Pricing & Reimbursement

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USA

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Abstract

The United States ("U.S.") accounts for the largest share of drug spending and innovation in the world, and its drug pricing regime is the most complex given its multi-payer model and unique overlay of market access requirements that collectively impact drug pricing and reimbursement decisions in the U.S.

The U.S. health care system includes both private and public health insurance coverage. Whether a drug product is covered, and at what price, is determined by each payer's coverage, coding, and payment criteria for health insurance plans. The largest government-funded programs are Medicare and Medicaid, under which plans are subject to detailed requirements set forth by statute or regulation. Private plans, which cover far more Americans than public plans, have more flexibility to make coverage and reimbursement determinations. All plans implement various cost containment measures which may impact plan beneficiaries' access to certain drug products. For Americans that either do not have insurance or have inadequate coverage to support their drug purchasing needs, a number of public safety net programs or private assistance programs (including manufacturer assistance) may be available to ensure access to needed medications.

Drug prices are highly dependent on the complexities of the U.S. drug supply chain. Between the initial manufacturing and ultimate dispensing of a given drug product, numerous transactions must take place among manufacturers, wholesalers, pharmacies, pharmacy benefit managers ("PBMs"), providers, and payers. These transactions typically involve price concessions in the form of discounts or rebates, as well as other fees. As a result, there is a significant gap between the list price a manufacturer initially sets for a drug product, and the net price reflecting the actual amount of money received.

Successful market access requires navigating this complex pricing and reimbursement system in a way that ensures drug products are available to patients, reimbursable by patients' private or public plans, and appropriately valued to ensure favorable coverage. These efforts also must comply with overlapping regulatory requirements and minimize risk related to enforcement action for violating regulatory or compliance obligations. Manufacturers should be aware of policy proposals and emerging trends that may significantly affect drug pricing and reimbursement in the U.S.

Market introduction/overview

The U.S. health care market

Health insurance

The U.S. health care system consists of a complex mix of payers and institutions. Government-

funded programs include Medicare (a federal program that primarily covers individuals 65 years of age and over) and Medicaid (a joint federal-state program that provides coverage for individuals with limited income and resources), as well as programs for military personnel, veterans, uninsured children, and others. Private health insurance coverage is more prevalent than public health insurance coverage, covering 67.3% of the population.[1] Most private insurance is offered through employers under favorable tax policies, although Americans can also purchase coverage directly. Coverage for prescription drugs is an important component of both private and government health insurance programs.

Over 90% of Americans have health insurance through such private or public plans, but a significant number of Americans do not have health insurance coverage at all. In 2018, the latest year for which coverage data is available, the U.S. population of 324 million had coverage as follows:

- 217.8 million received coverage under private plans, including 178.4 million through employment-based plans;
- 57.7 million received coverage under Medicare;
- 57.8 million received coverage under Medicaid;
- 3.2 million received coverage through the Veterans Health Administration and the Civilian Health and Medical Program within the Department of Veterans Affairs, and TRICARE (previously known as Civilian Health and Medical Program of the Uniformed Services); and
- 27.5 million were uninsured.[2]

Underinsurance remains a significant challenge. Many Americans face relatively high out-of-pocket health care costs in the form of premiums, deductibles, coinsurance, and copayments required by private and government payers for covered services, as well as costs for services not covered by insurance. In 2017, more than 1 in 50 Americans who interacted with the health care system had out-of-pocket costs above $5,000, and 1 in 200 had costs over $10,000.[3]

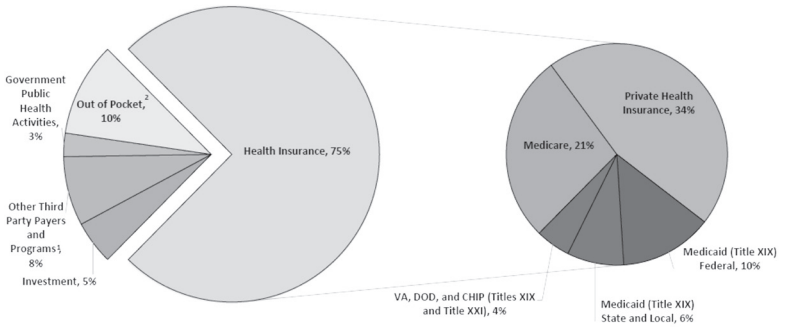
Although many developed nations choose to provide health care under a universal or single payer system, the U.S. has elected to use a multiple payer model combined with government- and privately-run safety net programs and mandatory access to emergency care for all residents.[4] In addition to funding Medicaid and other programs aimed at vulnerable populations, the federal government requires drug manufacturers to provide outpatient drugs to providers that primarily serve low-income and uninsured individuals under a program known as the 340B Drug Pricing Program. Private charitable foundations also provide financial assistance or free product to eligible patients who struggle to afford expensive prescription drugs.

Health care spending

The U.S. has the highest health care spending *per capita* in the world.[5] *Per capita* spending has increased dramatically in recent decades, rising by 290% between 1980 and 2018.[6] The health care sector accounts for 24% of all government spending and is one of the largest categories of consumer spending overall, accounting for 8.1% of consumer expenditures.[7]

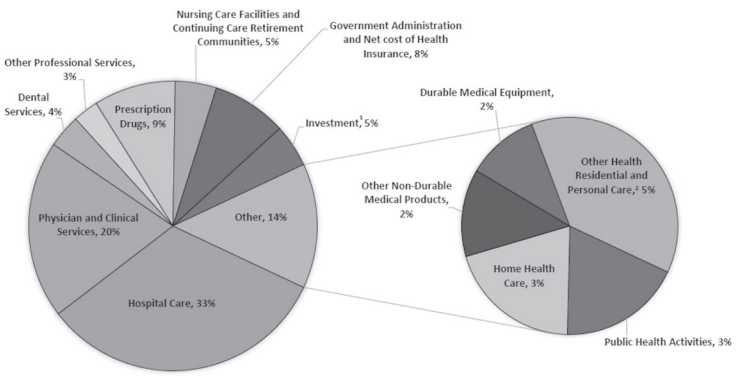
In 2018 alone, the U.S. spent approximately $3.6 trillion on health care.[8] Figures 1 and 2 show how health care spending breaks down across payers and services, as estimated by the Centers for Medicare & Medicaid Services ("CMS").

Figure 1: The nation's health dollar – where it came from[9]



[1] Includes worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, Substance Abuse and Mental Health Services Administration, school health, and other federal and state local programs.
[2] Includes co-payments, deductibles, and any amounts not covered by health insurance.
Note: Sum of pieces may not equal 100% due to rounding.

Figure 2: The nation's health dollar – where it went[10]



[1] Includes Noncommercial Research and Structures and Equipment.
[2] Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid.
Note: Sum of pieces may not equal 100% due to rounding.

As shown in Figure 2, CMS estimates that prescription drugs account for approximately 9% of health care spending. Some sources estimate that the percentage of spending on prescription drugs is actually higher – closer to 15% of total spending – when accounting for non-retail drug sales as well as the gross profits of other parties in the drug supply chain, such as wholesalers, pharmacies, PBMs, providers, and payers.[11]

In part because of the federal dollars at stake, health care is the primary target of federal civil enforcement actions, including with respect to drug pricing and market access issues. In 2019, the federal government recovered over $3 billion in settlements and judgments under the False Claims Act ("FCA"), which prohibits persons from making false claims (or causing false claims to be made) to the government – $2.6 billion related to health care cases, including those involving drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.[12] 2019 was the tenth consecutive year in which civil health care fraud recoveries exceeded $2 billion.[13] Additionally, the federal government utilizes the Anti-Kickback Statute ("AKS") to combat activity that increases utilization and costs to federal programs, skews prescribing

and other health care decisions, and creates an uneven competitor playing field.[14] Navigating this enforcement landscape requires a sophisticated understanding of the FCA, AKS, and government price reporting laws, as well as corresponding state laws.

The cost of prescription drugs

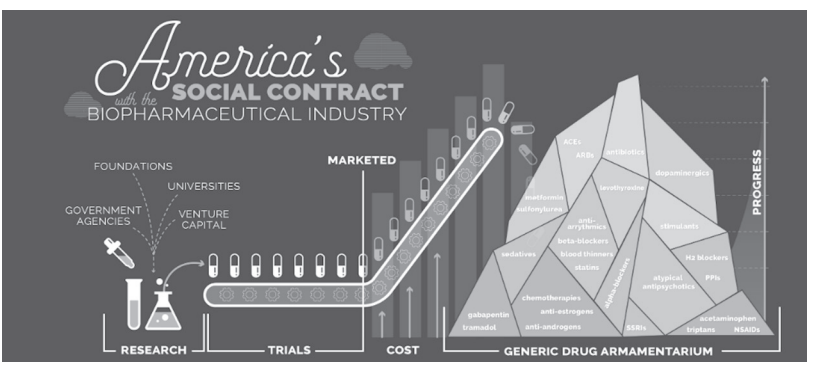
The high list price of prescription drugs in the U.S. is frequently discussed in the press and public discourse. Yet, the headlines often fail to capture both the types of drugs driving health care expenditures and the intricacies of the drug supply chain that create a significantly lower net price for a given drug product.

Branded versus generic drugs

Approximately nine out of 10 prescriptions filled are for inexpensive generic drugs.[15] Prescription drug spending is primarily driven by the price of on-patent drugs. In general, after 10–15 years, these branded drugs lose patent protection, and inexpensive generic versions enter the market.

As illustrated in Figure 3, from Peter Kolchinsky's article entitled "American's Social Contract with the Biopharmaceutical Industry", the high price of branded drugs supports a "growing mountain" of highly-utilized generic drugs.[16] Offering manufacturers higher prices for on-patent drugs for a limited period of time incentivizes innovation. The U.S. receives a return on its investment after the patent expires, at which point the drug rapidly declines in price. Payers encourage the utilization of generic drugs by implementing lower cost-sharing requirements.

Figure 3: America's social contract with the Biopharmaceutical Industry[17]



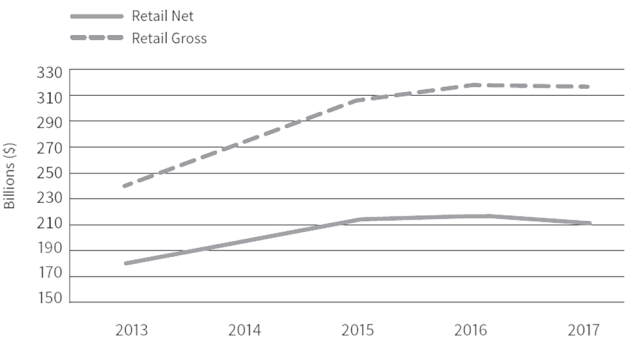
A small subset of branded drugs known as "specialty drugs" are a principal driver of prescription drug prices and expenditures. Medicare defines specialty drugs as pharmaceuticals costing $670 or more per month,[18] and other payers look at factors beyond price, designating products as specialty drugs if they (a) are novel therapies, (b) require social handling, monitoring, or administration, or (c) are used to treat rare conditions.[19] Specialty drugs account for approximately 2% of prescriptions but almost half of prescription drug spending.[20] Further, specialty share of net prescription drug spending increased from 26.2% in 2009 to 49.5% in 2018.[21] This trend is driven in part by innovation – specialty drugs represented the largest proportion of new drug products launched during this time period – and in part by patent expirations for traditional drug products.[22] In particular, cell and gene therapies represent the next frontier of specialty medications, with products such as chimeric antigen receptor T-cell ("CAR-T") therapy presenting tremendous promise to treat cancer on a highly personalized level. Many of these innovative treatments of are priced – or are

expected, once approved, to be priced – above $1 million for a course of treatment, but offer potential cures for otherwise fatal conditions. Often, companion diagnostics and/or next generation sequencing tests are required as a prerequisite to accessing specialty drugs, and these tests have their own reimbursement and pricing dynamics.[23]

List price versus net price

Figure 4, reproduced from the Trump Administration's "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs", illustrates that there is a significant gap between the list prices often cited in policy debates on drug pricing and the net prices actually reflecting the amount of money manufacturers receive.

Figure 4: List price *vs.* net price[24]



Source: Medicine Use and Spending in the U.S; A Review of 2017 and Outlook to 2022, April 19, 2018

The gap between list price and net price reflects various price concessions, such as discounts and rebates, associated with the numerous transactions throughout the U.S. drug supply chain, including among entities such as manufacturers, wholesalers, pharmacies, PBMs, and payers. According to the Pew Charitable Trust, manufacturer rebates grew from $39.7 billion in 2012 to $89.5 billion in 2016, significantly offsetting increases to drug list prices.[25] The prevalence of additional fees, such as administrative and service fees required by PBMs, may also impact pricing considerations.

Global comparisons

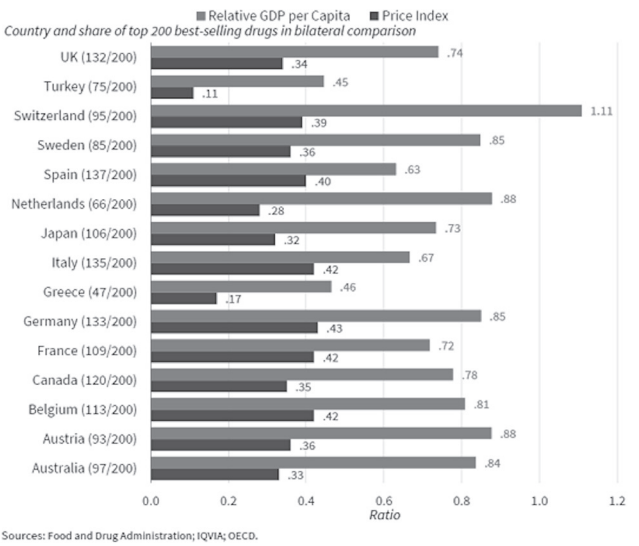
Health care spending in the U.S. far outpaces international averages. In 2018, national health care spending constituted 16.9% of GDP (in comparison to the Organisation for Economic Co-operation and Development ("OECD") average of 8.8%), totaling about $10,586 *per capita* (in comparison to the OECD average of $5,287).[26]

Prices for prescription drugs are significantly higher in the U.S. in comparison to other industrialized nations. Figure 5, reproduced from a report by the Council of Economic Advisers ("CEA"), shows the U.S. Price Index for 200 top-selling prescriptions, as well as relative GDP *per capita*. As the chart demonstrates, observed patented drug prices are far higher in the U.S. than can be explained by differences in *per capita* income alone. A price index of 0.34, for instance, indicates that prices in the United Kingdom are 34% of those in the U.S., even though the GDP in the United Kingdom is 74% of that in the U.S.

On the other hand, as demonstrated in the parentheticals along the y-axis, many of the 200 top-selling drugs are not available for sale in the countries of comparison. For example, in the United Kingdom, only 132 of the 200 drugs showed evidence of significant sales. Put another way, certain prescription drugs, such as some of the most innovative treatments for cancer, are more readily available in the U.S. than they are abroad. In its analysis, the CEA

states that "[t]he absence of significant sales volume for these drug products might be the result of delayed regulatory approval, a decision by a public insurance program not to cover a drug based on health technology assessment criteria, or other factors".[27]

Figure 5: Foreign-U.S. price index for 200 top-selling prescriptions and relative GDP *per Capita* for selected nations, 2017[28]



Pharmaceutical pricing and reimbursement

Marketing authorization

All drug products must be approved for use in the U.S. by the Food and Drug Administration ("FDA"), which is a government agency within the Department of Health and Human Services ("HHS"). FDA is charged with "protect[ing] the public health", including by ensuring that drugs are safe and effective, and "promot[ing] the public health" by efficiently reviewing and approving new drug products.[29] Currently, there are over 20,000 prescription drugs approved for marketing in the U.S., as well as 400 FDA-licensed biologics products.[30]

FDA approves new drugs and new uses of approved drugs on the basis of safety and effectiveness. Innovative drug products are approved through New Drug Applications ("NDAs") and Biologics Licensing Applications ("BLAs").[31] Manufacturers must demonstrate substantial evidence of effectiveness (or, for biologics, evidence that the product is "safe, pure, and potent") based on adequate and well-controlled clinical investigations.[32] FDA may also approve generic versions of an approved drug product as well as biological products that are biosimilar to a reference product.[33] Generic drug approval requires proof of bioequivalence, whereas a biosimilar must be highly similar to the reference product, with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product".[34] In 2019, FDA approved 70 new drugs and biological products, 107 first-time generic drugs, and 10 biosimilar products.[35]

FDA's timeline for reviewing NDAs and BLAs is generally set by a commitment letter issued by the Agency under the Prescription Drug User Fee Act of 1992 ("PDUFA"). Following criticism of the slow pace at which the FDA approved new drugs during the HIV/AIDS crisis in the 1980s, Congress passed PDUFA in 1992 to authorize the collection of user fees from drug manufacturers in order to help fund FDA's drug approval process.[36] Congress reauthorizes

PDUFA every five years, most recently in 2017, and parallel user fee programs now exist for generic drugs ("GDUFA") and biosimilars ("BsUFAs"). In 2019, 45% of FDA's budget was paid for by user fees, with the remaining 55% provided by federal budget authorization.[37] Performance goals under PDUFA stipulate that FDA aims to review and act on 90% of standard NDA and BLA submissions within 10 months of either filing (for new molecular entity ("NME") drug products and original BLAs) or receipt (for non-NME drug products).[38] Certain drug products may also be eligible for priority review, under which FDA aims to review and act on 90% of NDA and BLA submissions within six months of either filing or receipt.[39]

An NDA or BLA can receive priority review if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness.[40] In addition to priority review, other programs may be available to help expedite the development and review of drugs intended to address unmet medical need in the treatment of serious or life-threatening diseases or conditions, including: breakthrough therapy designation; fast track designation; and accelerated approval.[41]

In addition to approving new drugs, FDA also grants exclusive marketing rights to drugs approved under certain criteria. New chemical entities, meaning drugs that contain no active moiety that has been approved by FDA, benefit from five years of marketing exclusivity, running from the time of NDA approval.[42] During that time, FDA cannot accept for review any NDA or ANDA or a drug containing the same active moiety.[43] FDA offers 12 years of exclusivity for biologics, seven years for orphan drugs (drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S., or more than 200,000 with no hope of recovering costs), three years for applications or supplements containing new clinical investigations, and six additional months of market protection where the sponsor has conducted and submitted pediatric studies.[44] Other incentives are also available, such as priority review vouchers for drugs treating neglected tropical diseases, rare pediatric diseases, and medical countermeasures.[45]

Unlike regulators in many other countries, FDA does not consider price or cost-effectiveness in approving prescription drug products through the use of health technology assessment ("HTA") bodies or otherwise regulate the prices charged by manufacturers or reimbursement offered by payers. As described in further detail below, however, both government and private payers view FDA approval as a precondition for reimbursement.

Coverage and reimbursement

Whether a drug product is covered, and at what price, is determined by each payer's coverage, coding, and payment criteria. This section provides key terminology applicable to coverage and reimbursement,[46] followed by a summary of criteria for reimbursement under the two largest government-sponsored plans, Medicare and Medicaid, as well as the 340B Program. This section also includes considerations for coverage and reimbursement under private plans.

Key terminology

Actual Acquisition Cost ("AAC"). A state Medicaid program's determination of a pharmacy's actual price paid to acquire a drug product marketed or sold by a manufacturer.[47]

Average Manufacturer Price ("AMP"). The average price paid to the manufacturer for a drug in the U.S. by (1) wholesalers for drugs distributed to retail community pharmacies, and (2) retail community pharmacies that purchase the drug directly from the manufacturer.[48]

Average Sales Price ("ASP"). The average price of a manufacturer's sales of a drug (by National Drug Code) to all purchasers in the U.S., as calculated by sales divided by the total units of the drug sold by the manufacturer in the same quarter.[49]

Average Wholesale Price ("AWP"). The list price of a drug from a wholesaler to a pharmacy.[50]

Best Price. The lowest available price offered by the manufacturer to any wholesaler, retailer, or provider, excluding certain government programs.[51]

Wholesale Acquisition Cost ("WAC"). The list price of a drug from a manufacturer to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates or reductions in price.[52]

Government-sponsored plans and programs

A. **Medicare**

Medicare was established in 1965 under Title XVIII of the Social Security Act as a federally funded program to provide health insurance to individuals aged 65 and older.[53] It has since been expanded to cover individuals with disabilities or end-stage renal disease. The Medicare program, along with Medicaid and certain other federal health care programs, is administered by CMS.

i. Benefit designs

Medicare benefits are defined by statute, and Medicare provides coverage only for an item or service that falls within the statutorily identified benefit categories. In addition, the Medicare statute expressly excludes from coverage certain items or services, such as cosmetic surgery and some dental services. For a drug product to be covered by Medicare, it must, among other things, be "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member".[54]

The Medicare program is divided into four parts that offer different benefits for beneficiaries:

- Part A provides hospital insurance that covers inpatient hospital services, as well as post-hospital skilled nursing facility services, hospice care, and some home health services. Inpatient hospital services include drug products and biologics.[55] Individuals aged 65 and older generally qualify for premium-free Part A benefits based on payroll taxes they or their spouses paid. Individuals under age 65 who have received disability benefits for at least 24 months also qualify for premium-free Part A benefits. Part A benefits are managed by Medicare Administrative Contractors ("MACs"), which are private health care insurers awarded geographic jurisdictions to process certain Medicare claims.[56] MACs make coverage determination on a case-by-case basis or as local coverage determinations ("LCDs") or pursuant to national coverage determinations ("NCDs").[57]
- Part B provides supplemental medical insurance for a range of outpatient services, including physicians' services, laboratory services, durable medical equipment ("DME"), and other medical services.[58] Part B also provides coverage of certain items and supplies, such as outpatient drug products that are not usually self-administered and are furnished incident to a physician's services.[59] All individuals entitled to Part A may voluntarily enroll and obtain Part B benefits for a monthly premium.[60] Like Part A benefits, Part B benefits are managed by MACs, which determine coverage on a case-by-case basis or based on LCDs or pursuant to NCDs.[61] Parts A and B, together, constitute "original Medicare".[62]
- Part C Medicare Advantage ("MA"), formerly known as Medicare +Choice, provides an alternative method for beneficiaries to receive benefits. Instead of receiving benefits separately through Part A and Part B, beneficiaries may choose to enroll in a MA plan offering combined Part A and Part B benefits.[63] MA plans are administered by private health plans, such as health maintenance organizations ("HMOs"),

preferred provider organizations ("PPOs"), private fee-for-service ("PFFS") plans, and special needs plans ("SNPs"). These private plans contract with CMS to provide all the required Part A and B benefits through a managed care system.[64] Plans may also offer alternative cost-sharing arrangements for beneficiaries or coverage for additional benefits not covered under original Medicare, such as over-the-counter ("OTC") drugs, vision care, or dental services.[65] All MA plans, except PFFS plans, must offer options that include coverage for prescription drugs ("MA-PDs").[66] MA-PDs generally must comply with Part D requirements, discussed below.

- Part D was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") and first implemented in 2006. Part D offers voluntary prescription drug coverage for beneficiaries entitled to Part A benefits or enrolled in Part B. Beneficiaries with original Medicare can enroll in a stand-alone prescription drug plan ("PDP") that is administered by a private health plan.[67] Part D plan sponsors create formularies identifying the prescription drugs that are covered by their plans. Formularies must meet federally specified criteria, including coverage of all therapeutic categories and classes and providing at least two drugs in each category or class.[68] Part D plans must be reviewed and approved by CMS.[69]

ii. Coverage and reimbursement methodology

As a preliminary matter, drug products must be approved by the FDA in order to be reimbursed by Medicare. Parts A and B, however, generally cover only items or services that are "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member".[70] Thus, drug products also must be considered "reasonable and necessary" based on available clinical and scientific evidence, which is a different standard from FDA approval. In addition, Part D covers only outpatient prescription drug products that are FDA-approved and used for a medically accepted indication.[71]

As indicated above, coverage determinations for drug products vary depending on which Part of Medicare is reimbursing. With respect to Medicare Parts A and B, most coverage determinations are made by MACs on a case-by-case basis or through LCDs to determine whether a given product will be covered in the MAC's jurisdiction. CMS also makes NCDs to determine coverage of a drug product nationwide.[72] MACs typically review new drug products upon submission of an LCD request, which triggers a 60-day review period to determine whether the request is complete, and then a lengthier review to evaluate the request itself, invite and incorporate public comment, and ultimately issue a final determination.[73]

Under Part D, the private plan sponsors administering the PDP and MA-PD benefits determine which prescription drug products are covered. The plan sponsors develop formularies to identify which prescription drug products are covered, subject to the requirements above. Formularies usually include "tiers" setting forth different beneficiary cost-sharing requirements.[74] Part D formularies must be developed and reviewed by a pharmacy and therapeutics ("P&T") committee, which must "make a reasonable effort" to review new drug products within 90 days and make coverage determinations within 180 days of a drug's introduction to the market.[75] CMS reviews formularies to ensure that they are consistent with federal requirements related to formulary design. A plan must cover at least two drugs for a particular therapeutic class,[76] and must cover "substantially all" immunosuppressant (for prophylaxis of organ transplant rejection), antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[77]

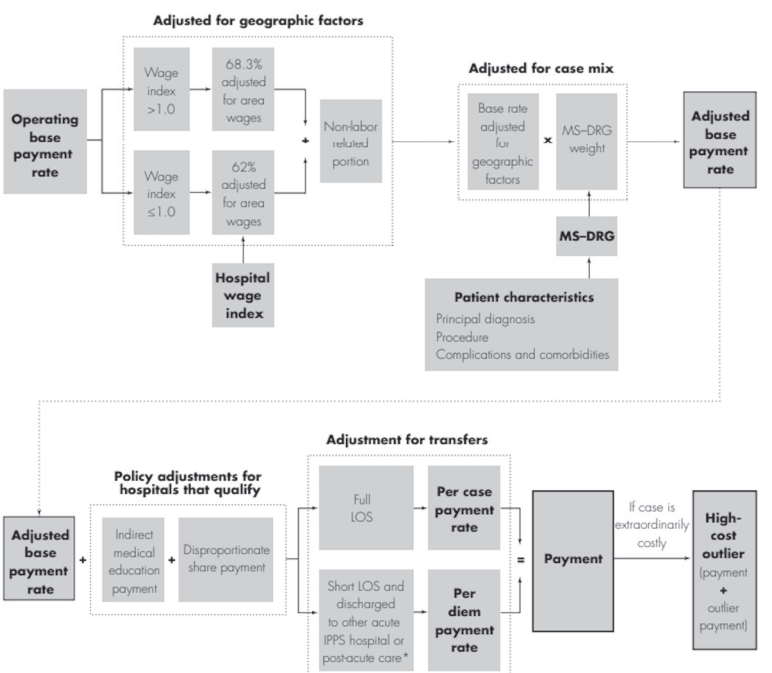
Part A reimbursement

Reimbursement for most acute care hospital services under Part A is determined using the inpatient prospective payment system ("IPPS") based on diagnosis-related groups. The IPPS was established by Congress through the Social Security Amendments of 1983.[78] Reimbursement under Part A is intended to cover all of the services and supplies provided during the beneficiary's spell of illness, including any drug products provided to the beneficiary; hospitals are statutorily prohibited from billing for items and services separately, or "unbundling" items and services.[79]

The IPPS formula contains two basic components. First, a base payment amount is prospectively determined by CMS to cover the operating and capital expenses per discharge, adjusted by a wage index for the geographic area in which the hospital is located.[80] Second, a weighting factor is associated with the diagnosis related group ("DRG") to which the beneficiary is assigned, to account for the resources required to treat the beneficiary.[81] The base payment amount, adjusted by the wage index, is multiplied by the weight of the beneficiary's DRG to determine the reimbursement payment amount. Medicare may also provide add-on payments, on top of the adjusted base payment, to cover costs associated with extraordinary treatment cases ("outliers"), teaching hospitals, or qualified new technologies. Disproportionate share hospitals ("DSHs") that treat a certain volume of low-income patients receive additional payments for operating and capital expenses.[82] Additionally, Medicare has established several quality incentive programs under which hospitals may receive incentive payments or penalties associated with quality of care criteria set by CMS.[83]

Certain hospitals, or hospital units, are exempted from the IPPS and receive reimbursement based on alternative methodologies. These include psychiatric hospitals or units, rehabilitation hospitals or units, children's hospitals, and long-term care hospitals.[84]

Figure 6: Acute inpatient prospective payment system for Fiscal Year 2020[85]



Note: MS–DRG (Medicare severity diagnosis related group), LOS (length of stay), IPPS [inpatient prospective payment system]. Capital payments are determined by a similar system. In addition to the inpatient operating and inpatient capital payments per discharge, hospitals may receive additional payments, such as those related to direct graduate medical education, uncompensated care, and bad debts. Additional payments are also made for certain rural hospitals. Hospitals may received penalties or additional payments based on their performance on quality standards.

** Transfer policy for cases discharged to post-acute care settings applies for cases in 278 selected MS–DRGs.*

Part B reimbursement

Medicare reimburses certain drug products under Part B when they are administered "incident to" a physician's services, generally in the physician's office or other outpatient setting.[86] Part B drugs include, for example, drugs that are infused or injected. These drugs are reimbursed under the "buy and bill" model, through which providers first purchase drugs and then submit claims for reimbursement after the drugs have been administered to a beneficiary. In order to obtain reimbursement for Medicare Part B drugs, providers must submit claims to MACs using Healthcare Common Procedure Coding Systems ("HCPCS") codes.[87]

The current reimbursement methodology for most Part B drugs was established by the MMA.[88] Under this methodology, reimbursement payments for Part B drugs are generally calculated based on the ASP, which the manufacturer reports to CMS.[89] A drug's ASP is calculated by dividing the manufacturer's sales of the drug to all purchasers in the U.S. in a specific quarter (excluding nominal sales to certain entities and sales that are exempt from the determination of Medicaid best price) by the number of units of the drug sold by the manufacturer in the same quarter.[90]

Manufacturers report ASP on a quarterly basis. Certain manufacturers, such as those with Medicaid rebate agreements, are obligated to report ASP data,[91] while other manufacturers voluntarily report ASP data or WAC data.[92] Reimbursement rates are updated quarterly; however, the rates are calculated using the reported ASP from two quarters ago.[93]

Reimbursement for Part B drugs administered in the physician office setting is statutorily set at 106% of ASP, referred to as "ASP+6".[94] Beneficiaries are generally responsible for 20% of the cost of drug products under Part B.[95] ASP+6 is intended to account for variability in provider acquisition costs and to compensate providers for the additional costs associated with the complexity of Part B drugs, many of which are used to treat serious illnesses such as cancer, cerebral palsy, and multiple sclerosis. Specific Part B drugs, including newly launched drugs, certain preventative vaccines, compounded drugs, and certain radiopharmaceuticals, are reimbursed under alternative formulas, rather than at ASP+6.[96]

Under certain circumstances, reimbursement for Part B drugs is included, or "bundled", with the payment for other services. For example, payments for certain drugs administered in hospital outpatient departments are bundled with the payments for services under the hospital outpatient prospective payment system ("OPPS").[97] Other drug products, such as drugs with pass-through status, are reimbursed separately under OPPS. Reimbursement rates for such drugs vary from year to year and are currently set at ASP+6 for most drugs and ASP minus 22.5% for most drugs acquired through the federal 340B program, discussed below.[98]

Part C reimbursement

Medicare Advantage plans contract with CMS to provide all required Part A and Part B items and services to Medicare beneficiaries in exchange for a monthly capitated payment. MA contracts are awarded based on a competitive bidding process. Reimbursement payments are then calculated by comparing the plan's bid, which establishes the plan's estimated costs of providing Part A and Part B services to the average beneficiary, to the benchmark plan. If the plan's bid is lower than the benchmark, the reimbursement payment equals the bid

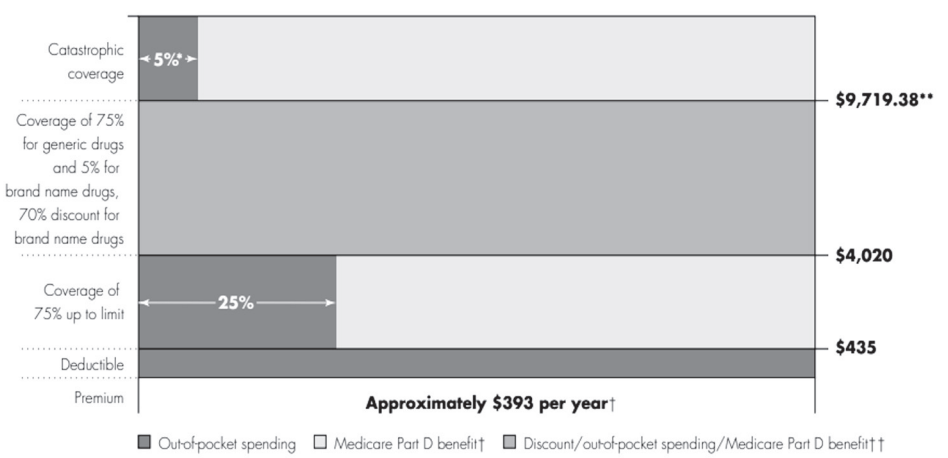
amount, plus a rebate based on the difference between the bid and the benchmark that is passed on to the beneficiaries. However, if the bid is equal to or greater than the benchmark, the benchmark will be the reimbursement payment and beneficiaries are required to pay an additional premium based on the difference between the bid and the benchmark.[99]

For MA-PD plans offering prescription drug coverage, a separate Part D bid must be submitted to CMS. Reimbursement for the prescription drug part of the MA plan is then calculated separately, in the same manner as stand-alone PDPs, discussed below.[100]

Part D reimbursement

Under Part D, stand-alone PDPs must provide standard prescription drug coverage, as set forth by statute, or alternative coverage that provides actuarially equivalent benefits.[101] In 2020, the standard benefit included a $435 deductible and 25% coinsurance for the cost of drug products between $435 and $4,020. Beneficiaries then enter the coverage gap, referred to as the "doughnut hole", until they reach the catastrophic limit and out-of-pocket threshold of $6,350. After reaching the catastrophic limit, beneficiaries pay the higher of either a 5% coinsurance or a set amount per prescription.[102] Under Part D as it was originally implemented in 2006, beneficiaries were responsible for all drug costs incurred while they were in the coverage gap. However, provisions of the Patient Protection and Affordable Care Act (often shortened to the Affordable Care Act or "ACA") slowly reduced cost-sharing requirements during the doughnut hole, including by phasing in larger Medicare subsidies and requiring manufacturers to provide discounts for brand-name during purchased by beneficiaries in the coverage gap.[103] As of 2020, the doughnut hole is closed, meaning beneficiaries are responsible for only the 25% coinsurance until they reach the catastrophic limit.[104]

Figure 7: Standard drug benefit in 2020[105]



Note: Benefit structure applicable to an enrollee who has no supplementary drug coverage.

Cost sharing above the out-of-pocket ("OOP") threshold is the greater of either 5% coinsurance or a copay of $3.60 for generic drugs, or $8.95 for brand name drugs.

Equivalent to $6.350 in OOP spending: $435 (deductible) + $896.25 (25% cost sharing for generic drugs, 25% cost sharing for brand name drugs, and 70% manufacturer discount for brand name drugs in the "coverage gap"). The amount of total covered drug spending at which a beneficiary meets the annual OOP threshold depends on the mix of brand name and generic drugs that the individual fills during the coverage gap. The estimated amount of total drug expenses at the annual OOP threshold for 2020 ($9,719.38) is for an individual not receiving Part D's low-income subsidy ("LIS") who has no other sources of supplemental coverage.

There is a base beneficiary premium of about $393 per year, which is 25.5% of expected Medicare Part D benefits

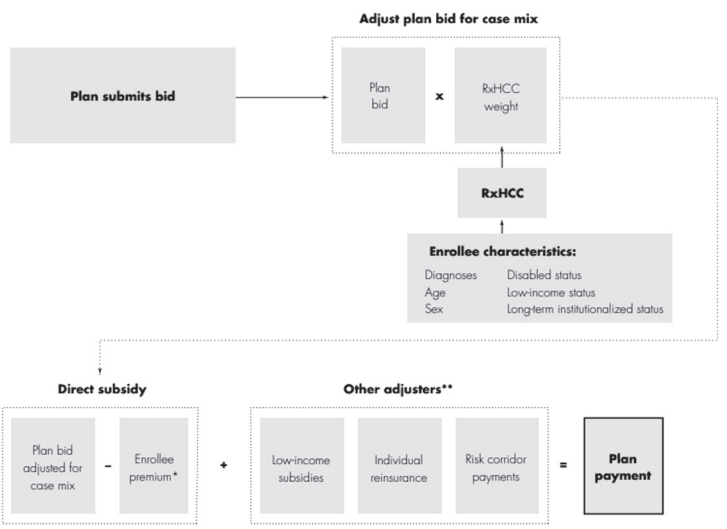
per person, but the actual premiums that beneficiaries pay vary by plan. Federal subsidies pay for the remainder of covered Part D benefits.

In 2020, cost sharing for drugs filled during the coverage gap will be 25% for generic drugs (the remaining 75% will be picked up by the Part D benefit) and about 25% for brand name drugs. The actual cost sharing amount for brand name drugs will depend on the dispensing fee charged by a plan since the 5% covered by the Part D benefit applies to both the ingredient and the dispensing fee, while the 70% manufacturer discount applies only to the ingredient cost.

Part D reimbursement payments made to both PDPs and MA-PDs are based on a competitive bidding process. Plan sponsors determine their bids based on the expected costs of providing coverage for the average Medicare beneficiary. CMS provides monthly capitated payments to plans to subsidize the standard benefit coverage. CMS also pays additional subsidies for low-income beneficiaries and reinsurance subsidies to cover the costs of beneficiaries with high prescription drug expenses.[106]

Unlike reimbursement under Medicare Part A and Part B, the federal government does not play a role in determining the calculation for drug product reimbursement under Part D. Instead, plan sponsors usually contract with PBMs to negotiate prices with manufacturers. Plans also establish a network of pharmacies to provide access to covered drug products for its beneficiaries.[107] The Medicare statute prohibits the federal government from interfering with Part D price negotiations or establishing a required formulary or reimbursement formula for Part D drug products.[108]

Figure 8: Part D payment system[109]



Note: RxHCC (prescription drug hierarchical condition category). The RxHCC is the model that estimates the enrollee risk adjuster. Beginning in 2011, CMS replaced its single model of risk scores with five separate sets of model coefficients for: long-term institutionalized enrollees; aged low-income enrollees; aged non-low-oncome enrollees; disabled low-income enrollees; and disabled non-low-income enrollees. Prior to 2011, payments on behalf of beneficiaries with low-income and long-term institutionalized status were adjusted using multipliers intended to reflect those individuals' higher levels of drug spending.

** Figure 8 outlines the process for calculating enrollee premiums.*

*** Plans receive interim prospective payments for indivudals reinsurance and low-income subsidies that are later reconciled with CMS.*

B. Medicaid

Medicaid was established by the Social Security Act of 1965 to provide health care services to low-income individuals.[110] The program is funded jointly by federal and state governments. States are not required to participate in Medicaid, but all 50 states, Washington, D.C., and the U.S. territories have chosen to participate. The federal Medicaid statute establishes federal requirements that states must satisfy in order to receive matching federal funds. However, the statute also provides flexibility for states to design their programs within the federal guidelines.[111]

In order to receive Medicaid benefits, individuals must qualify through an eligibility pathway that provides coverage to identified populations. Some pathways are mandated by federal law, while others are optional pathways that states may choose to offer. States may also apply for a Medicaid waiver in order to offer coverage to populations beyond the mandatory and optional pathways. The federal Medicaid statute defines the categories of individuals who are covered by a certain pathway ("categorical eligibility") and whether there are any financial requirements ("financial eligibility"), as well as the extent to which a state can alter or adjust the pathway's requirements.[112]

i. Benefit designs

Medicaid coverage includes a range of benefit options, including primary care, preventative care, and long-term care services and supports. Medicaid beneficiaries may receive benefits through a fee-for-service system or a managed care system, depending on which systems are offered by the state. Through the fee-for-service system, states provide reimbursement to health care providers for each service they provide to beneficiaries. Through the managed care system, states pay managed care organizations ("MCOs") a monthly capitated fee to provide benefits to eligible individuals.[113]

An individual's benefits vary based on the eligibility pathway through which he or she obtains coverage. State programs may offer either traditional Medicaid benefits, which include a range of required and optional benefits specified by federal law, or alternative benefit plans ("ABPs"), which are based on a coverage benchmark but must include the essential health benefits ("EHBs") that private health plans are generally required to provide. States may also apply for a Medicaid waiver to provide additional services.[114] Under the traditional Medicaid benefit framework, prescription drug coverage is an optional benefit, but all states have chosen to offer it; for ABPs, prescription drug coverage is a mandatory benefit.[115] Further, some state Medicaid programs also provide coverage for OTC drug products.[116]

Individuals who are eligible for both full Medicaid benefits and Medicare, known as "dual eligibles", generally must obtain prescription drug coverage through a Medicare Part D plan. State Medicaid agencies are statutorily prohibited from providing reimbursement for drug products covered by Part D for dual eligibles, but agencies may provide reimbursement for drug products that are expressly excluded from the definition of a covered Part D drug.[117]

ii. Coverage and reimbursement methodology

Pursuant to the Medicaid Drug Rebate Program ("MDRP"),[118] state Medicaid programs must maintain an "open formulary" covering all drugs by a participating manufacturer. In exchange, manufacturers agree to make rebate payments intended to ensure that Medicaid pays the "best price" for drug products.[119] Many states also have developed preferred drug lists ("PDLs"), which include drugs

for which manufacturers offer supplemental rebates beyond those offered by the MDRP. Providers are encouraged to prescribe drugs on the state PDL to Medicaid beneficiaries; the drugs on the PDL are generally subject to fewer utilization management controls. Additionally, the federal Medicaid statute allows state programs to exclude certain drugs, classes of drugs, or drug uses from coverage.[120]

State Medicaid programs usually reimburse community retail pharmacies for drug products dispensed to Medicaid beneficiaries. In addition, some states may require Medicaid beneficiaries to pay a nominal copayment for outpatient prescription drug products.[121]

Fee-for-service Medicaid reimbursement payments to pharmacies are generally based on the drug product's ingredient cost and the pharmacist's dispensing fee. In 2016, CMS issued a final rule requiring states to use the AAC to determine ingredient cost.[122] However, federal regulations permit states to choose how they calculate AAC by using either a survey of pharmacy providers, the AMP, or the National Average Drug Acquisition Cost ("NADAC").[123] The drug's ingredient cost is combined with a professional dispensing fee, which is usually a fixed amount intended to cover the pharmacy's costs for obtaining, storing, and dispensing the drug.[124]

Medicaid managed care plans also reimburse pharmacies for drug products dispensed to beneficiaries. Like payments made by fee-for-service Medicaid, managed care reimbursement rates are based on the drug's ingredient costs and dispensing fees. To calculate ingredient costs, MCOs are not required to use the AAC but must make payments sufficient to ensure appropriate access for their beneficiaries.[125] MCOs negotiate reimbursement terms with pharmacies rather than creating a generally applicable payment formula. They also may negotiate their own rebates and other discounts from manufacturers.[126]

Many states contract with PBMs, which serve as intermediaries between the state Medicaid agencies, pharmacies, manufacturers, and beneficiaries. States may use PBMs for Medicaid programs administered on a fee-for-service basis or through a managed care system to perform multiple administrative and financial functions. PBMs working on behalf of MCOs may negotiate drug prices with pharmacies; conversely, PBMs working with fee-for-service Medicaid programs must comply with federal and state requirements for drug reimbursement.[127] Concerns regarding the lack of transparency for PBMs have led some states to consider disclosure requirements for PBMs.[128]

To control the cost of prescription drugs, federal and state governments have implemented policies to create certain payment limitations for Medicaid reimbursements. The federal upper limit ("FUL") is a payment limitation that caps the reimbursement payment for ingredient costs of certain multiple source drugs.[129] Currently, CMS has set the FUL at 175% of the weighted average of the most recently reported AMP for the specific form and strength of a drug.[130] In addition, most states have created a maximum allowable cost ("MAC") program to limit reimbursements for certain multiple source drugs. State MAC programs operate similarly to the FUL cap; however, states have discretion to decide which drugs are included in the program and how the reimbursement limitation for those drugs is calculated. As of 2014, 45 states had established MAC programs.[131] Finally, for single source drugs and drugs not subject to FUL or MAC limitations, reimbursement – in the aggregate

– may be determined by the lower of either (1) the AAC and dispensing fee, or (2) the providers' usual and customary charges to the general public.[132]

Pursuant to the MDRP, as discussed above, a drug product is covered by Medicaid only if the manufacturer enters into a Medicaid rebate agreement.[133] The agreement requires the manufacturer to provide a rebate to the state's Medicaid agency, which is then shared between the federal and state governments in order to reduce federal and state expenditures. For single source and innovator multiple source drugs, Medicaid's basic rebate formula requires a payment in the amount of the greater of either the difference between a drug's quarterly AMP and the best price for the same period, or a flat percentage (23.1%) of the drug's quarterly AMP.[134] Drug manufacturers owe an additional rebate when their AMPs for individual products increased faster than inflation. For other drug products, separate rebate structures would apply, as demonstrated in Figure 9.

Figure 9: Medicaid drug rebate formulas[135]

Drug Category	Basic Rebate	Additional Rebate
Single Source	The greater of either 23.1% of AMPa per unit or AMP minus best priceb per unit	Required when prices rise faster than the inflation rates – difference between the products' per unit current AMP and the base period AMP adjusted by CPI-Uc for each quarter since launch
Innovator Multiple Source Drugs	The greater of either 23.1% of AMP or AMP minus best price per unit	Required when prices rise faster than the inflation rates – difference between the products' per unit current AMP and the base period AMP adjusted by CPI-U for each quarter since launch
Line Extension Productsd	The greater of (1) the basic and additional rebate for the new drug or (2) the product of the line extension drug's AMP and the highest additional rebate for any strength of the original brand drug and the number of units of each dosage form and strength of the line extension drug	
Blood Clotting Factorse	The greater of 17.1% of AMP per unit or AMP minus best price per unit	Required when prices rise faster than the inflation rates – difference between the products' per unit current AMP and the base period AMP adjusted by CPI-U for each quarter since launch
FDA Approved Pediatric Indicationf	The greater of 17.1% of AMP per unit or AMP minus best price per unit	Required when prices rise faster than the inflation rates – difference between the products' per unit current AMP and the base period AMP adjusted by CPI-U for each quarter since launch
Non-innovator Multiple Source and Other Drugs	13% of AMP	Not applicable

Source: Congressional Research Service ("CRS") review of the SSA §1927. Payment for Covered Outpatient Drugs, and 42 CFR §447.502. Definitions.

a. AMP is the average manufacturer price, or the average U.S. price manufacturers received for their product when sold to retail community pharmacies.

b. Best price (single source and innovator multiple source) is the drug manufacturer's lowest U.S price during the reporting period (see the glossary in Appendix E).

c. CPI-U is the consumer price index for all urban consumers as updated by the U.S. Department of Labor (http://www.bls.gov/cpi/).

d. A line extension is an oral solid dose (generally a pill or capsule) of a single source or multiple source innovator drug that is a new formulation of an existing drug, such as an extended release formulation (SSA §1927(c)

(2)(C). CMS proposes to use the FDA regulation 21 CFR §206.3, which is defined solid oral dosage form as capsules, tablets, or similar drug products intended for oral use (77 Federal Register 5324, February 2, 2012).

e. *Clotting factor drugs receive a separate payment under SSA §1842(o)(5) and are included on a regularly updated list maintained by the Secretary (SSA §1927(c)(I)(B)(iii)(II)(aa)).*

f. *FDA approved pediatric drugs are those approved for marketing by the FDA for pediatric indications (SSA §1927(c)(I)(B)(iii)(II)(bb)).*

C. 340B drug pricing program

The federal 340B program requires manufacturers to provide outpatient prescription drugs to providers that primarily serve low-income and uninsured individuals (frequently referred to as "safety net providers").[136] Established in 1992, the 340B program was conceived to address an unintended consequence of the MDRP – the requirement to report the best price resulted in manufacturers no longer offering voluntary discounts to safety net providers.[137] Under the 340B program, any manufacturer that participates in the MDRP must: (1) offer the 340B price if the drug is made available to any other purchaser at any price; (2) to cover entities (defined by statute to include federally qualified health centers, various disease-specific programs, and publicly owned hospitals treating a disproportionate number of low-income patients; (3) cover outpatient drugs (defined by statute to include all outpatient drugs, including infusion therapies, provided they are not associated with an inpatient stay); and (4) set the 340B price at no more than a statutorily defined ceiling (the "ceiling price").[138]

The ceiling price is calculated quarterly using MDRP figures (AMP minus the Unit Rebate Amount) from two quarters prior, except that 340B pricing is estimated for new drugs until the MDRP figures become available. Manufacturers may voluntarily offer lower "sub-ceiling" pricing to covered entities. After purchasing the drug at the ceiling price, the covered entity generally seeks reimbursement from the patient's insurance (commercial or government) or potentially the patient. The statute prohibits covered entities from obtaining duplicate discounts under 340B and MDRP, and bans them from diverting discounted drugs to anyone but their own patients.

The mandatory discounts required under the 340B Program are exempt from best price (and related) calculations. This exclusion is not limited to sales under the 340B Program but applies to *all* sales to a covered entity, including commercial sales. Consequently, one of the critiques of the program is that a gap exists between the prices hospitals pay to acquire 340B drugs and the price at which payers reimburse those drugs.[139]

In 2010, the ACA expanded 340B eligibility to include additional categories of hospitals, and draft guidance from the Health Resources and Services Administration ("HRSA") removed the restriction on 340B entities using only one contract pharmacy, leading to growth in 340B dispensing.[140] In addition, hospital acquisition of oncology practices has driven increased 340B profitability for hospitals.[141] 340B spending has increased significantly in recent years, rising from $5.3 billion in 2010 to $24.3 billion in 2018.[142]

In 2018, HHS reduced Medicare Part B reimbursement rates for certain drugs acquired under the 340B program from ASP +6% to ASP minus 22.5%, so as to "better, and more appropriately, reflect the resources and acquisition costs that these hospitals incur".[143] In litigation challenging this change in reimbursement, the U.S. District Court ruled that HHS exceeded its statutory authority by reducing the reimbursement rate in this manner,[144] but the case is currently on appeal before the U.S. Court of Appeals for the District of Columbia.

Private plans

Over two-thirds of Americans are covered by private insurance. The vast majority of those with private insurance have employment-based coverage – in 2018, 178.4 million Americans

had coverage through an employer.[145] The ACA requires large employers to provide full-time employees and their dependents with coverage, and plans must meet minimum standards for affordability and coverage.[146] Employers generally pay most of the insurance premium on behalf of employees and their dependents, while employees are responsible for the remainder of the premium and cost-sharing requirements. On average, employers pay 82% of the premium for single coverage and 71% for family coverage.[147] Americans can also purchase insurance directly through state-based and multi-state Affordable Health Insurance Exchanges (also known as "Health Insurance Marketplaces"), where subsidies are available to individuals with incomes between 100% and 400% of the federal poverty level ("FPL").[148] Additionally, individual and group plans are also available for purchase outside of the Health Insurance Marketplaces.[149]

Private plans typically include medical and pharmacy benefits. Drugs used with DME are often covered under the pharmacy benefit. Physician-administered drugs, regardless of formulation, are typically covered and paid under the medical benefit. FDA approval is typically a prerequisite for coverage, but private plans have greater flexibility than public plans in defining the benefit category and placement of drugs on formularies, as well as adopting utilization controls, as discussed below.

Medicare rates frequently serve as a floor for payments under private plans. However, unlike Medicare's Part A and B benefits, private payers can and do negotiate prices and payments, often through negotiated aggregate rebates with drug manufacturers facilitated by PBMs. Drug payment rates vary depending on contracts with providers, manufacturers, vendors, and employers. Private payers often consider cost or cost-effectiveness in the coverage process, with many utilizing complex formularies to determine patient cost-sharing responsibilities, as discussed below.

Additional issues that affect pricing and reimbursement

Other parties in the drug supply chain

Understanding the pharmaceutical supply chain is key to understanding the cost of prescription drugs in the U.S., particularly in the private market. Manufacturers rarely receive the WAC or list price set by manufacturers because products are frequently discounted throughout the distribution system and subject to various forms of service fees. These discounts flow through wholesale distributors, pharmacies, payers, and PBMs and are often paid retrospectively by the manufacturer in the form of rebates.

Wholesale distributors buy drugs from manufacturers and distribute them to pharmacies, hospitals, and other medical facilities. Pharmacies negotiate with wholesalers to purchase prescription drugs for their inventory, and, in turn, wholesalers negotiate with manufacturers to obtain drugs to distribute to pharmacies and other purchasers. Wholesalers also facilitate charge-backs for manufacturers to effectuate negotiated prices for their customers.

PBMs represent payers and employers in the selection, purchase, and distribution of prescription drug benefits, and often serve as a broker, without fiduciary obligations, between individual employers, payers, drug manufacturers, and pharmacies.[150] PBMs play several roles throughout the supply chain. These include:

- **Developing and maintaining prescription drug formularies for insurance plans.** PBMs maintain a national formulary, as well as custom client formularies, to provide tiered coverage for branded and generic prescription drugs.
- **Negotiating discounts from manufacturers.** PBMs negotiate discounts from manufacturers on behalf of insurance plans, in exchange for preferred formulary placement. Discounts generally come in the form of rebates. PBMs retain these rebates and pass

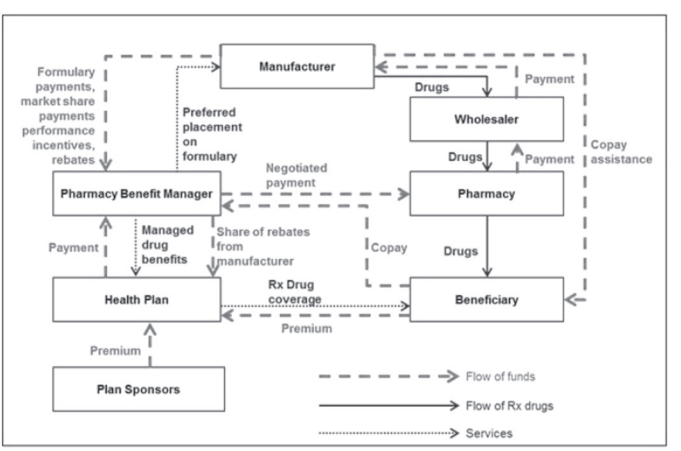
along some portion of the manufacturer price concession under a blended effective rate for an employer's or plan's branded drug spend. Rebate agreements between PBMs and manufacturers often contain price protection provisions that require the manufacturer to pay additional concessions to the payer or PBM in the form of a penalty if the list price of the product increases above a predefined threshold year over year, on a cumulative multi-year basis, or both. Some larger payers negotiate directly with manufacturers for rebates and use the PBM for other administrative services such as Drug Utilization Review ("DUR") and claims processing. Rebates are not passed down to plan beneficiaries, but they may help reduce beneficiaries' overall insurance premium costs.

- **Creating pharmacy networks and negotiating lower dispensing fees.** PBMs create networks of pharmacies that agree to dispense prescription drugs under agreed-upon terms. PBMs negotiate a reimbursement rate for each drug product, as well as a dispensing fee. When a plan beneficiary pays for a prescription, the pharmacy generally passes the copayment or coinsurance to a PBM, which then pays the pharmacy the negotiated reimbursement and dispensing fee. This arrangement allows the PBM to create spread pricing profits and impose penalty fees on pharmacies that do not achieve contracted performance goals such as rate of generic dispensing. PBMs also may operate pharmacies themselves, including mail-order and specialty pharmacies. When payers and PBMs operate and drive utilization to their own pharmacies through narrow networks, they can negotiate additional bulk purchase discounts from manufacturers that are retained by the payer or PBM pharmacy.

The rebates paid to PBMs have come under recent criticism, including from the Trump administration, which views rebates as a key driver of increased drug costs.[151] In 2019, the administration proposed a rule that would have eliminated traditional retrospective rebates from government drug plans to PBMs in favor of point of sale discounts at the pharmacy counter that provided patients with a portion of the manufacturer's price concessions.[152] However, this rule has since been withdrawn.

Figure 10 illustrates the flow of funds, prescription drugs, and services for non-specialty drugs covered under private insurance and purchased in a retail setting.

Figure 10: The Flow of Funds in the Pharmaceutical Distribution System[153]



Various entities across the drug supply chain are increasingly contracting and consolidating both horizontally and vertically. For example, three PBMs – Express Scripts, CVS Caremark and OptumRx – currently control the majority of the market, together totaling an estimated

71% of Medicaid and Medicare Part D beneficiaries and 86% of the private market.[154] This demonstrates a high level of horizontal consolidation in the PBM industry. Further, these PBMs have some form of common ownership with large retail chains and/or specialty pharmacies, as well as payers, demonstrating an increasing level of vertical integration: CVS Caremark is affiliated with CVS and Aetna; Express Scripts is affiliated with Accredo and Cigna; and OptumRx is affiliated with BriovaRx and UnitedHealthcare. While the PBMs generally consider vertical integration to be to the benefit of patients,[155] there are concerns that extensive consolidation has reduced transparency in the financial relationships among payers and other participants in the drug supply chain and may adversely impact patient access due to significant bargaining power of the consolidated entities. On the other hand, PBMs generally have demonstrated success in keeping payers' net prices low and increasing the overall rate of price concessions achieved from manufacturers, providing a benefit to plans and payers. For example, a survey by the Pew Charitable Trust found that 91% of rebates were passed through to plans in 2016 (up from 78% in 2012).[156] PBMs retained roughly the same volume of rebates despite the higher rates of rebate pass-through due to an overall growth in rebate volume, including an estimated increase of manufacturer rebates from $39.7 billion in 2012 to $89.5 billion in 2016,[157] reflecting in part the impact of PBM bargaining power and negotiations.

Efforts to manage costs

Payers and PBMs have various tools at their disposal with which to control spending on prescription drugs. These tactics include:

- **Requiring greater cost sharing for high-cost products.** As indicated above, PBMs and payers have wide discretion to design formularies that determine how drugs are reimbursed, as well as the rate of patient cost sharing for drug products (although, for Medicare Part D plans, these formulary designs must adhere to federal requirements and be approved by CMS). Tiered formularies are used to steer patients toward generics and branded drugs for which there exists no generic equivalent by requiring lower cost sharing for these drugs. Within a given formulary, tier 1 generally includes covered generic drugs (also called "preferred drugs"), and tier 2 generally includes preferred branded drugs for which there is no generic equivalent. Traditionally, PBMs used a three-tier structure, placing non-preferred drugs in tier 3. Today, many PBMs utilize a four-tier or five-tier structure, reserving the highest tiers (tiers 3, 4, or 5) for high-cost specialty drugs. PBMs shift a significant portion of the cost for non-preferred drugs to the patient, in the form of higher copays (fixed dollar amounts) or co-insurance (a percentage of the cost of the drug). Negotiations with manufacturers typically involve the use of bidding tables where each manufacturer offers varying levels of rebates for exclusive, preferred, or parity formulary placement within competitive therapeutic classes (i.e., diabetes) where multiple clinically effective treatments are available for prescribing. Manufacturer bidding for government payer lives are typically separated from bidding activity for commercial payer lives due to the different coverage and reimbursement dynamics of each market. A developing trend is to show physicians the relative formulary status of a treatment option within their electronic health records at time of prescribing, in order to better align the physician's decisions with the lowest cost option for the patient, employer, or health system.[158]
- **Utilization controls.** PBMs and insurance plans frequently require patients to obtain prior authorization before covering expensive medications. PBMs and insurance plans also may require a patient to try a preferred product (usually a lower cost generic) before agreeing to reimburse a more expensive product, a process known as "step therapy" or "fail first". Additionally, plans and PBMs may block coverage of certain drugs altogether, or utilize narrow pharmacy networks to limit patient access.

- **Mandatory substitution of generics.** Most state Medicaid plans require pharmacies to dispense a generic version of a drug product, if available, unless the patient's prescriber specifies that the branded version is medically necessary. Payers and PBMs also may encourage or require generic substitution, state law permitting. Multiple states require pharmacists to replace brand-name drugs with generics, unless a prescriber affirmatively blocks pharmacist substitution.[159] At least one state, Oklahoma, prohibits pharmacists from substituting pharmaceutical products without the consent of both the prescriber and the patient.[160]
- **Cost sharing/copay accumulators and maximizers.** PBMs and insurance plans have increasingly utilized benefit designs such as accumulators and maximizers to minimize and/or capture the effect of drug manufacturer copay assistance. Under accumulator programs, the plan does not allow the value of manufacturer copay assistance to count toward the beneficiary's deductible or out-of-pocket maximum, so that once the copay assistance is exhausted, the beneficiary must pay the entire amount of his or her deductible before plan benefits are available. Under a maximizer program, the plan aligns the beneficiary's copay obligation with available copay assistance from manufacturers (i.e., by dividing the annual maximum benefit to set monthly copay amounts for beneficiaries). Manufacturer assistance applies to the beneficiary's copay obligation but not toward the beneficiary's deductible or out-of-pocket maximum. Recent federal rulemaking clarifies that accumulator programs (and, by extension, any accumulator elements included in maximizer programs) are expressly permitted for health plans sold on the Affordable Health Insurance Exchanges, as well as most other plans, to the extent permitted by state law.[161] Certain states have recently proposed legislation to limit these benefit design programs. In 2019, Arizona, Illinois, Virginia, and West Virginia enacted provisions that effectively prohibit accumulator programs by requiring health care plans to apply any third-party payments such as copay assistance from manufacturers toward a patient's cost-sharing obligations.[162] In some instances, the accumulator prohibition only applies if there is no generic version of the prescription medication available or the patient has received permission to take the name brand drug through prior authorization, step therapy, or an issuer's appeals process.[163] This is a rapidly evolving area with significant variation at the PBM, plan, and manufacturer level.
- **Value-based contracts.** Manufacturers and payers are increasingly negotiating agreements to link the purchase price to clinical outcomes or financial measures, especially for high-cost specialty drugs. These arrangements are sometimes referred to as Outcomes Based Contracts ("OBCs") and Performance Based Risk Sharing Agreements ("PBRSAs").[164] To date, Medicaid's "best price" requirement represents a key challenge to adopting such value-based arrangements, as the terms of such agreements can lead to significant variance in pricing at the per-patient level and potentially drop unit prices for certain patients below the "best price" traditionally offered for the drug product. Manufacturers and payers must also comply with the federal Anti-Kickback Statute ("AKS"), which prohibits anyone from soliciting, receiving, offering, or paying any remuneration in return for a referral for an item or service that may be paid for by a federal health care program.[165] Statutory and regulatory safe harbors protect certain arrangements from AKS liability, including qualifying discount and warranty arrangements,[166] but it is unclear how enforcement agencies would apply these safe harbors to value-based contracting arrangements. VBC arrangements may also raise issues related to off-label promotion, for instance if there is a need to share data on potential outcomes that are helpful to identify value but are not otherwise included in labeling. FDA guidance expressly permitting the communication of health care

economic information ("HCEI") consistent with approved labeling lowers the risk related to such communications, and FDA has stated explicitly that it does not regulate contract terms for value-based arrangements.[167]

- **Cost-effectiveness assessments.** PBMs and payers make coverage determinations based on certain cost-effectiveness information, including, where available, formal assessments conducted by the Institute for Clinical and Economic Review ("ICER"). ICER is a nongovernmental entity that, similar to HTAs in other countries such as the National Institute for Health and Care Excellence ("NICE"), produces reports analyzing evidence on the effectiveness and value of drugs and other medical services in the U.S.[168] ICER's assessments evaluate two concepts: long-term value for money; and short-term affordability.[169] The assessments utilize the Quality-Adjusted-Life-Year ("QALY") to compare incremental cost-effectiveness of care options, with a health-benefit price benchmark of $100,000 to $150,000 per additional QALY.[170] Although ICER cannot directly control coverage decisions, ICER has become increasingly important in payer and PBM coverage and utilization determinations. For example, CVS Caremark has initiated a program allowing clients to exclude drugs from coverage if they are launched at a price exceeding $100,000 per QALY in analyses carried out by ICER.[171] ICER has received criticism for failing to include all evidence supporting clinical and economic benefits, lack of transparency in its assessments, and failing to incorporate enough of a patient-centered perspective, among other concerns.[172]

Efforts to facilitate access

A. Manufacturer financial assistance

Manufacturers frequently provide financial assistance or free product to patients to facilitate access. Such assistance may include manufacturer-sponsored patient assistance programs ("PAPs") (i.e. free drugs or diagnostic services), commercial copay assistance (i.e. copay coupons), and assistance provided by independent, third-party charitable entities (often referred to as "independent charity PAPs"). Eligibility for these types of programs may depend on income level, insurance status, and type of insurance. Additionally, manufacturers often provide other support services, such as assistance with navigating insurance coverage for specialty drugs.

Financial assistance to patients is highly regulated, particularly where this assistance is provided by drug manufacturers. The AKS limits the ability of manufacturers to provide coupons or discounts to patients enrolled in government health care programs, prohibiting manufacturers from providing direct subsidies to offset their out-of-pocket expenses for copays and deductibles.[173] Although free drug programs for financially needy patients have historically not raised extensive concerns under anti-kickback laws, the Office of Inspector General ("OIG"), which is tasked with identifying and combating waste, fraud, and abuse within HHS, has articulated concerns with PAPs related to Medicare Part D.[174] For example, PAPs and copay coupons may increase costs to the federal government under Medicare Part D because cost-sharing subsidies for Part D-covered drugs count toward patients' true out-of-pocket expenses ("TrOOP") and will therefore increase the number of beneficiaries who qualify for catastrophic benefit in any given coverage year and the point during the year at which they reach the catastrophic benefit.[175] PAPs may also have the effect of locking beneficiaries into the manufacturer's products, even if there are other equally effective, less costly alternatives, and patients may transition from a PAP to a government program such as Medicare Part D at some point in time.[176] The OIG has also scrutinized charitable organizations that are not truly independent from manufacturer donors.[177] For example, OIG is concerned about independent charity PAPs defining disease-specific funds so narrowly that a donor earmarking funds for a given disease fund effectively results in subsidization of the donor's own products.[178]

B. Coverage of off-label use

In general, drug products must have FDA approval to be reimbursed by public or private payers. Coverage for "off-label" use of approved products – drugs used for a different disease or medical condition, given in a different way, or given in a different dose than specified in the approved label[179] – may be available in certain circumstances. For example, Medicare Part D covers drugs prescribed for off-label use if the drugs are listed in CMS-recognized compendia for determining medically accepted indications.[180] Under Part B, reimbursement for off-label use is permitted if the MAC determines the use to be medically accepted, taking into account the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.[181] State Medicaid programs mandate coverage of off-label uses where the drug is listed in CMS-recognized compendia.[182] Additionally, many states also currently require Medicaid programs and private payers to cover off-label use of drugs that meet certain criteria, with some requiring off-label coverage only for certain disease states such as cancer or other life-threatening or chronic and seriously debilitating conditions, and others mandating off-label coverage more broadly.[183] Off-label use is particularly widespread in oncology, where payers often use independent National Comprehensive Cancer Network Drugs and Biologics Compendium ("NCCN") guidelines to cover off-label treatments.

Off-label use remains controversial. On the one hand, off-label use may represent a physician's determination regarding which treatment would be medically appropriate for a given patient and is an important aspect of the physician-patient relationship. On the other hand, many off-label uses are being prescribed without strong evidence of their safety or efficacy in treating the off-label indication, raising patient safety concerns.[184] In any case, communications regarding off-label use outside of the physician-patient relationship are highly regulated, and manufacturers are prohibited from promoting drug products for any off-label use (although certain communications with payers or other communications consistent with labeling may be permissible).[185]

C. Expanded access and right to try

Even if reimbursement for unapproved drugs is not available, patients may gain access to investigational drug products through FDA's expanded access or "compassionate use" program. Expanded access allows patients with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

There are three types of expanded access INDs: individual patient expanded access INDs, including for emergency use;[186] intermediate-size patient population expanded access INDs;[187] and treatment INDs for widespread use.[188] In all cases of expanded access use, FDA must determine that: (1) the patient(s) to be treated "have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy"; (2) the potential patient benefit justifies the potential risks, and the risks are reasonable given the disease or condition to be treated; and (3) granting the expanded access "will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use".[189] Additional criteria apply to each type of expanded access.

As a separate pathway, federal and state "right to try" laws permit patients with life-threatening diseases to access certain unapproved therapies without going through the FDA expanded access process. Following recent enactment of state-level laws in a significant majority of states,[190] the federal Right to Try Act was signed into law in 2018 to permit access to investigational drugs.[191] Under the federal Act, eligible patients must be diagnosed with a life-threatening disease or condition, have exhausted approved treatment options and be

unable to participate in a clinical trial involving the eligible investigational drug, and have provided written informed consent.[192] Manufacturers have discretion over whether to make their products available to patients who qualify for access under the law.

Policy issues that affect pricing and reimbursement

Cost of innovation, U.S. drug pricing, and "Foreign Underpricing"

Amidst global controversy over the high prices of innovative drug products, there is increasing debate regarding whether drug prices reflect the cost of innovation and, if so, whether this cost is appropriately distributed.

According to one study, the cost to develop a new prescription drug that gains marketing approval was estimated to be $2.6 billion as of 2013.[193] This is a significant increase from $802 million in 2003 (approximately $1 billion in 2013 dollars), representing a 145% increase in the 10-year time period between studies. Accounting for post-approval research and development ("R&D"), the cost of total development increases to nearly $2.9 billion.[194] Key drivers of this significant price tag include high failure rates for potential clinical drug candidates (an estimated seven out of eight compounds that enter the clinical testing pipeline fail in development) as well as high out-of-pocket clinical costs for drug trials, including increased complexity or clinical trial design and larger trials, higher cost of inputs, increased focus on targeting chronic and degenerative diseases, changes in protocol design to include efforts to gather health technology assessment information, and testing on comparator drugs to accommodate payer demands for comparative effectiveness data.[195]

The cost of this development appears to fall disproportionately on the U.S., where drug prices far outpace prices in other countries. For example, a recent HHS report found that drug acquisition costs in the U.S. exceed those in Europe, Canada, and Japan.[196] Among the 27 drug products included in HHS's analysis, acquisition costs in the U.S. for Medicare Part B drugs were 1.8 times higher than in comparator countries.[197] Other analyses indicate that this price disparity may be even higher. For example, a study conducted by the Johns Hopkins Bloomberg School of Public Health found that prices for 79 brand-name prescription drugs averaged 3.2 to 4.1 times higher in the U.S. compared with other countries.[198]

The CEA recently issued a report evaluating how the costs and benefits of medical innovation are distributed across developed nations. According to the CEA, while "[t]he U.S. Government and the biopharmaceutical industry have been critical to improving health worldwide by leading the way in the [R&D]", "foreign countries often do not make equal investments in the R&D that is necessary to fuel innovation and ensure the economic viability of biopharmaceutical products".[199] The report found that foreign "free-riding" has increased over the past 15 years, with patented drug prices in European countries falling from 51% of U.S. prices in 2003 to about 32% of U.S. prices in 2017.[200] The CEA concluded that "[f]oreign governments have implemented stricter price controls, enabling these products to be sold below fair market value, with Americans picking up the tab for making the availability of such products feasible in the first place", leading to a "slower pace of innovation" and "fewer potential new life-saving therapies for patients in all countries".[201] By contrast, "[r]educing foreign price controls would increase profits and innovation, thereby leading to greater competition and lower prices for U.S. patients".[202]

Addressing U.S. drug prices has been the subject of significant debate. Reform proposals range from addressing payment and reimbursement of drug prices in the U.S. (see discussion below), to exercising trade policy tools to combat drug pricing practices in foreign markets.[203] Additionally, states are actively considering proposals that would address drug pricing practices by a variety of mechanisms.

Transparency in setting drug prices

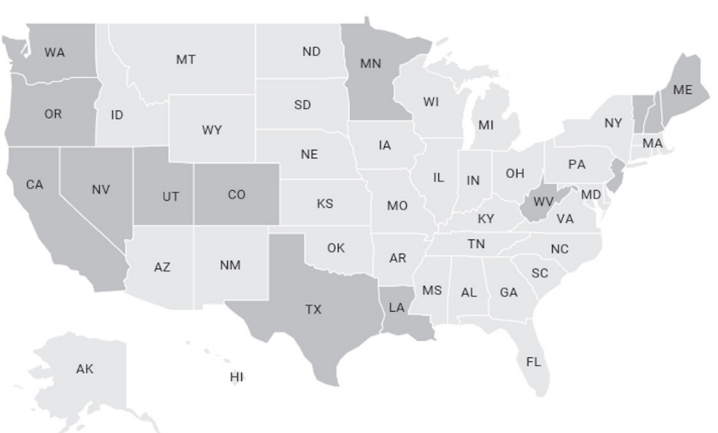
A number of states have enacted laws requiring drug price reporting by manufacturers, payers, PBMs, and other entities. These laws are designed to incentivize manufacturers to lower drug prices by requiring them to report information about launch prices and price increases, as well as their justification for how drug prices are set.

While reporting requirements vary by state, these laws generally require manufacturers to report information regarding drug prices and drug price increases above a certain threshold. For example, California requires manufacturers to report price increases exceeding 16% of WAC,[204] whereas Oregon requires reporting for price increases exceeding 10% of WAC.[205] Both states also require reporting upon the introduction of new prescription drugs to market with a WAC that exceeds the Medicare Part D specialty drug threshold.[206] Oregon requires manufacturers to report this information to a state government agency,[207] whereas California also requires manufacturers to provide advance notice to certain purchasers.[208] Oregon also requires the submission of non-public information.[209] States that have collected such information have also begun publishing reports of the drug pricing information received from manufacturers, and relevant state agencies often send follow-up requests for information if initial submissions are deemed vague or incomplete. Failure to comply with state disclosure requirements can lead to significant penalties. For example, in late 2019 and early 2020, California fined more than a dozen manufacturers a total of $17.5 million for failing to report information required under the state drug pricing transparency law.[210]

States also have adopted other mechanisms for price reporting, such as authorizing an independent board to compile a list of drugs on which the state spends significant dollars and/or for which the WAC has increased significantly over a period of time (e.g., Connecticut).[211] Manufacturers of the drugs identified by the board are required to report certain information about the drugs' costs and pricing. Reporting requirements in some states apply only to certain types of drugs. For example, Nevada's drug price transparency law initially applied only to certain drug products essential for diabetes treatment.[212] In 2019, Nevada expanded the law to apply to drugs essential for asthma treatment as well.[213]

Although state laws requiring drug price reporting are proliferating, a number of these laws have been subject to legal challenges or struck down by the courts.[214]

Figure 11: State drug pricing transparency laws[215]



Emerging trends

International Pricing Index ("IPI") model for Medicare Part B

Given that Medicare Part B covers many of the highest cost drug products, on October 25, 2018, the Trump administration released an Advance Notice of Proposed Rulemaking ("ANPRM") on a proposal to tie Medicare Part B reimbursement rates to an international pricing index ("IPI").[216] Under this model, the following changes would apply for qualifying drug products and participants in Medicare Part B:

- CMS would contract with private-sector entities to serve as vendors that would negotiate drug acquisition prices with manufacturers. These vendors would then supply health care providers with the drugs to provide to patients and submit claims to Medicare for reimbursement.
- CMS would reimburse vendors based on a "Target Price", which would be calculated based on the drug's average price in fourteen "economically-similar" countries: Austria; Belgium; Canada; Czech Republic; Denmark; Finland; France; Germany; Greece; Ireland; Italy; Japan; the Netherlands; and the United Kingdom. HHS has stated that the Target Price would equal 126% of the average international price.[217] If the drug's ASP is lower than the Target Price, then reimbursement would be set at ASP.
- CMS would pay health care providers a flat fee based on the historical 6% add-on payment the providers typically would have received under the "buy-and-bill" system. Providers would also continue to receive an administrative fee.

The IPI Model would initially focus on Part B single-source drugs, biologicals, and biosimilars, as well as drugs that are technically multi-source but have only a single manufacturer. The IPI Model proposes to include 50% of all Medicare Part B spend based on physician practices and hospital outpatient departments ("HOPDs") in select geographic regions to participate in the IPI Model. The remaining practices and HOPDs would continue to operate under the existing "buy-and-bill" system.

Although the Trump administration originally proposed to follow this ANPRM with a proposed rule in 2019 with implementation planned for 2020, the proposed rule has not yet been issued. It is unclear when the proposed rule might be released or whether the proposed rule will meaningfully differ from the ANPRM (e.g., by expanding to Part D drugs). Critics argue the IPI model would inappropriately tie reimbursement to faulty health technology assessments conducted in other jurisdictions and adversely impact pharmaceutical innovation in the U.S. Legal challenges to the rule are anticipated.

The Administration's proposal follows prior efforts to overhaul the reimbursement structure under Medicare Part B. In 2006, as required by the 2003 Medicare Modernization Act, CMS launched the Competitive Acquisition Program ("CAP") as an alternative to the buy-and-bill system. Under CAP, providers could acquire certain Part B drugs through third-party vendors.[218] CAP was suspended in 2008 after facing significant implementation challenges. Additionally, in March 2016, CMS proposed the "Part B Drug Payment Model", which would have changed the 6% add-on to 2.5% plus a flat fee, with phased-in value-based purchasing payment structures.[219] CMS withdrew this proposal due to "complexity of the issues".[220]

Other proposals related to drug pricing

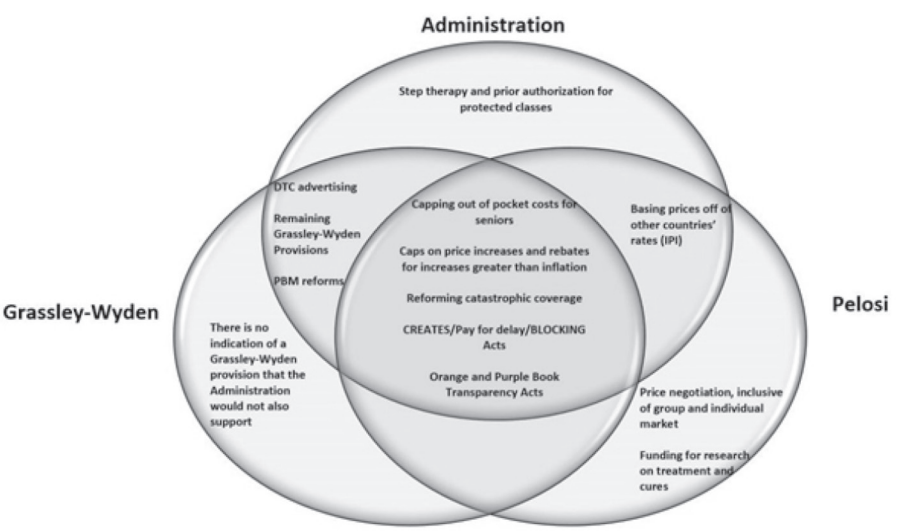
Several legislative proposals also contemplate significant reform to Medicare and Medicaid reimbursement based on international reference pricing or other mechanisms. For example, the Prescription Drug Pricing Reduction Act ("PDPRA") of 2019 (also known as the Grassley-Wyden bill) is a bipartisan bill in the U.S. Senate that proposes to: (a) penalize

manufacturers for price increases above inflation on Medicare Part B and Part D drugs by requiring manufacturers to pay additional rebates to Medicare if they increase their relevant prices (Average Sales Price in Part B, list price in Part D) more rapidly than the inflation rate; (b) cap patients' out-of-pocket costs in Part D (starting at $3,100 in 2022) and redesign the responsibilities within the benefit structure to incentivize plans to negotiate prices; (c) adjust incentives under Part B by reducing payments for new single-source drugs from 106% to 103% of WAC, among other changes; (d) exclude authorized generics from the calculation of Average Manufacturer Price in Medicaid; (e) improve information disclosure, including with respect to ASP reporting and drug pricing/rebates; and (f) create easier process for state Medicaid programs to engage in risk-sharing value-based agreements with manufacturers. The CBO estimates beneficiaries will save $27 billion in OOP over a 10-year period from Part D redesign and inflation-rebate policies (approximately $20 billion and $7 billion, respectively).[221]

The Lower Drug Costs Now Act of 2019 (also known as the Pelosi bill) is a partisan bill with 106 Democratic co-sponsors in the U.S. House of Representatives. In addition to including an out-of-pocket cap for Medicare Part D drugs and limiting price increases to the inflation rate like the Grassley-Wyden bill above, the bill would: (a) allow the HHS secretary to directly negotiate prices on the 250 drugs posing the greatest total cost to Medicare and the U.S. health system that do not have at least two competitors (includes some insulins, cancer treatments and specialty drugs); (b) set the maximum price for the negotiated prices at 1.2 times the average price of the drug in six foreign countries (Australia, Canada, France, Germany, Japan, and the United Kingdom); and (c) steeply fine drug companies if they don't participate in the negotiation process or abide by the agreed-on price.[222]

In addition to supporting the IPI Model, the Trump Administration has advanced several proposals both consistent with and inconsistent with potential legislation. Figure 12 illustrates the commonalities and differences among these proposals.

Figure 12: Comparing legislative and executive proposals[223]



Democratic frontrunner Joe Biden's platform largely aligns with the House bill.[224] Thus, regardless of who wins the 2020 election, drug pricing issues are likely to remain at the forefront of national politics. The COVID-19 pandemic has also brought forth proposals for pricing control and march-in rights with respect to COVID-19 treatments.[225]

Status and future of the Affordable Care Act

In 2010, the U.S. Congress enacted the ACA,[226] which was the most significant regulatory overhaul and expansion of coverage since the creation of Medicare and Medicaid in 1965. The ACA implemented numerous reforms aimed at making affordable health insurance available to more people and decreasing the rate of uninsured Americans. For example, the ACA:

- required most individuals to purchase insurance (the so-called "Individual Mandate");
- expanded Medicaid eligibility to individuals with incomes up to 138% of the FPL for individuals under age 65;
- prevented insurers from denying coverage to individuals with pre-existing conditions;
- created health insurance exchanges through which individuals could buy insurance and provided premium and cost-sharing subsidies to households with incomes between 100% and 400% of the FPL;
- required employers of a certain size to offer health insurance to their employees; and
- mandated that all individual and small group plans cover certain "essential health benefits", including prescription drugs.[227]

Since the ACA was enacted in 2010, an additional 20 million Americans have gained health insurance.[228] However, the Act remains highly controversial. Republican legislators have worked to "repeal and replace" the ACA, most notably with the American Healthcare Act ("AHCA") in 2017, which failed in the Senate and thus was not enacted.[229] Since taking office, the Trump administration also has introduced regulations relaxing the essential health benefit requirements[230] and issued Executive Orders delaying or attempting to forestall the implementation of other ACA provisions.[231] The Tax Cuts and Jobs Act of 2017 effectively eliminated the individual mandate by reducing the tax penalty that the ACA imposed on individuals who refused to purchase health insurance to zero.[232]

The ACA also has faced constitutional challenges, including two petitions currently pending before the Supreme Court.[233] In 2012, the U.S. Supreme Court upheld the constitutionality of the individual mandate, holding that the penalty imposed on individuals who do not buy health insurance is a tax and thereby permissible under Congress's power to "lay and collect taxes".[234] Following the passage of the Tax Cuts and Jobs Act of 2017, a group of states and individuals challenged the mandate on the grounds that, because the tax penalty is now zero, it is not a tax and therefore the mandate is not constitutional.[235] These plaintiffs also argue that, because the mandate is such an integral part of the ACA, the entire Act should be invalidated. In March 2020, the Supreme Court agreed to review a decision by the U.S. Court of Appeals for the Fifth Circuit[236] on the constitutionality of the mandate and to review the constitutionality of the ACA overall. The Justices will hear oral arguments during the Court's next term, which begins in October 2020.[237]

Successful market access

As demonstrated by this chapter, the drug pricing and reimbursement infrastructure in the U.S. consists of a complex patchwork of policies and institutions. Successful market access requires navigating this infrastructure in a way that ensures drug products are available to patients, reimbursable by patients' health care plans, and appropriately valued. These efforts must be compliant with various overlapping regulatory requirements and minimize enforcement risk under the Anti-Kickback Statute, False Claims Act, and other federal and state laws.[238]

Accordingly, drug manufacturers and investors funding development of investigational products should consider the following in designing both U.S. and global market access strategies:

- **Access.** Manufacturers should evaluate the criteria for favorable coverage under various private and public plans and coordinate appropriate engagement with PBMs facilitating coverage with these payers, as well as the relative use by patients who are covered under government *versus* private payers and the likely settings of care for one time or chronic use of the product. Successful market access strategies will include plans for patient assistance and patient support services, pharmacy and wholesaler distribution networks, and other key features facilitating access to drug products.
- **Pricing.** Manufacturers should investigate the coverage, coding, and payment structures that will apply to their drug products for each payer type in the U.S. Pricing strategies should include conducting a reimbursement assessment, including comprehensive coding and payment analysis across all relevant settings of care, and developing rebate bidding and contracting strategies, preparing payer budget impact moles, conducing payer market research, and using HCEI to support the proposed pricing structure. Manufacturer list and net pricing scenarios for new products must account for all supply chain concessions over a multi-year time horizon with growing limitations on ability to increase pricing year over year, as well as model impacts based on government price reporting obligations (e.g., best price, AMP, and ASP) and mandatory rebate liabilities (e.g., MDRP).
- **Value.** Manufacturers should develop appropriate evidence, including real world evidence, and messaging to communicate the value proposition for their drug products, including by developing a thorough understanding of the prescribing pathway, comparator treatments, quality measures, patient need, and direct and indirect costs of treatment with the new drug. Manufacturers should prepare to demonstrate the cost-effectiveness of drug products, in the event of a potential ICER assessment or requests for such information from payers more generally. Consideration should be given to potential value-based pricing structures that link the purchase price to patient outcomes and product warranties, as well as provide more predictable cost outlays for both government and private payers.

If possible, manufacturers should develop U.S. market access strategies at least two years before approval and launch in the U.S. and integrate these strategies with global market access efforts. When appropriately structured, market access strategies can inform clinical development and clinical trial outputs, help guide positioning during the drug approval process, and facilitate market entry upon approval. Market access strategies also should include frequent review and updates based on changes in the U.S. reimbursement framework. The payers and programs involved in drug coverage and reimbursement are constantly evolving, and current or future proposals for reform and growing government enforcement activity focused on market access could significantly impact drug pricing in the U.S.

* * *

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38. U.S. Food & Drug Admin., *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022* 6, https://www.fda.gov/media/99140/download (last visited May 13, 2020).
39. *Id.*
40. Priority review is also available to manufacturers that have a priority review voucher or where other criteria are met. *See, e.g.*, U.S. Food & Drug Admin., *Guidance for Industry, Expedited Programs for Serious Conditions—Drugs and Biologics* 24–25 (May 2014), https://www.fda.gov/media/86377/download.
41. 21 U.S.C. §§ 356(a) (breakthrough therapy designation), 356(b) (fast track designation), 356(c) (accelerated approval); *see also* 21 C.F.R. part 314, subpart H; 21 C.F.R. part 601, subpart E; U.S. Food & Drug Admin. *Guidance for Industry, Expedited Programs for Serious Conditions—Drugs and Biologics* (May 2014), https://www.fda.gov/media/86377/download. Additional pathways and designations may also be available. *See, e.g.*, 21 U.S.C. §§ 356(g) (Regenerative Advanced Therapy designation), 356(h) (Limited Population Pathway for Antibacterial and Antifungal Drugs), 355f(d) (Qualified Infectious Disease Product designation).
42. 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii); 21 C.F.R. § 314.108.
43. 21 C.F.R. § 314.108(b)(2). An NDA or ANDA can be submitted after four years if it contains a certification of patent invalidity or noninfringement.
44. 21 U.S.C. §§ 355(c)(3)(E)(iii), 355a(b), 360cc(a); 42 U.S.C. § 262(k)(7); 21 C.F.R. §§ 314.108, 316.31.
45. 21 U.S.C. §§ 360n, 360ff, 360bbb-4a.
46. In many cases, the definitions provided herein are summaries of statutory or regulatory definitions.
47. 42 C.F.R. § 447.502.
48. 42 U.S.C. § 1396r-8(k)(1).
49. *Id.* § 1395w-3a(c)(1).
50. Medicaid & CHIP Payment & Access Comm'n, *Medicaid Payment for Outpatient Prescription Drugs* 11 (May 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
51. 42 U.S.C. § 1396r-8(c)(1)(C).
52. *Id.* § 1395w-3a(c)(6)(B).

53. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. XVIII, 79 Stat. 286, 291–343 (1965).
54. *Id.* § 1395y(a)(1)(A).
55. *Id.* § 1395c *et seq.*
56. *Id.* § 1395kk-1.
57. *Id.* §§ 1395ff(f)(1)(B), 1395ff(f)(2)(B); *see also* Ctrs. for Medicare & Medicare Servs., *Medicare Program Integrity Manual*, ch. 13, § 13.1.1, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf (last updated Feb. 12, 2019).
58. 42 U.S.C. § 1395j *et seq.*
59. *Id.* § 1395k(a).
60. Some low-income beneficiaries may qualify for premium and cost-sharing assistance, either by qualifying for full Medicaid benefits or Medicare Savings Programs. *Id.* § 1396u-3.
61. *Id.* § 1395kk-1.
62. *Id.* §§ 1395j-1395w-6.
63. *Id.* § 1395w-21. MA plans are either local plans that serve a particular area, or regional plans that contract with CMS to provide services to one or more defined regions. Beneficiaries may choose to enroll in MA if there is a plan offered in their area. *Id.* § 1395w-28(4)–(5).
64. *Id.* § 1395w-22(a).
65. *Id.* § 1395w-22(a)(3); 42 C.F.R. § 422.100(c).
66. 42 U.S.C. § 1395w-131.
67. *Id.* § 1395w-101.
68. *Id.* § 1395w-104(b)(3)(C); *see also id.* § 1395w-104(b)(3)(G) (setting forth specified categories for which plans must include all covered Part D drugs). CMS automatically approves formulary classification systems that are consistent with the U.S. Pharmacopeia ("USP") category and class system. Alternative classification systems must be reviewed by CMS to determine if they are sufficiently similar to the USP or other common systems, such as the American Hospital Formulary Service classification system. Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual*, ch. 6 § 30.2.1, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (last updated Jan. 1, 2016).
69. 42 C.F.R. § 423.272(b)(2); *see also generally* Cong. Research Serv., *Medicare Part D Prescription Drug Benefit* (Aug. 13, 2018), https://crsreports.congress.gov/product/pdf/R/R40611.
70. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k).
71. 42 U.S.C. § 1395w-102(e); 42 C.F.R § 423.100.
72. 42 U.S.C. § 1395ff.
73. Ctrs. for Medicare & Medicaid Servs., *Medicare Program Integrity Manual*, ch. 13, § 13.2.2.3, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf (last updated Feb. 12, 2019).
74. Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Manual*, ch. 6, § 30, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (last updated Jan. 15, 2016); *see also* Ctrs. for Medicare & Medicaid Servs., *Medicare Managed Care Manual*, ch. 4, § 10.1, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf (last updated Apr. 22, 2016) (referring to the "Medicare Prescription Drug Manual" for requirements prescription drug coverage).

75. 42 U.S.C. § 1395w-104(b)(3)(A); 42 C.F.R. § 423.120(b)(1); *see also* Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.1.5, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (last updated Jan. 15, 2016).
76. 42 C.F.R. § 423.120(b)(2)(i).
77. 42 U.S.C. § 1395w-104(b)(3)(G)(iv). These classes of drugs are often referred to as "protected classes".
78. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983).
79. 42 U.S.C. § 1395cc(a)(1)(H).
80. 42 C.F.R. § 412.2.
81. *Id.* § 412.60.
82. *Id.* § 412.2(f).
83. *Id.* §§ 412.150-412.172.
84. *Id.* § 412.22.
85. Medicare Payment Advisory Comm'n, *Hospital Acute Inpatient Services Payment System* 2 (Oct. 2019), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_hospital_final_v2_sec.pdf?sfvrsn=0.
86. *See* 42 U.S.C. §§ 1395k(a)(1) (providing for coverage of medical or other health services), 1395x(s)(2) (defining medical and other health services to include drugs not usually self-administered).
87. 42. C.F.R. § 419.2(a).
88. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).
89. 42 U.S.C. § 1395w-3a(b). For certain drug products that lack ASP data, reimbursement payments may be calculated using the WAC. *Id.* § 1395w-3a(c)(4). WAC may also be used if lower than the ASP. *Id.* § 1395w-3a(b)(4).
90. *Id.* § 1395w-3a(c)(1).
91. *Id.* § 1396r-8(b)(3).
92. For example, manufacturers of products paid as drugs under Part B but considered devices by Medicaid (and FDA) often do not have rebate agreements and thus would not be required to report ASPs. *See, e.g.*, Office of Inspector General, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, OEI-12-13-00040, 8 n.24 (July 2014), https://oig.hhs.gov/oei/reports/oei-12-13-00040.asp.
93. Ctrs. for Medicare & Medicaid Servs., *Medicare Claims Processing Manual*, ch. 17, § 20.1.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf (updated Aug. 30, 2019).
94. 42 U.S.C. § 1395w-3a(b); 42 C.F.R. § 414.904. The Budget Control Act of 2011 included sequestration requirements that reduced the payment rate for Part B to 4.3%. *See* Pub. L. No. 112-25, § 302, 125 Stat. 240, 256, 258-59 (2011). Additionally, for new drug products reporting WAC instead of ASP, the statutory reimbursement rate for these drugs is WAC plus 3%. 42 U.S.C. § 1395w-3a(c)(4) (amended from WAC plus 6% pursuant to Sustaining Excellence in Medicaid Act of 2019, Pub. L. No. 116-39, § 6, 133 Stat. 1062 (2019), following CMS rulemaking that had previously reduced this amount).
95. 42 U.S.C. § 1395*l*(a)(1).
96. 42 C.F.R. § 419.2(b); Ctrs. for Medicare & Medicaid Servs., *Medicare Claims Processing Manual*, ch. 17, § 20.1.3, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf (last updated Aug. 30, 2019).
97. Ctrs. for Medicare & Medicaid Servs., *Medicare Claims Processing Manual,* ch. 17, §

10, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf (last updated Aug. 30, 2019).

98. 42 U.S.C. § 1395u(o)(1)(C); 84 Fed. Reg. 61142, 61145 (Nov. 12, 2019). The reimbursement rate of ASP minus 22.5% for 340B-acquired Part B drugs is currently being challenged in federal court. *See American Hosp. Ass'n v. Azar*, 385 F. Supp. 3d. 1 (D.D.C. 2019).
99. 42 U.S.C. § 1395w-23; 42 C.F.R. § 422.304.
100. 42 C.F.R. § 422.304(b).
101. 42 U.S.C. § 1395w-102(a).
102. 42 C.F.R. § 423.104.
103. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 3301-3315, 124 Stat. 119, 461-80 (2010).
104. For brand-name drug products purchased by beneficiaries in the coverage gap, manufacturers provide a 70% discount and Medicare pays an additional 5%. For generic drug products, Medicare pays 75% of the cost. Ctrs. for Medicare & Medicaid Servs., *2020 Medicare Advantage and Part D Advance Notice Part 2 and Draft Call Letter* (Jan. 30, 2019), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf.
105. Medicare Payment Advisory Comm'n, *Part D Payment System* 2 (Oct. 2019), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_partd_final_sec.pdf?sfvrsn=0.
106. 42 U.S.C. § 1395w-115.
107. Cong. Research Serv., *Medicare Part D Prescription Drug Benefit* (Aug. 13, 2018), https://crsreports.congress.gov/product/pdf/R/R40611.
108. 42 U.S.C. § 1395w-111(i).
109. Medicare Payment Advisory Comm'n, *Part D Payment System* 3 (2019), http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_19_partd_final_sec.pdf?sfvrsn=0.
110. Social Security Amendments of 1965, Pub. L. No. 89-97, tit. XIX, 79 Stat. 286, 343-53 (1965).
111. 42 U.S.C. § 1396a.
112. *Id.* § 1396a(a)(10). Other statutes and regulations promulgated by CMS also defined eligibility pathways. *See, e.g.*, *id.* § 1396v; 42 C.F.R. Part 435.
113. 42 U.S.C. §§ 1396b(m), 1395mm(a)(1).
114. *Id.* §§ 1396a, 1396u-7.
115. *Id.* §§ 1396a(a)(54), 1396u-7(b)(2)(A).
116. *See Medicaid Benefits: Over-the-Counter Products*, Kaiser Family Found., https://www.kff.org/other/state-indicator/medicaid-benefits-over-the-counter-products/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited May 14, 2020).
117. 42 U.S.C. § 1396u-5(d)(1).
118. *See generally id.* § 1396r-8.
119. *Id.* § 1396r-8(a)-(b).
120. *Id.* § 1396r-8(d)(2).
121. 42 C.F.R. § 447.53.
122. Medicaid Program: Covered Outpatient Drugs, 81 Fed. Reg. 5169, 5174-76, 5347 (Feb. 1, 2016) (codified at 42 C.F.R. § 447.502) (replacing the estimated acquisition cost ("EAC") with AAC).
123. *Id*. at 5176.

124. 42 C.F.R. § 447.502.
125. 42 U.S.C. § 1396a(a)(30)(A).
126. Medicaid & CHIP Payment & Access Comm'n, *Medicaid Payment for Outpatient Prescription Drugs* 6 (May 2018), https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf.
127. Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, Kaiser Family Found. (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.
128. For example, the Ohio state auditor released a report finding that state PBMs collected $208 million in fees for generic Medicaid prescriptions paid my managed care plans between April 1, 2017 and March 31, 2018. *See* Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* 2 (Aug. 16, 2018), https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.
129. *See* 42 U.S.C. § 1396r-8(e)(4).
130. *See id.* § 1396r-8(e)(5); 42 C.F.R. § 447.514. If the FUL is less than the average AAC for retail community pharmacies, FUL is calculated using a higher multiplier to reflect average retail community pharmacies' acquisition costs. 42 C.F.R. § 447.514.
131. Cong. Research Serv., *Medicaid Prescription Drug Pricing and Policy* 13 (Nov. 7, 2014), https://crsreports.congress.gov/product/pdf/R/R43778.
132. 42 C.F.R. § 447.512(b).
133. 42 U.S.C. § 1396r-8(b).
134. *Id.* § 1396r-8(c).
135. Cong. Research Serv., *Medicaid Prescription Drug Pricing and Policy* 17 (Nov. 7, 2014), https://crsreports.congress.gov/product/pdf/R/R43778.
136. The 340B program was established in 1992 through section 340B of the Public Health Services Act. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (1992) (enacting Section 340B of the Public Health Service Act). 340B is administered by Health Resources and Services Administration ("HRSA"), an agency within HHS, through HRSA's Office of Pharmacy Affairs ("OPA"), and effectuated through the Pharmaceutical Pricing Agreement and addendum (collectively "PPA").
137. Mike McCaughan, *The 340B Drug Discount Program*, Health Affairs (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171024.663441/full/.
138. 42 U.S.C. § 256b.
139. *See e.g.*, Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0540.
140. Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821-22 (2010); Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010); Stephen Barlas, *Health Care Reform Bill Expands Access to Section 340B Discounted Drugs for Hospitals*, 35 Pharmacy & Therapeutics 632, 632-34 (2010).
141. Avalere, *Hospital Acquisitions of Physician Practices and the 340B Program* 4 (June 2015), https://avalere.com/insights/avalere-white-paper-hospital-acquisitions-of-physician-practices-and-the-340b-program.
142. Adam J. Fine, *Exclusive: 340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospital Charity Care Flatlines*, Drug Channels (May 14, 2019), https://www.drugchannels.net/2019/05/exclusive-340b-program-purchases-reach.html; Adam J. Fine, *Exclusive: 340B Program Hits $16.2 Billion in 2016; Now 5% of U.S. Drug Market*, Drug Channels (May 18, 2017), https://www.drugchannels.net/2017/05/exclusive-340b-program-hits-162-billion.html.

143. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (effective Jan. 1, 2018).
144. *American Hosp. Ass'n v. Azar*, 385 F. Supp. 3d. 1 (D.D.C. 2019).
145. Edward R. Berchick *et al.*, *Health Coverage in the United States: 2018,* U.S. Census Bureau 3 (Nov. 2019), https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf.
146. Pub. L. No. 111-148, § 1511, 124 Stat. 119, 252 (2010); *Minimum Value and Affordability*, Internal Revenue Serv., https://www.irs.gov/affordable-care-act/employers/minimum-value-and-affordability (last visited May 15, 2020).
147. Karen Pollitz *et al.*, *What's The Role of Private Health Insurance Today and Under Medicare-for-all and Other Public Option Proposals?*, Kaiser Family Found. (Jul. 30, 2019), https://www.kff.org/health-reform/issue-brief/whats-the-role-of-private-health-insurance-today-and-under-medicare-for-all-and-other-public-option-proposals/.
148. The Health Insurance Marketplaces were created under the ACA. *See* Pub. L. No. 111–148, 124 Stat. 119 (2010).
149. Many of those covered by government programs have some form of coverage through a private health insurer. This includes Medicaid enrollees covered by MCOs, which contract with MCOs, Medicare enrollees in Medicare Advantage Plans, and traditional Medicare enrollees who have supplemental private coverage, including Medicare Part D stand-alone prescription drug plans.
150. *Health Policy Brief Series: Pharmacy Benefit Managers*, Health Affairs 1 (Sept. 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.
151. *See, e.g.*, U.S. Dep't of Health & Hum. Servs., *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.
152. Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 84 Fed. Reg. 2,340 (Feb. 6, 2019).
153. Neeraj Sood *et al.*, *Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System*, Health Affairs Blog (June 13, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170613.060557/full/.
154. Transcript, Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance, 116th Cong. (Apr. 9, 2019) (unofficial transcript available through CQ.com) (statement of Senator Grassley, citing information reported by the U.S. Department of Justice).
155. *See, e.g.*, *id.*; *see also* Statement of Steve Miller, M.D. Executive Vice President & Chief Clinical Officer Cigna Corporation, Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the S. Comm. on Finance, 116th Cong. (Apr. 9, 2019), https://www.finance.senate.gov/imo/media/doc/Cigna%20ExpressScripts%20Testimony%20of%20Steven%20Miller%20MD.pdf ("The 2018 Cigna Value of Integration Study shows that clients with Cigna medical, pharmacy, and behavioral benefits reduce annual medical costs by an average of $645 for each person with an identified health improvement opportunity—savings that can increase to nearly $10,000 for individuals with certain chronic conditions.").
156. *The Prescription Drug Landscape, Explored*, Pew Charitable Trust (Mar. 8, 2019), https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored.
157. *Id.*

158. Two of the nation's largest PBMs, CVS Caremark and ESI, own 50% of Surescripts, the nation's leading e-prescribing network. Surescripts is subject to an open Federal Trade Commission investigation.
159. As of 2019, this includes Florida, Kansas, Kentucky, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Puerto Rico, Vermont, and Washington. *See* Nat'l Conference of State Legislatures, *Prescription Drug Resource Center: Generic Drug Substitution Laws*, (May 3, 2019), https://www.ncsl.org/portals/1/documents/health/Generic_Drug_Substitution_Laws_32193.pdf.
160. *Id.*
161. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans, 85 Fed. Reg. 29164 (May 14, 2020) (revising 42 C.F.R. § 156.130).
162. *See, e.g.*, H.B. 2166, 54th Leg., 1st Sess. (Ariz. 2019); H.B. 465, 101st G.A. (Ill. 2019); S.B. 1596, 2019 Sess. (Va. 2019); H.B. 2770, 2019 Sess. (W. Va. 2019).
163. H.B. 2166, 54th Leg., 1st Sess. (Ariz. 2019).
164. *See* Daniel S. Mytelka *et al.*, *Managing Uncertainty in Drug Value: Outcomes-Based Contracting Supports Value-Based Pricing*, Health Affairs Blog (Jan. 30, 2020), http://healthaffairs.org/do/10.1377/hblog20200128.542919/full/; *Performance Based Risk Sharing Database*, University of Washington, https://sop.washington.edu/department-of-pharmacy/research/performance-based-risk-sharing-database/ (last visited May 14, 2020).
165. 42 U.S.C. § 1320a-7b(b).
166. 42 U.S.C. § 1320a-7b(b)(3)(A); 42 C.F.R. § 1001.952(g)-(h).
167. U.S. Food & Drug Admin., *Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers* (June 2018), https://www.fda.gov/media/133620/download.
168. *See generally*, Inst. for Clinical & Econ. Rev., https://icer-review.org/. Additionally, ICER has published reports such as its "Report on Unsupported Price Increases" calling attention to drug products it determined had "price increases unsupported by new clinical evidence". David M. Rind *et al.*, *Unsupported Price Increase Report: 2019 Assessment*, Inst. for Clinical & Econ. Rev. (Oct. 8, 2019), https://icer-review.org/wp-content/uploads/2019/01/ICER_UPI_Final_Report_and_Assessment_100819_Final.pdf.
169. *2020–2023 Value Assessment Framework*, Inst. for Clinical & Econ. Rev. (Jan. 31, 2020), https://icer-review.org/wp-content/uploads/2019/05/ICER_2020_2023_VAF_013120-3.pdf.
170. *Id*.
171. *Current and New Approaches to Making Drugs More Affordable*, CVS Health (Aug. 2018), https://cvshealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf.
172. *See, e.g.*, Letter from Robert Dubois, MD, Chief Science Officer, *et al.*, National Pharmaceutical Council, to Steven Pearson, MD, President, Institute for Clinical and Economic Review (June 10, 2019), https://www.npcnow.org/newsroom/commentary/npc-public-comments-icer-2020-value-assessment-framework; Letter from Robert Dubois, MD, Chief Science Officer, *et al.*, National Pharmaceutical Council, to Steven Pearson, MD, President, Institute for Clinical and Economic Review (Mar. 30, 2017), https://www.npcnow.org/newsroom/commentary/npc-comments-proposed-updates-icers-value-assessment-framework.
173. 42 U.S.C. § 1320a-7a(i)(6).
174. Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

175. *Id.* at 70,625–26.
176. *Id.* at 70,626.
177. Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014).
178. *Id.* at 31,121.
179. *Off-Label Drug Use*, Am. Cancer Soc'y, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/off-label-drug-use.html (last visited May 13, 2020).
180. CMS-recognized compendia include the American Hospital Formulary Service-Drug Information ("AHFS-DI") and DrugDex Information System ("DrugDex"). Ctrs. for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual*, ch. 6, § 10.6, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf (last revised Jan. 15, 2016).
181. Ctrs. for Medicare & Medicaid Servs., *Medicare Benefit Policy Manual*, ch. 15, § 50.4.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf (last revised July 12, 2019). Cancer drugs must be covered-off label if listed in one of five compendia—AFHS-DI, DrugDex, the NCCN, Clinical Pharmacology, and Lexi-Drugs. Contractors are also permitted to rely on peer-reviewed research published in one of 26 specified journals. *Id*. § 50.4.5.
182. 42 U.S.C. § 1396r-8 (stating that the program shall assess data on drug use against predetermined standards consistent with AFHS-DI, DrugDex, and a third compendium that is no longer published).
183. *See*, *e.g.*, N.Y. Ins. Law § 3221 (requiring payers to cover drugs prescribed for a different type of cancer than the type for which it was approved, provided that the drug has been recognized in AHFS-DI, NCCN, DrugDex, Clinical Pharmacology, or other authoritative compendia as identified by HHS or CMS or recommended by review article or editorial comment in a major peer reviewed professional journal, unless the drug has been determined to be contraindicated for the specific type of cancer for which it is being prescribed); Md. Ins. § 15-804 (prohibiting the exclusion of a coverage if the off-label use is recognized for treatment in "any of the standard reference compendia or in the medical literature").
184. *See*, *e.g.*, Tewodros Eguale *et al.*, *Association of Off-Label Drug Use and Adverse Drug Events in an Adult Population*, 176 JAMA Intern. Med. 55 (2016) (finding that four in five off-label prescriptions lacked strong scientific evidence, and that patients on these drugs had higher rates of adverse drug events).
185. *See, e.g.*, 21 U.S.C. §§ 331(a), (d), 355; *see also* U.S. Food & Drug Admin., *Medical Product Communications that are Consistent with the FDA-Required Labeling—Questions and Answers* (June 2018), https://www.fda.gov/media/133619/download; U.S. Food & Drug Admin., *Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers* (June 2018), https://www.fda.gov/media/133620/download.
186. 21 C.F.R. § 312.310.
187. 21 C.F.R. § 312.315.
188. 21 C.F.R. § 312.320.
189. 21 C.F.R. § 312.305(a)(1)–(3).
190. Right to Try in Your State, http://righttotry.org/in-your-state/ (last visited May 13, 2020).
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current as of Jan. 14, 2020). An eligible investigational drug is one (a) for which For which a Phase 1 clinical trial has been completed, (b) that hat has not been approved or licensed by the FDA for any use, (c) for which an application has been filed with FDA or is under investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval and is the subject of an active IND application, and (d) for which active development or production is ongoing, and has not been discontinued by the manufacturer or placed on clinical hold by the FDA. *Id.*

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201. *Id.* at 20.
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224. *Health Care*, Biden for President, https://joebiden.com/healthcare/.
225. *See*, *e.g.*, Michael Liu *et al.*, *March-In Rights And Compulsory Licensing—Safety Nets For Access To A COVID-19 Vaccine*, Health Affairs (May 6, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/.
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