers not connected to the school.

People with severe mental illness are jailed at a rate four to six times greater than the general population.

Most schools—96 percent over the 2021–2022 school year—offer some form of mental health care, with individual services like counseling or therapy the most common (84 percent). However, 43 percent of school staff responding to a survey described themselves as "strongly or moderately not believing they could effectively provide services to all students in need." Some of those pressures may ease in the future, with the Bipartisan Safer Communities Act designating $1 billion over five years for mental health supports in schools. It includes funding to double the number of school counselors, social workers, and other mental health professionals.

SECURING CARE

When people seek care directly from a provider, rather than through another system, they usually do not see a mental health specialist. More than 60 percent of mental health visits are with primary care providers. In these encounters, patients are somewhat rarely referred to psychiatrists. Two out of three primary care providers report having difficulty referring patients to mental health specialty providers, either because they do not know of any that are accepting new patients, or they do not know any who accept the patient's insurance. Those reasons reveal two necessities for a truly accessible system: a sufficient number of providers and adequate payment they will accept. (See more on this in the sustainable workforce section.)

When patients are not able to get a referral from their primary care provider, or they have no primary care provider, they must search for a source of mental health services on their own. For anyone in emotional distress, especially people with severe mental illness, this is a challenging task amid what one psychiatrist calls "the uncoordinated panoply of practitioners with disparate and confusing titles and qualifications." The assistance of an approachable, nonjudgmental, knowledgeable advocate can make this process more accessible.

Getting care is easier, especially for people with serious mental illness or with unstable access to food and housing, if patients have navigational assistance. This assistance is one role provided by peer support workers or community health workers.

Coordinating and Integrating Care

Overall health care costs are higher for people with mental illness than for people without mental health conditions, and significantly, a large share of the cost difference is related to *physical* health conditions. Twenty-nine percent of adults with medical conditions have mental health disorders and 68 percent of adults with mental health disorders have physical medical conditions. Despite this overlap, mental health and substance-use treatment providers usually are located separately from each other as well as from physical health care providers, with little coordination among health records, payment sources, or care planning. Patients whose mental health or substance abuse conditions cannot be adequately treated in primary care must try to navigate going to a specialty provider, often via referral. Even with a referral, as many as 50 percent of patients may drop off, and never go to one appointment with the specialty provider.

Structuring care delivery to best treat and support the patient across physical, mental, and social service needs is the heart of coordinated, integrated care. There are three defined levels of collaboration:

- Coordination, at its most basic level, relies primarily on communication across providers who work largely independently.
- Co-location, i.e. having multiple providers that can support physical, mental, and wrap-around services in one building or area, facilitates closer communication. Some shared systems like scheduling and record-keeping, and warm hand-offs of patients between providers can also meet this goal.
- Truly integrated care takes a team approach with multiple provider types, care managers, and paraprofessionals working together with patients on their treatment plans.

Strengthening the relationship between a patient's physical and mental health care providers is just one aspect of collaboration that can yield better outcomes and better value.

More than 5,700 geographic areas are designated as having provider shortages, including a more than one third of the U.S. population.

In many cases non-clinical services are also essential for improved mental health. For example, income support and housing stability both help lower psychological distress.

Integrating care is a goal for state and federal health care agencies, provider associations, and advocacy groups, with multiple designs to guide implementation. Some examples include:

- *The Certified Collaborative Behavioral Health Clinic model, which began under federal planning grants to 24 states in 2015.* The clinics coordinate and integrate physical health care, mental and substance use treatment and prevention, human services, and other systems. Grant funds and special Medicaid reimbursement rates allow the clinics, although they cannot provide food or housing directly, to compensate outreach workers or peer-support specialists who help patients navigate those resources via community partners.
- *The General Health Integration Framework*, presented by the National Council for Mental Wellbeing. This organizing model brings physical health screening and prevention, care, and care management into behavioral health practices, with flexibility around the number and complexity of medical services included over time.
- *The Bridge Model of Transitional Care,* developed by the Health and Medicine Policy Research Group and multiple health agencies. The model uses intensive case management to guide people with opioid use disorder into treatment and recovery services. A "provider champion" connects appropriate patients to buprenorphine treatment, and a team of mid-level practitioners and navigators lays out a system of individualized care that is immediately accessible following discharge from the emergency department.

Developing a Sustainable Mental Health Care Workforce

As already mentioned in other sections, when a person seeks mental health care, they are likely to confront the shortage of mental health care providers, either in absolute terms, or among those covered by their insurance. The Health Resources and Services Administration (HRSA, an agency of the Department of Health & Human Services) has designated more than 5,700 geographic areas as having provider shortages, covering a population of more than 119 million Americans, or more than one third of the population. Throughout these areas, mental health workforce capacity meets only about 27 percent of the estimated need. Shortages are more common in rural areas, with 60 percent of rural Americans living in shortage areas.

HRSA maintains a dashboard with estimates of future U.S. supply and demand of the mental health care professionals. The projections show that by 2023, the mental health workforce will have too few psychiatrists and addiction counselors to meet the public's needs, but the number of social workers, psychologists, mental health counselors, marriage and family therapists, and psychiatric nurse practitioners and physician assistants are forecast to be adequate.

Access to providers is narrowed by insurance networks. Among individual plans sold on Affordable Care Act exchanges, only 21 percent of mental health care providers participated in insurer networks, compared to 46 percent of primary care providers. Multiple stakeholders consulted by the Government Accountability Office, including consumers, health plans, providers, and state officials, pointed to low reimbursement rates as a reason some mental health care providers—including graduate-level social workers, psychologists, school and clinical counselors, psychiatric nurse practitioners, marriage and family therapists, and other behavioral health professionals—may choose not to participate in insurance networks.

Insurers reimburse psychiatrists less than other medical doctors for the same diagnoses and services. In one analysis of services billed for 3.8 million patients, payment by private insurers was 13 percent lower to psychiatrists for low-to-moderate severity cases, and 20 percent lower for moderate-to-high severity cases, compared to payment to non-psychiatrist physicians for the same types of cases. A separate study of 11 state Medicaid programs found that in 9 states, psychiatrists were compensated between $1 and $34 less for a low-severity office visit and between $5 and $40 less for moderate-severity visits compared to primary care physicians providing the same services.

The participation of mental health care providers in Medicaid, especially, has implications for racial and ethnic health equity. As of 2020, Medicaid covered about 30 percent of Black, American Indian and Alaska Native, and Native Hawaiian or Other Pacific Islander non-elderly adults and more than 20 percent of Hispanic non-elderly adults, compared to 17 percent of white people in the same age group. The impact on children is even greater. Medicaid and CHIP cover more than half of U.S. children who are Hispanic, Black, American Indian and Alaska native, compared to 27 percent of white children.

Building Equity, Inclusivity, and Cultural Relevance for All

Meaningful, effective mental health and substance abuse disorder treatment requires not only that providers are within geographic and financial reach of patients, but also that those practitioners are diverse in racial and other identities, and that they are culturally competent.

Only 21 percent of mental health care providers participated in insurer networks, compared to 46 percent of primary care providers.

Trust, comfort, and understanding are essential in the therapeutic relationship between a patient and a mental health professional. Non-white consumers of mental health services get higher-quality mental health care when they share a racial background with their provider, or their provider demonstrates knowledge of discrimination and prejudice. Still, 83 percent of U.S. psychologists in 2015 were white, and in 2019, nearly 70 percent of social workers and 88 percent of mental health counselors were white. SAMHSA operates the Minority Fellowship Program (MFP), which provides grants to master's- and doctoral-level graduate students training to be mental health practitioners. The goal is to increase the number of culturally competent professionals in the workforce. In a 2020 workshop, three professionals connected to the MFP program named additional steps for recruiting, educating, and retaining people of color and people from other minoritized backgrounds. They stressed bringing social determinants of health into graduate education for mental health careers, building a clear path to financial security for students and trainees, connecting career education to the community, and incorporating mentorship and support for new professionals.

Diversity in the mental health care workforce is important for improving inclusivity, and at the same time, all providers need to show cultural competence. Culturally-competent providers recognize the importance of culture, stay alert to ways cultural differences affect communication, and adapt services to culturally unique needs. Language access is essential for a field as communication heavy as mental health care and substance use treatment. Title VI of the Civil Rights Act of 1964 requires that public services receiving federal funding provide reasonable accommodations for language assistance. In many health care settings, medical interpreters serve in person, by telephone, or by video connection. Researchers in New York recommend that interpreters should not just convert the language between the patient and provider, but actively serve as clarifiers, cultural brokers, and advocates or mediators to deliver the most effective mental health care to people with low English proficiency.

Showing respect for a person's language, culture, and background is implicit in the patient-centered care model, an approach that is "respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions." Providers adhering to these principles can begin to overcome disparities in care not only for racial and ethnic minorities, but also for other historically underserved populations or those maltreated in the mental health care system: lesbian, gay, bisexual, and transgender individuals; immigrant populations, people experiencing housing instability and homelessness; people with severe mental illness, and people with substance use disorders. The patient-centered care model also has potential to make mental health care more relevant for any patient, as it prioritizes the patient's goals and comfort.

Innovative in Delivering and Paying for Care

PAYMENT INNOVATION

Some of the most promising practices for improving mental health care are constrained by the dominant payment design in the U.S., the fee-for-service system. Innovative models will be necessary for transforming mental health care.

Most health care is compensated, by public and private coverage alike, at a dollar amount assigned to each service or type of encounter, represented by hundreds of billing codes, paid by volume of services delivered. This system limits which type of provider can be paid for each service, and for which diagnoses. In a truly patient-centered system of care, where physical health, mental health, and social service needs are addressed to produce the best outcome for the patient, extensive care coordination is necessary, and a variety of providers may serve a patient's needs.

Under traditional fee-for-service payment arrangements, however, many of those services would be difficult to reimburse. Care coordination is often not compensated or paid at a rate too low to be sustainable, and reimbursement for peer-support, navigation, and services like transportation or housing assistance are not available at all in many cases. There are options for alternative payment structures to facilitate comprehensive physical and mental health for patients, including modified fee-for-service arrangements that pay extra for high-quality outcomes, bundled payments that allocate a flexible budget for treatment of a condition, and "global" payments that cover all health needs per person in a population.

There are benefits and drawbacks to each approach, but innovating on *any* of the models may yield an even better option for facilitating mental health care. However, the global or "capitated" payment model incorporates mental health on par with physical health within the payment, allowing "seamless and unfettered access" to "mental health care as a natural extension of the primary care team."

PHARMACEUTICAL INNOVATION

Prozac® became a true blockbuster drug for treatment of depression when it was released in the late 1980s, but in the following years new compounds or pharmacological mechanisms developed for treating mental illness frequently failed in clinical trials. The pharmaceutical industry's research into new psychiatric medications has slowed over the past two decades, dropping by as much as 70 percent between 2009 and 2019. Financial losses, especially from costly late-stage trials after preclinical research indicated promise for a new drug, led the industry to scale back research

and development of truly novel mental health drugs, focusing instead on refining existing compounds and repurposing drugs for additional conditions.

Despite this slowdown in research, two new mental health drugs designated Breakthrough Therapies by the Food and Drug Administration were approved in 2019, Esketamine nasal spray for treatment-resistant depression and intravenous Brexanolone for post-partum depression. Although Esketamine is based on a longtime anesthetic, both new drugs rely on novel mechanisms to treat depression, potentially opening a "new frontier" in mental health drug development.

The National Institute of Mental Health (NIMH) funds research to design and develop novel drugs to treat mental illnesses, with its focus shifting from clinical research (testing new drugs in patients) to preclinical neurological research and early clinical research. The goal is to establish a potential drug's interactions with a cellular or molecular target in the brain, using biomarkers or imaging. NIMH clinical trial funding requires researchers to conduct a "proof-of-molecular-mechanism" test before moving on to clinical study in patients. This arrangement is intended to end research projects early if tests of the mechanism fail, and to contribute to the knowledge base of those mechanisms. However, some researchers and practitioners consider the requirement an unnecessary burden that slows or impedes development of badly-needed new drugs.

TECHNOLOGICAL INNOVATION

New payment options helped unleash the potential in a technological innovation in mental health care: telehealth. In most states before the COVID-19 pandemic, people with Medicaid coverage, if they had the necessary connection, could use telehealth as a covered benefit. However, Medicare would only pay for telehealth appointments in limited circumstances. During the COVID-19 public health emergency, the federal government waived that restriction and use of the services increased tenfold in 2020, to 53 million uses. Medicare coverage of telehealth services for mental health, including audio-only services, was made permanent. Today, more than a dozen states allow telehealth for mental health services, and require the services be paid on par with in-person visits, even once the public health emergency ends.

Measured for Quality

Assessing the value of mental health interventions requires measurement. However, there is very little standardization of quality measures across mental health and substance use treatment. Developing and tracking quality data is key for improving care, and for allowing mental health care and substance use treatment to be compensated appropriately in value-based payment models.

Quality data is abundant in the health care system in general, but quite limited around mental health. Among 39 active federal programs requiring data reporting in health care, more than 1,400 measures and metrics are collected. Only 35 measures are unique to mental health and substance use disorders.

Ideally, quality metrics can help inform patient decisions. However, existing mental health and substance use disorder care measures, according to the National Committee for Quality Assurance (NCQA), do not include care coordination, patient experience, or health outcomes.

NCQA has developed a framework of measurement that integrates physical and behavioral health along with social systems.

Developing and tracking quality data is key for improving care.

NCQA'S BEHAVIORAL HEALTH QUALITY FRAMEWORK

When NCQA researchers interviewed stakeholders throughout the health care system, they found that behavioral health care (mental health and substance use prevention and treatment) integration is widely supported, but different quarters of the system are unclear on who is accountable for achieving integration and how to measure its quality. They developed a customizable framework to help diverse entities resolve those uncertainties.

Key components of the framework:

1. Organizes around population health management
2. Includes measures that hold purpose for many participants across the system and are aligned with the population health goals
3. Requires investment in infrastructure to drive accountability and improvement

Stakeholders from throughout the system will coordinate to identify the goal-related measures most relevant to each level among:

1. The macro level—state and federal government
2. The meso level—managed care plans or accountable care organizations
3. The micro level—facilities and providers

Essential steps to implementing the program:

1. Identify priority populations and set population-level goals
2. Develop bundles of evidence-based quality measures at each level aligned with each goal and publicly report them
3. Invest in data infrastructure, collaboration tools, workforce development, and cultural sensitivity, and improve behavioral health financing structures

Figure 7.2 Showing Metric Association with an Opioid-Related Mortality Reduction Goal

Purposeful Data/Information Exchange Across System

MEASURE BUNDLE FOR POPULATION GOAL: *Reducing Opioid-Related Mortality*	
Federal & State	**Outcome:** Opioid-related death
	Process: Follow-up post emergency department for OUD
	Structure: Prior authorization for MOUD, reimbursement for telehealth
Managed Care	**Outcome:** Repeat opioid overdose/poisoning events
	Process: Treatment continuity, care coordination for high-risk members
	Structure: BH network adequacy, coverage of non-opioid pain therapy
	Member experience
Facility/Provider	**Outcome:** Treatment dropout/show rates
	Process: Access to MOUD, treatment engagement, preventive and chronic care management for patients with OUD, care coordination
	Structure: Waivered providers, telehealth infrastructure, care team communication infrastructure
	Patient experience

CONCLUSION: A SYSTEM READY FOR CHANGE

The widespread emotional distress brought on by the COVID-19 pandemic has prompted unprecedented attention on the United States mental health care and substance use treatment system. More Americans are discovering what providers, advocates, patients, and their families have long known: mental health care, though essential and often life-changing, can be taxing to navigate, difficult to afford, and disconnected from other health care.

The spotlight on the system and the billions in new federal investment present opportunities to transform mental health care and substance use treatment. Experts and other leaders in every corner of the system have formulated hard-won and deeply researched recommendations for developing a system that works for everyone. Collaborating with stakeholders, policymakers can help establish a system that is accessible, coordinated, sustainable, equitable, and measured for quality.

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Author: Elizabeth Cronen

RESOURCES

MENTAL HEALTH CARE LANDSCAPE

The Alliance for Health Policy Summit on Mental Health in America https://www.allhealthpolicy.org/signatureseries_summit_mentalhealth_agenda.

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