

CHAPTER 4

**Medicare drug spending
in its broader context**

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Prescription drugs are a critical component of health care. Because of the role of drugs in treating conditions, it is important that Medicare ensures that its beneficiaries have access to appropriate medication therapies. By providing benefits that include prescription drug coverage, Medicare has expanded patient access to needed medications. However, it is becoming increasingly difficult to make sure that access to medications remains affordable for beneficiaries and to keep Medicare financially sustainable for taxpayers.

In recent years, manufacturers have introduced products at launch prices of tens of thousands of dollars per treatment regimen, and sometimes higher (Howard et al. 2015, LaMattina 2016). Prices for some medications that have already been on the market—including certain generics—have also grown faster than other components of health care spending (Martin et al. 2015, Nisen 2015). However, payers, including Medicare, have found it difficult to assess the relative value of these drugs and, thus, whether they are worth the high prices. In some cases, clinical evidence and real-world experience have indeed demonstrated calculable value for Medicare beneficiaries. In other cases, however, evidence of effectiveness that head-to-head clinical trials would provide is lacking. In addition, available clinical trial evidence often does not include patients with demographic and clinical characteristics similar to those of Medicare beneficiaries.

As the primary source of health care benefits for 57 million individuals, Medicare is the largest source of financing for small-molecule drugs and biologics.¹ The Commission estimates that, in 2013, Medicare paid for about \$112 billion in prescription drugs across all settings of care, or 19 percent of total program spending (Medicare Payment Advisory Commission 2015a). This spending was about one-third of U.S. pharmaceutical sales for that year (Long 2015). Because the Medicare program accounts for such a large share of overall drug spending, program payment policies can have a significant financial effect on health care providers and other parts of the industry, including pharmaceutical manufacturers, drug supply chains, pharmacies, pharmacy benefit managers, and insurers.

However, Medicare's influence on drug pricing is indirect, and the program pays for drugs differently depending on the care setting. Medicare pays for most drugs used during the course of a hospital stay, outpatient department visit, or skilled nursing facility stay as part of prospective payment bundles. However, physicians and hospital outpatient departments also bill Medicare separately for certain expensive infusible or injectable drugs covered under Medicare Part B. In that case, the program pays providers on the basis of the drug's average sales price (ASP) plus a 6 percent add-on. For Medicare Advantage plans, the program pays capitated amounts based in part on average drug costs in traditional Medicare. Under Part D, which

covers prescription drugs, Medicare pays private plans a combination of capitated amounts and reinsurance subsidies to provide outpatient prescription drug benefits to enrollees. Thus, hospitals, skilled nursing facilities, physicians, and private health plans and their pharmacy benefit managers negotiate drug prices, and this “market” mechanism determines Medicare drug costs.

In addition, it is important to recognize that Medicare exists within an American health care environment that involves a broad mix of not only public and private payers and local provider markets but also federal and state laws, agencies, and policies. These external environmental factors also have a significant influence on the prices Medicare pays for prescription drugs. Major influences include:

- **Biomedical research and development**—Funding for medical research through the National Institutes of Health and other organizations creates and influences basic knowledge about the mechanisms of disease and can provide the foundation on which new drugs are developed and manufactured. Similarly, tax credits for research and experimentation affect the extent to which developers and manufacturers invest resources in new compounds to treat disease and decisions about which diseases will be targeted. Such financial resources can lead to more investment, which can lead to the creation of larger numbers of new drugs and biologics.
- **Patents and exclusivity**—The federal government, through the Patent and Trademark Office and the Food and Drug Administration (FDA), grants temporary monopolies to pharmaceutical companies in the form of patents as well as data and marketing “exclusivity” for a period of time. Laws such as the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) and the Biologics Price Competition and Innovation Act of 2009 (enacted as part of the Patient Protection and Affordable Care Act of 2010) laid out processes by which manufacturers may market approved drugs and biologics without entry of competitors. Patents and periods of exclusivity provide a financial incentive for innovation by permitting the innovator to price products higher than if there were free entry of competitors. Patents are awarded for 20 years, and FDA approval to market a therapy triggers a period of 5 years of exclusivity for new small-molecule drugs and a 12-year period for new biologics. The length of a drug’s effective market protection depends on when the developer received a patent, how long the developer takes to assemble evidence on safety and effectiveness, and how long the FDA takes to evaluate that evidence. In addition, there are legal processes that affect how and when competitors may challenge manufacturers’ market protection and processes manufacturers use to extend patents.
- **Drug approval and oversight**—Laws and regulations of the FDA describe the process for approving drugs and biologics, evidentiary standards for approval, and rules about the indications for and processes by which the drug can be marketed (e.g., through direct-to-consumer advertising). The FDA’s processes for reviewing applications and the speed at which it does so directly affects the number of medicines available on the market, as well as how many therapeutic substitutes and generics are available within a drug class.
- **Importation and resale of drugs**—The Federal Food, Drug, and Cosmetic Act prohibited interstate shipment and importation of unapproved drugs. A subsequent provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 allowed the FDA to permit some importation of drugs from Canada, but only if the Secretary of Health and Human Services certifies that such an action would pose no additional risk to the public’s health and safety and would reduce costs for consumers. The FDA enforces these rules to promote the safety of drugs sold in this country and, to date, pharmacists and wholesalers have not been permitted to import drugs. At the same time, drug prices in the United States are significantly higher than they are in other developed countries (Congressional Budget Office 2004, Engelberg et al. 2016).
- **Policies of other government programs**—Policies established for certain government programs affect drug prices for other payers, including Medicare. For example, the Department of Veterans Affairs receives statutory discounts on drug prices, and Medicaid’s “best price” provision requires makers of innovator drugs to provide either a rebate of about 23 percent of the average manufacturer price or the lowest price that a manufacturer has negotiated with other payers, whichever results in lower prices net of rebates. Those discounts, in turn, may increase Medicare drug costs and those of other payers and lead to higher launch prices for new drugs (Congressional Budget Office 1996).

- **State laws and regulations**—States have varying types of laws under which pharmacists may substitute generic drugs for their brand-name counterpart, often without involving the prescriber. This practice has helped promote expansion of generic market shares, which puts downward pressure on prices for competing brand-name drugs (Shrank et al. 2010). Many states are enacting laws that set standards for substitution of a highly similar biologic product in place of an original biologic product (National Council of State Legislatures 2015).

Medicare’s drug payment policies can affect drug pricing, prescribing, and spending patterns indirectly. For example, the Commission has examined the ASP system that reimburses physicians for Part B drugs and will continue to examine the effects of the 6 percent add-on and whether that policy should be revised (Medicare Payment Advisory Commission 2015b). The Commission is continuing to examine other potential policy changes that could provide greater “value-based” incentives for managing Part B drug use, such as consolidated billing codes, bundled payments, reference pricing, risk-sharing arrangements, and coverage with evidence development (Medicare Payment Advisory Commission 2015b, Medicare Payment Advisory Commission 2010). In addition, the structure of Medicare Part D reinsurance for plan beneficiaries with high drug spending may serve to weaken plan incentives to manage

the drug spending of high-cost enrollees (Medicare Payment Advisory Commission 2015b). Part D beneficiary incentives and the ability of plans to manage drug costs also affect Medicare drug costs. Finally, while Part D has broadened access to drugs, that access, in turn, raises concerns about risks of polypharmacy and opioid misuse, which have their own costs for beneficiaries and program spending (Medicare Payment Advisory Commission 2015b).

The Commission remains concerned about the rapid growth in drug prices because that growth can affect beneficiary access to needed medications, as well as the financial sustainability of the Medicare program. Within the context in which Medicare operates, the Commission will continue to recommend changes to Medicare policies intended to promote drug price competition and improve incentives for providers and beneficiaries to seek better value when they purchase drugs. Accordingly, in the chapters that follow, the Commission has advanced its thinking in two areas: (1) Part B drug payment approaches (e.g., the ASP add-on payment, reactivation of the competitive acquisition program, and bundling of oncology drugs) and (2) the Part D outpatient prescription drug benefit (reduction of reinsurance payments, changes to beneficiary incentives, and greater flexibility for plans to manage drug costs). ■

Endnotes

- 1 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. (See Chapter 5 of the Commission's June 2009 report to the Congress for more detail.)

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